The Korean Drug Approval-Patent Linkage System: A Comparison with the US Hatch-Waxman Act

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Pursuant to the implementation of the Korea-US Free Trade Agreement, Korea has introduced a drug approval-patent linkage system, which is the Korean version of the US Hatch-Waxman Act. Implemented in two phases, the first phase was implemented in March 15, 2012 and required (i) originators to list patents covering a drug on the patent list (hereinafter “Patent Listing Regime”) and (ii) generic applicants to provide notification to the listed patent owner and the marketing approval holder who applies for and receives listing of a patent (hereinafter “Patent Listing Entity”) when a generic application for marketing approval is filed with an Item (6) Certification, i.e., the listed patent is invalid or not infringed, (hereinafter “Certification Notice”). The second phase, which will be implemented on March 15, 2015, will introduce (i) a stay of the generic sales (hereinafter “Stay Regime”) and (ii) generic exclusivity to the first generic that meets certain criteria (hereinafter “First Generic Exclusivity Regime”). More details about the procedure for a stay of sales are currently being legislated. In this article, we will first explain the drug approval-patent linkage system based on the proposed amendments to the Pharmaceutical Affairs Act of Korea, which was proposed by the Korean government in October, 2014 and is being reviewed by the National Assembly. In addition, for a better understanding of the system, we will compare it with the US counterpart. However, since various stakeholders have suggested different views in relation to the proposed amendments, certain aspects of the final legislation may be subject to change, such as a change or elimination of the First Generic Exclusivity Regime. Therefore, the ongoing legislative development must be closely followed.
1. A Comparison of the Patent Listing Regimes

The Korean Patent Listing Regime covers *biological* products, as well as traditional chemical synthetic products,¹ while the US Patent Listing Regime covers only chemical synthetic products. In addition, unlike the US, the Korean Patent List includes the relevant claim and detailed information of a particular patent.²

The US FDA takes a purely administrative approach to listing patents, i.e., the FDA merely reviews whether the formal requirements are met based on the assumption that it does not intervene in patent-related issues. In contrast, the Korean Ministry of Food and Drug Safety (hereinafter “MFDS”), the Korean equivalent of the US FDA, exercises the power and authority to substantively examine the patent listing, which requires more detailed information than the US Patent Listing Regime, thereby making the listing more difficult compared to the US counterpart.

Specifically, a Patent Listing Entity must meet the following requirements to list a drug patent on the Korean Patent List:

1. similar to the US system, the drug patent must cover the drug substance, dosage form, composition or pharmaceutical use;
2. the application for the drug patent must be made before the marketing approval date or amended approval date (hereinafter the term “marketing approval” also includes amendment approval);
3. the drug patent must be directly related to the drug product for which approval is made; and
4. the drug patent must not be expired, held invalid, or not maintained due to failure to pay the maintenance fee.³

Requirement (2) above was added for the purpose of allowing on the Patent List only the patents actually used in drug development. Furthermore, the application for patent listing must be filed within 30 days after the date of marketing approval or the date of patent registration. Requirement (3) above often becomes an issue during the listing process, because criteria for determining relevancy are somewhat unclear. Accordingly, the MFDS frequently requires submission of additional documentation to show that the claims are “directly related” to the drug product.

¹ Pharmaceutical Affairs Act, Article 2(4).
² Pharmaceutical Affairs Act, Article 31-3(1); Enforcement Regulation on the Safety of Pharmaceuticals, etc., Article 18(2).
³ Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-2(4).
Furthermore, the US FDA does not allow third parties to participate in the patent listing process and has no authority to delete or amend any listed information from the Orange Book. Therefore, patents are listed in accordance with the application filed by the patent owner in the US. Even if a patent is inappropriately listed, no procedure exists to dispute such inappropriate listing, unless the generic drug applicant certifying Paragraph IV brings a counterclaim against the originator company to correct or delete the patent information in patent infringement proceedings. In contrast, Korea has procedures to simply and quickly amend or delete incorrectly listed patents. Specifically, the MFDS has the authority to delete or amend the patents listed on the Patent List if (i) the drug no longer meets the listing requirements or (ii) the listing process involves any fraudulent or other wrongful conduct.\(^4\) Furthermore, even when a Patent Listing Entity applies for amendment of the listed information, the Korean system procedurally protects the rights of third party stakeholders, including generic applicants for marketing approval, to submit their opinions during the amendment process.\(^5\) All amendments or deletions of the listed information by a Patent Listing Entity or the MFDS are required to be publicly disclosed on the MFDS website.

