Overview and implications of the drug patent-approval linkage system in South Korean Regulation

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BACKGROUND TO THE IMPLEMENTATION OF THE PATENT-APPROVAL LINKAGE SYSTEM

The United States first adopted the drug patent-approval linkage system by enacting the Drug Price Competition and Patent Term Restoration Act of 1984 (21 U. S. C. § 355 (2006)) (Hatch-Waxman Act of 1984). Other countries, such as Canada and Australia, which have entered into free trade agreements (FTAs) with the US, have implemented a drug patent-approval linkage system. However, most countries maintain the separation between the drug marketing approval system and the patent system.

South Korea had also been implementing a system under which patents were managed by the Korean Intellectual Property Office (KIPO), and drug marketing approvals were managed independently by the Ministry of Food and Drug Safety (MFDS). However, South Korea adopted the drug patent-approval linkage system as it entered into its FTA with the US in 2007.

Agreements relating to the patent-approval linkage system under the FTA between South Korea and the US

Under the FTA between South Korea and the US, the provisions relating to the patent-approval linkage system stipulate that the bodies which have jurisdiction over the approval of marketing for drugs must:

- Have a notification process in place, which gives notice to a drug patent holder of an application for approval of marketing for a generic drug, which relies on the safety and efficacy data of the patented drug (notice system).
- Implement measures to prevent marketing of such a generic drug in the marketing approval stage (marketing prevention system).

The FTA does not prescribe specific methods of implementation for the notice system and marketing prevention system. Because South Korea is not obligated to implement the same regime as applies under the US Hatch-Waxman Act, the South Korean Government can implement its own process with respect to the specifics of the notice system and marketing prevention system. The MFDS announced on 29 November 2013 that it would prepare a unique patent-approval linkage system that takes into account the South Korean legal system and the characteristics of its pharmaceutical industry.

CURRENT STATUS OF THE IMPLEMENTATION OF THE PATENT-APPROVAL LINKAGE SYSTEM

The notice system took effect on 15 March 2012 and the marketing prevention system is expected to become effective on 15 March 2015. Currently, the bill prescribing the specifics of the marketing prevention system is being prepared for legislation. This article first briefly examines the patent dispute resolution system in South Korea before discussing the above, because it is closely related to the patent-approval linkage system. It then discusses and explains the major characteristics of the notice system as it currently stands, and the proposals for the introduction of the marketing prevention system.

Patent dispute resolution system

Patent-related civil lawsuits, generally called patent infringement litigation, include lawsuits claiming infringement and damages, and are heard and tried in the district courts rather than the Patent Court. Disputes relating to the generation, amendment, expiry and scope of patent rights are resolved by a patent dispute resolution system administered by the Korean Intellectual Property Tribunal (KIPT) affiliated with the KIPO. KIPT proceedings are frequently used in practice because they generally take less time than patent infringement litigation. The Patent Court has exclusive jurisdiction over the review of rulings and decisions rendered by the KIPT. Because appeals to any decision or ruling rendered by the KIPT are referred to the Patent Court, and then to the Supreme Court, the KIPT serves the role of a de facto court of first instance.

A patent holder may assert its rights against an applicant seeking marketing approval for generic drugs by either:

- Filing a lawsuit with a district court to seek prohibition or prevention of infringement based on the infringement on its patent.
- Filing a positive scope confirmation with KIPT to seek a decision that the generic drug is within the scope of its patent rights.

An applicant seeking marketing approval for generic drugs may challenge a patent with the KIPT against a patent holder by either:

- Filing a negative scope confirmation claim to seek a decision that the generic drug is not within the scope of the patent rights.
- Filing a patent invalidation claim.

MAIN CHARACTERISTICS OF THE NOTICE SYSTEM

An applicant seeking marketing approval of a generic drug must give notice to the original patent holder by fulfilling a number of steps. These include registering the patent information on the drug patent list and making sure the patent is eligible to be registered. The applicant must then state the relationship between the generic drug and the original patented drug, and notify the original patent holder of their application for marketing approval.

Registration in the Green List

An applicant who has obtained marketing approval of a drug needs to register the patent information of the approved drug in the drug patent list (the Green List). The applicant must file an application for registration in the Green List to the MFDS within 30 days from
the date of the marketing approval. The MFDS will register the information in the Green List if the patent satisfies the statutory standards and requirements.

**Eligibility.** Unlike the US patent list (the Orange List), both chemically synthesised and biological drugs can be registered in the Green List. The patents eligible for registration in the Green List are those regarding the patent type classification of substance, composition, dosage form, or medical usage.

**Criteria for registration.** A patent must satisfy all of the following criteria to be registered:

- Be directly related to the main ingredient and its specifications, drug substance and its amount, formulation, efficacy, effectiveness, administration method and dosage, out of the approved matters of the relevant drug.
- Be found to be different from the existing patents in the Green List in terms of efficacy, effectiveness, and quality.
- Have a remaining patent period and be effective.
- Have drug marketing approval.

**Substantive examination and management.** The US Food and Drug Administration (USFDA) only examines the formalities of patent information and does not examine or manage the substance. By contrast, the MFDS conducts substantive examination of the direct relevance between the patent applied and the drug approved. In addition, if a patent of a drug registered in the Green List (listed drug) fails to satisfy the eligibility criteria, the MFDS can delete or change, *ex officio*, the patent information of the listed drug in the Green List, the purpose of which is to prevent a patent holder from delaying approval of generic drugs by registering a patent with little relevance.

In addition, anyone can request that the MFDS delete or change the items entered in the Green List.

**Listed claim.** The MFDS conducts examinations and makes the registration of a claim for patent registration separately. Additionally, the MFDS registers a "listed claim" which edits the contents of the relevant claim for patent registration to be consistent with the contents of the drug approved.