\(^4\) Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-3 (4).
\(^5\) Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-3 (4).
2. A Comparison of Patent Certification and Notification Regimes

Under the US regulatory regime, an ANDA applicant or a 505(b)(2) NDA applicant must file one of four patent certifications to each patent listed on the Orange Book, i.e., commonly referred to as Paragraph I, II, III and IV Certifications. A generic applicant who has submitted a Paragraph IV patent certification, i.e., a certification that the listed patent is invalid or the product does not infringe the listed patent, is required to give notice of filing the generic application for marketing approval to the listed patent owner and the NDA holder within the notification period of 20 days.

In Korea, when a generic applicant applies for marketing approval (or approval of any amendment on efficacy or effectiveness of the listed drug) based on the safety and efficacy data of an approved drug, the generic applicant must submit a patent certification specifying one of the following six certifications with the application for marketing approval:

(1) The listed patent has expired (hereinafter “Item 1 Certification”; equivalent to Paragraph II Certification in the US);

(2) The applicant applies for marketing approval to sell products after expiration of the patent (hereinafter “Item 2 Certification”; equivalent to Paragraph III Certification in the US);

(3) The listed patent owner and the Patent Listing Entity have consented to waiver of the applicant’s notice obligation (hereinafter “Item 3 Certification”, e.g., in case of so-called “authorized generics”);

(4) The Korean Intellectual Property Tribunal (hereinafter “KIPT”) or a court rendered a decision that the listed patent is invalid or a drug for which the generic applicant seeks marketing approval does not fall within the scope of the listed patent (hereinafter “Item 4 Certification”);

(5) The listed patent is not related to the drug for which the generic applicant seeks marketing approval (hereinafter “Item 5 Certification”; e.g., where the application is filed for a use other than the patented use); or

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6 Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-4 (1); Enforcement Regulation on the Safety of Pharmaceuticals, etc., Article 4(1) Subparagraph 10.

7 Note that “filing an application for marketing approval based on the safety and efficacy data of an approved drug” includes (i) application for approval of the generic drugs with the same active ingredient, dosage form, efficacy/effectiveness, and usage/dosage as the originator drug, which is the Korean equivalent of an ANDA application in the US, as well as (ii) application for approval of modified drugs, or drugs for data-based re-evaluation, which is the Korean equivalent of the 505(b)(2) NDA application in the US.
(6) The listed patent is invalid or not infringed (hereinafter “Item 6 Certification”; equivalent to Paragraph IV Certification in the US and requires providing Certification Notice to the owner of the listed patent and the Patent Listing Entity).³

Item 4 Certification above specifically relates to patent disputes in Korea. A generic drug maker may, at any time even prior to release of the generic drug or prior to application for marketing approval, file an action for patent invalidation with the KIPT or file a patent scope confirmation action seeking the KIPT’s decision that the generic drug concerned does not fall within the scope of the originator’s patent. As further discussed below, an action seeking confirmation of the scope of a patent is a unique litigation regime that does not exist in the US. As a result, there are substantial differences between Korean and US Drug Approval-Patent Linkage Systems in terms of stay of sales, the patent challenger’s exclusivity, and the impact on the relevant stakeholders.

Another difference arises with respect to the notice requirement. In Korea, an applicant who has given notice is further required to file a written document evidencing such notice with the MFDS without delay, and the MFDS will subsequently publicly disclose the date of application for marketing approval, main ingredients, dosage form and other information on its website.⁹ Unlike in the US, there is no specific restriction on the notice period in Korea, but the MFDS will not grant marketing approval if the applicant fails to perform the notice obligation.

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³ If a generic applicant is required to give notice regarding the filing of his/her application for marketing approval (or amendment thereof), such generic applicant must give notice to the Patent Listing Entity and also the listed patent owner regarding his/her application and the reason thereof. Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-4(1). Currently, generic applicants are required to give such notice only in case of Item (6) Certification, but the notice obligation is expected to expand to Item (4) Certification in the future.

⁹ Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-4(3).
3. A Comparison of Stay Regimes

In the US, a patent owner may file a patent infringement lawsuit against the ANDA or 505(b)(2) NDA applicant within 45 days from the date of receipt of the notification from such applicant on the marketing approval. If no lawsuit is filed, the FDA will complete its review and grant marketing approval. If, however, there is a lawsuit brought by a patent owner, the FDA will grant conditional approval, which becomes effective for 30 months from the date of the patent owner’s receipt of the generic applicant’s notice regarding filing of its application for marketing approval. As a result, sale of the generic drug may be restricted by the patent owner’s lawsuit in US.

In Korea, however, a listed patent owner seeking market entry delay of a generic drug must, prior to application for marketing prevention, (i) initiate an injunctive action or an action prohibiting patent infringement or (ii) initiate an action or counteraction for confirmation of patent scope of the listed patent against all generic applicants providing notice of Item (6) Certification.\(^\text{10}\) Upon filing of the foregoing action, the patent owner may then apply for delay of market entry within 45 days from receipt of the Certification Notice.\(^\text{11}\)

Upon receiving the patent owner’s application, the MFDS may delay market entry of the drug concerned for a maximum of 12 months from the date the Patent Listing Entity and the listed patent owner received the Certification Notice. However, the following exceptions can apply:\(^\text{12}\)

1. the patent owner fails to apply for a delay of market entry within the 45-day application period;
2. the patent owner applies for a delay of market entry based on a patent that cannot be asserted due to expiration, waiver or any other reason;
3. the patent owner applies for delay of market entry without filing a patent infringement action or a patent scope confirmation action;
4. the patent listing was fraudulent or otherwise wrongfully obtained;

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\(^{10}\) Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-5(2).

\(^{11}\) Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-5(1).

\(^{12}\) Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-6(1).
(5) the patent owner selectively applies for delay of market entry against one or some of the applicants filing for marketing approval of the same drug\(^\text{13}\) when there are two or more applicants providing certification for the same drug, which prevents collusion with specific applicants among the many applicants;

(6) there already exists the same drug (i.e., as the drug subject to application for delay of market entry) for which the MFDS has already granted marketing approval and can be sold in the market;

(7) the KIPT or a court has rendered a decision that the listed patent is invalid or the drug subject to application for delay of market entry falls outside the scope of the listed patent (in case of the Item 4 Certification); or

(8) the listed patent is subject to compulsory licensing.

In addition, if there is a reversal of the decision under exception (7) above before the MFDS grants marketing approval for a particular notified drug, the MFDS must impose a delay of market entry of such drug for 12 months from the date of receipt of the notice of reversal.\(^\text{14}\)

Except for (i) the case falling under the Item 4 Certification and (ii) the case where there is a decision holding a particular drug patent listing unlawful, the MFDS may not grant marketing approval for the notified drug during the period of application for delay of market entry.\(^\text{15}\) Accordingly, if a generic drug applicant files a patent invalidation action or a patent scope confirmation action and subsequently obtains a favorable decision before applying for marketing approval, and then files the application for market approval with Item 4 Certification after expiration of the post marketing surveillance (PMS) period, such applicant can obtain marketing approval without being subject to a stay of sales. Such an exception to the Stay Regime is a result of the institutional characteristics of patent disputes in Korea, which do not exist in the US. In fact, generic drug applicants are highly likely to actively initiate patent invalidation actions or patent scope trials in order to avoid the Stay Regime, thereby significantly diminishing the impact of delay of market entry sought by patent owners.

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\(^\text{13}\) Note that the same drug means the drug with the same main ingredients, content, dosage form, use, dosage, efficacy and effectiveness.

\(^\text{14}\) Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-6(2).

\(^\text{15}\) Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-5(4).
As in the US, a patent owner can only apply once for delay of market entry on the notified drug in Korea. However, if the generic applicant applies for amendment approval regarding the efficacy and effectiveness or if the applicant adds an indication to the existing marketing approval, multiple delays of market entry can be imposed in Korea.\footnote{Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-5(3).}

The delay of market entry can be removed on the earlier of the following:\footnote{Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-6(3).}

1. Date of decision or judgment that the drug subject to the stay does not fall within the scope of the listed patent;
2. Date of judgment that the drug subject to stay does not infringe the listed patent;
3. Date of decision or judgment that the listed patent is invalid;
4. Date of decision or judgment that the patent listing is unlawful;
5. Date of completion of an action seeking patent infringement injunction or an action seeking confirmation of patent scope due to withdrawal by the patent owner, settlement or dismissal;
6. Date of arbitral award or settlement in an action seeking patent infringement injunction or an action seeking confirmation of patent scope;
7. Date on which marketing approval of the listed drug expires;
8. Date on which the listed patent term expires;
9. Date of decision by the Korea Fair Trade Commission (hereinafter “KFTC”) or judgment of the court holding that the listed patent owner violated the Monopoly Regulation and Fair Trade Act of Korea in relation to the Stay Regime or First Generic Exclusivity Regime; or
10. Date on which the delay of market entry is found to have been imposed due to a fraudulent or otherwise wrongful conduct.

Delay of market entry will become applicable after March 15, 2015 upon the Certification Notice given by an applicant for marketing approval.\footnote{Proposed Amendments to the Pharmaceutical Affairs Act, Addendum, Article 2.}
4. A Comparison of the First Generic Exclusivity Regimes

In the US, the first generic applicant to file an ANDA containing a Paragraph IV Certification is awarded 180 days of marketing exclusivity. During the 180-day marketing exclusivity period, the FDA may not approve a subsequent generic applicant’s ANDA containing a Paragraph IV Certification for the same drug. Although winning the patent infringement lawsuit is not an explicit requirement for the 180-day exclusivity, an applicant who loses the lawsuit will lose the 180-day exclusivity.

In the US, the 180-day marketing exclusivity is granted to ANDA applicants only and not to 505(b)(2) NDA applicants. Under the Korean regime, however, all applicants for marketing approval relying on the safety and efficacy data of the listed drug are entitled to the first generic marketing exclusivity.\footnote{Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-7(1).}

In addition, there is an important prerequisite before requesting marketing exclusivity in Korea. Similar to the US, the generic applicant must provide Item 6 Certification at the time of filing the application for marketing approval. Before applying for marketing approval, however, the generic applicant must first initiate a patent invalidation action, a patent term extension invalidation action, or a patent scope confirmation action in relation to the listed patent.\footnote{Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-7(2).}

In Korea, marketing exclusivity is granted to an applicant who (A) is the first to file an application for marketing approval and (B) obtains a favorable decision or judgment declaring that the listed patents is invalid, the registration for patent term extension is invalid, or the drug falls outside the scope of a listed patent in a patent invalidation action, a patent term extension invalidation action or a patent scope confirmation action in connection with the listed patent.\footnote{Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-8(1).}

With respect to the requirement (A) above, the first applicant for marketing approval includes all applicants who apply for marketing approval on the same day.\footnote{Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-8(1) Subparagraph 3 Item Ga.} If an applicant does not give notice within 20 days from the date of application for marketing approval, the date on which the Certification Notice is actually made to the listed patent owner and the Patent Listing Entity, whichever comes later, will be deemed the date of application for marketing approval.\footnote{Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-8(2).} In addition, in the case where...
a generic applicant changes its intent to challenge the patent (e.g., changing Item 1 Certification to Item 6 Certification), the date of change will be deemed the date of application for marketing approval for purposes of generic exclusivity. The MFDS is expected to disclose the relevant information of the notified drugs (i.e., drugs for which Item 6 Certification has been made and notice provided) in order to inform the generic public of the “first” applicant for marketing approval. The MFDS further plans to set a detailed standard regarding the list of essential documents required for application for marketing exclusivity at the time of application for marketing approval to avoid incomplete or insufficient applications. Furthermore, the MFDS appears to be taking an approach of denying generic exclusivity to an applicant who failed to submit any essential documents required for generic exclusivity.

With respect to the requirement (B) above, the applicant must be the first to file such action or the first to obtain a favorable decision or judgment. However, an applicant who does not obtain a favorable decision or ruling within 12 months from the notification date will not be awarded marketing exclusivity. If there are two or more listed patents in relation to one listed drug, the first generic exclusivity may still be granted to an applicant who successfully challenges one of the listed patents, i.e., no need to successfully challenge all of the relevant patents. The first to file an action includes the applicants who initiate actions within 14 days from the date of the first action.

With respect to the application for first generic exclusivity, all invalidation actions, patent term extension invalidation actions, or patent scope confirmation actions filed before March 15, 2015 will be deemed to be filed on March 14, 2015. Therefore, it is highly likely that the number of actions initiated by the companies planning to release generic drugs through patent challenges will sharply increase before the March 15, 2015 threshold approaches.

In the event that there are two or more applicants who challenge the listed patents at different times (assuming they have filed applications for marketing approval on the same date) and if applicant B obtains a favorable decision earlier than applicant A who is the first to file a lawsuit (even though applicant B filed its lawsuit later than 14 days from the date applicant A first filed the lawsuit), the first generic exclusivity will be granted to applicant B who is the first to file the lawsuit among those

24 Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-8(1) Subparagraph 3 Items Na and Da.
25 Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-8(1) Subparagraph 2.
26 Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-8(1) Subparagraph 3 Item Da.
27 Proposed Amendments to the Pharmaceutical Affairs Act, Addendum, Article 3.
who have obtained a favorable decision. If applicant A, the very first to file the lawsuit, later obtains a favorable decision, the first generic exclusivity will also be granted to applicant A from the moment applicant A obtains such favorable decision. As a result, companies that have committed considerable efforts and costs to prepare for a patent challenge may not be able to fully enjoy generic exclusivity due to free riding competitors, thereby negatively diminish the incentive of generic drug makers to challenge listed patents. In particular, because it is crucial to be the first to win the patent lawsuit to secure first generic exclusivity to the fullest extent possible, even though the amendments are yet to be finalized, there is already a tendency of patent challengers trying to initiate lawsuits as early as possible before any other challengers to increase the likelihood of being the first to obtain a favorable decision.

Once generic exclusivity is granted, the MFDS may, for a period not exceeding 12 months from the date of approval, restrict the sales of the same generic drug (i.e., drugs have the same (i) main ingredients and content, (ii) dosage form, (iii) use and dosage, and (iv) efficacy and effectiveness as the drugs with the first generic exclusivity) relying on the safety and efficacy data of an originally approved drug.

Therefore, generic exclusivity may be separately granted for different (i) main ingredients and content, (ii) dosage form, (iii) use and dosage, or (iv) efficacy and effectiveness of the listed drug. For instance, in the case where A obtains the first generic exclusivity for 50 mg tablets, B can still obtain generic exclusivity for 50 mg capsules that are isomers having the same major ingredients, while C can also obtain generic exclusivity for 50 mg sustained-release tablets. Consequently, although D may not be able to sell 50 mg tablets, capsules or sustained-release tablets, it may still be able to sell 100 mg tablets or capsules.

We also note that there is controversy over the proposed bill, because it does not clearly specify whether authorized generic drugs may obtain marketing approvals during the period of first generic exclusivity. If authorized generic drugs are allowed to be sold during the period of first generic exclusivity, there is a high likelihood that originators will use this strategy to minimize the effect of marketing exclusivity for

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29 Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-9(1).
the first generic drug by using authorized generics to take a significant portion of the sales profits that would have gone to the first generic drug maker.

Furthermore, it is also controversial whether combination drugs can be included within the scope of the drugs subject to marketing approval application filed relying on the safety and efficacy data of listed drugs, and subsequently can be subject to the drug with the first generic exclusivity. According to an MFDS presentation dated October 20, 2014, combination drugs will be deemed to be applicable under the First Generic Exclusivity Regime as long as the safety and efficacy data of single-ingredient drugs are used for the marketing approval application.

In principle, the generic exclusivity period must not exceed 12 months. For drugs covered by the national health insurance, however, where it usually takes 2 months from the marketing approval date to be listed on the reimbursement drug list, the period for first generic exclusivity can be extended up to 2 months. The effect of delayed market entry arising from generic exclusivity expires on (i) the date on which the marketing approval of the drug with the first generic exclusivity expires, or (ii) the listed patent becomes extinct due to expiration of the patent term, invalidation (excluding invalidation by the person who obtains the first generic exclusivity) and any other reason, whichever is earlier.

The MFDS must disclose on its website the main ingredients, dosage form, approval date and other relevant information relating to first generic exclusivity. Similar to the US FDA, which allows the transfer of the market exclusivity, the MFDS announced at a briefing on November 29, 2013 that it plans to allow the transfer of generic exclusivity in Korea.

The MFDS must also remove delayed marketing entry arising from generic exclusivity if any of the following events occurs:

1. If there is a judgment overturning the decision or judgment invalidating the listed patent, invalidating the patent term extension, or confirming that the drugs do not fall within the scope of the listed patent;

2. If the applicant, who has obtained generic exclusivity, does not sell the drugs concerned within 2 months from the date of marketing approval without any justifiable cause;

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30 Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-8(3).
31 Proposed Amendments to the Pharmaceutical Affairs Act, Article 50-10(2).
(3) If there is a decision by the KFTC or a court holding that the generic drug maker with generic exclusivity has violated the Monopoly Regulation and Fair Trade Act of Korea in relation to the delay of market entry or generic exclusivity; or

(4) If generic exclusivity was obtained by fraudulent or otherwise wrongful means.

With respect to (2) above, in the US, if the first applicant for marketing approval does not commence marketing of drugs pursuant to the typical pay-for-delay settlement, the 180-day exclusivity period will not elapse. The US FDA will, therefore, not be able to grant approval for subsequent generic applications for marketing approval, thereby blocking other generic drugs from entering the market. In Korea, however, the applicant enjoying generic exclusivity will lose the exclusivity if the applicant does not commence marketing of the drug within 2 months from the marketing approval date without any justifiable reason. Therefore, unlike the US, the incentive for drug makers in Korea to enter into pay-for-delay settlements in order to block other generic drugs’ market entry is significantly lower.

Delayed market entry arising from generic exclusivity will be applicable to the drugs for which marketing approval applications are filed after March 15, 2015.32

Additionally, similar to the US system, in order to prevent unfair practices among drug makers (such as pay-for-delay settlements), any of the following agreements between a Patent Listing Entity or a listed patent owner and an applicant for marketing approval of an Item 6 Certification drug must submit to the MFDS and KFTC: (i) any agreement concerning manufacture or sale of a concerned drug; (ii) any agreement concerning obtaining or termination of generic exclusivity; or (iii) any agreement concerning obtaining or termination of generic exclusivity between the applicants for marketing approval of the Item 6 Certification drug.33 This submission requirement will apply to the agreements made after March 15, 2015.34

32 Proposed Amendments to the Pharmaceutical Affairs Act, Addendum, Article 4.
33 Proposed Amendments to the Pharmaceutical Affairs Act, Article 69-3.
34 Proposed Amendments to the Pharmaceutical Affairs Act, Addendum, Article 6.
5. Disgorgement of Patent Owner’s Unjust Enrichment

In Korea, almost all citizens are mandatorily covered by the national health insurance operated by the government. As such, it is the government, not pharmaceutical companies, that actually decides and publicly announces the maximum reimbursement price for those drugs reimbursable by the national health insurance. The maximum price of generic drugs is determined in certain proportion to the prices of original drugs pursuant to the calculation method set forth in the applicable regulations. Generally, for the first one year after generic drugs enter the market, the maximum price of original drugs will be fixed at 70% of the previous maximum price, while the maximum price of generic drugs will be fixed at 59.5% of the previous maximum price of original drugs. After one year, the maximum price of drugs, regardless of whether original or generic, will be lowered to 53.55% of the initial maximum price of original drugs.

From the Korean government perspective, if a patent owner loses a patent litigation, a delay of market entry of generic drugs due to the request filed by the patent owner will in turn cause a delay of decrease in the maximum drug price, thereby resulting in the patent owner’s unjust enrichment from the national health insurance funds. As an effort to address this problem, the proposed amendments to the National Health Insurance Act dated June 20, 2014 added a provision demanding disgorgement of the unjust enrichment gained by patent owners in the foregoing case. If these proposed amendments are passed without change, a patent owner, who genuinely believes that his/her patents are valid and brings a patent infringement lawsuit to defend his/her patent right but loses the lawsuit, can be forced by the government to disgorge the unjust enrichment obtained by delay of market entry of generic drugs. The amount of the unjust enrichment will be calculated based on the difference between the current price and the lowered price if there was no delay of market entry imposed on the generic drug. As a result, there is a strong concern in the pharmaceutical industry over the proposed amendments, which can effectively preclude patent owners from applying for delay of market entry of the generic drug.

35 Proposed Amendments to the National Health Insurance Act, Article 101-2(1).
6. Conclusion

In principle, one of the primary objectives of the drug approval-patent linkage system is to facilitate research and development, and investment in innovative drugs by providing effective protection mechanisms for patent owners in light of the considerable time and efforts required to develop and release new drugs in the pharmaceutical industry. While the system may strengthen patent rights, one-sided protection of patent owners may also cause abuse of patent rights. As a balancing mechanism, the government will grant patent challengers generic exclusivity to adjust the balance of rights by encouraging stakeholders to raise challenges against weak patent rights.

On the one hand, most of the drug makers in Korea significantly rely on generic drugs rather than patented drugs due to the historical nature of the Korean pharmaceutical industry. Thus, the Korean drug approval-patent linkage system has to consider protection of generic drug makers to a certain extent, particularly protection of the first generic makers challenging the listed patents. On the other hand, in order to maintain the nationwide mandatory health insurance system, it is essential to ensure soundness of the insurance funds. Thus, it is important for the Korean drug approval-patent linkage system to facilitate much faster and easier market entry of generic drugs. As a consequence, the current proposed bill is designed to be more difficult than the US system for patent owners to delay market entry of generics, while obtaining generic exclusivity by patent challengers tends to be easier than the US counterpart. However, this system may likely cause serious unintended consequences, such as delayed release of innovative new drugs in Korea by patent owners. In addition, there is also an increased risk that leaving the possibility of allowing multiple generic drug makers to have generic marketing exclusivity at the same time will likely diminish and weaken the advantages of having exclusivity status, thereby decreasing the willingness of generic drug makers to challenge patents. If such risks become reality, the Korean drug approval-patent linkage system will not only fail to properly achieve its original objectives, it is also likely to become an incomplete and unpopular system that could not gain any support from patent owners as well as generic makers. Currently, the MFDS is of the position that it will prepare and introduce specific measures under the relevant regulations to ensure that the system will be more tailored to the actual circumstances of Korea while further realizing its intended objectives by soliciting diverse opinions from a wider group of stakeholders. As a result, because many uncertainties still remain at this stage, the stakeholders in the market must keep themselves up to date on the ongoing legislative development until the proposed bill is finalized to determine whether the Korean drug approval-patent linkage system can become a successful system fully achieving its original objectives.