The MFDS argues that the registration of a listed claim will not cause any problems, since a claim for patent registration is also registered with the listed claim. On the other hand, applicants argue that it is illegal and unjust that a claim for patent registration is not registered on an "as is" basis, but is registered in an edited and modified version as a listed claim, because the scope of protection under the listed claim will be narrower than that of a claim for patent registration.

At the moment, it is difficult to predict the legal effects of such a listed claim since the specific legal provisions on the marketing prevention system have not been enacted yet. There are a number of lawsuits pending that applicants have filed to challenge the registration of a listed claim.

**Notice of an application for drug approval.** If an applicant files an application for the approval of a generic drug by relying on the safety and efficacy information of a listed drug, the applicant is required to submit a document showing the relationship between the patent of the listed drug and the drug applied for approval (a patent relationship confirmation letter) and supporting documents. The applicant must then notify (within seven days from the date of application) the person who obtained the original approval of the listed drug, and the patent holder of the following:

- The filing date of the application for approval of a generic drug.
- The fact that the application for approval of a generic drug has been filed in order to commercially manufacture or import and market a generic drug prior to the expiration of the patent of the listed drug.
- The reason for the judgement that the patent of the listed drug is invalid or not to be infringed on.

The applicant can be exempted from the requirement to provide notice of an application for drug approval if the patent relationship confirmation letter states that one of the following apply:

- The patent period of the listed drug has expired (patent relationship number one).
- Marketing approval has been applied for after the patent period of the listed drug expired (patent relationship number two).
- The person who obtained the approval of the listed drug and the patent holder of the listed drug has waived the notice requirement (patent relationship number three).
- The applicant has obtained a KIPT decision or a court decision that the patent of the listed drug is invalid, or the drug applied for approval is not within the scope of the patent rights of the listed drug (patent relationship number four).
- The patent of the listed drug is not relevant to the drug applied for approval (patent relationship number five).

Patent relationship number four is attributable to the difference in the patent dispute resolution systems of South Korea and the US. Unlike in the US, in South Korea an applicant for generic drug approval can file a claim at any time with the KIPT, seeking patent invalidation or a negative scope confirmation of the patent rights against a patent holder of the listed drug, before the patent holder initiates patent infringement litigation (see above, Patent dispute resolution system).

US patent law contains a provision which deems filing of an application for approval of a generic drug as an infringement of a patent of an original drug, to allow the patent holder to initiate patent infringement litigation. On the contrary, under South Korean patent law, the application for generic drug approval does not constitute implementation of a patent and is not deemed to be an infringement on the patent.

Before the patent-approval linkage system was introduced, a patent holder of an original drug could not initiate patent infringement litigation just because generic drug approval had been obtained. To initiate patent infringement litigation, a patent holder of an original drug also needed to show sufficient feasibility of marketing in the near future. An example of this might have included the situation where the application for listing the generic drug on South Korea’s health insurance system had been made by the person who obtained the generic drug approval. Since the introduction of the patent-approval linkage system, the patent holder of a listed drug can initiate a lawsuit to seek the prevention of patent infringement if a generic drug approval application has been submitted with patent relationship number six marked.

**Items to be notified and the scope of notice.** The items to be notified are as follows:

- The date of the application for approval.
- The fact that approval of a generic drug has been applied for, in conjunction with the submission of bio-equivalence test data relying on the safety and efficacy information of a listed drug, for the purpose of commercial manufacturing and importing before the expiry of the patent period of the listed drug.
- The reasons for concluding that the patent of a listed drug is invalid or that the generic drug applied for approval does not infringe on the relevant patent of the listed drug.
When giving notice that the patent of a listed drug is invalid or that the generic drug applied for approval does not infringe on the relevant patent of the listed drug, there are no detailed provisions or established criteria regarding how specific the notice should be.

The MFDS determines the scope of notice to be based on a claim for patent registration.

**Method and deadline of notice**

Notice should be given by registered contents or certified mail and the applicant who has given notice must immediately submit a document evidencing such notice to the MFDS.

Notice must be given within seven days of the date of the application for an approval. The MFDS has announced that, where the deadline was not observed, it was considering imposing a disadvantage by taking the notice date as the application date when determining which generic drug producer would be granted marketing exclusivity.

**EXAMINATION OF APPLICATION FOR APPROVAL**

The MFDS, whether or not notice is given, will proceed with an examination of an application for approval upon receiving an application for a generic drug approval. However, if the MFDS becomes aware of an applicant's failure to give notice, the MFDS may proceed with cancellation of approval.

If the generic drug applied for approval is found to be safe and effective as a result of an examination, the MFDS will issue an approval with conditions based on the chosen items stated in the patent relationship confirmation letter. For example, if an application for marketing approval of a generic drug is submitted after the expiry of the patent period of the listed drug, the approval will be given with the condition that "this drug is allowed to be marketed after the expiration of the patent period of the listed drug (with a date inserted)".

**THE MARKETING PREVENTION SYSTEM**

The marketing prevention system is expected to take effect on 15 March 2015 and the detailed criteria for the subordinate laws and regulations for the amendment to the Pharmaceutical Affairs Act are expected to be announced in the second half of 2014. Although it is in its preparatory stage, the overview of the marketing prevention system, revealed through the MFDS hearing on 29 November 2013, is set out below. Such an overview may be subject to revision in the course of the legislation.

**Plans for the application and implementation of the marketing prevention**

A patent holder of a listed drug will be able to apply for marketing prevention to the MFDS. The patent holder can do this within 45 days of receiving notice of an application for generic drug approval, only when it has filed:

- A claim for "positive scope confirmation of patent rights with KIPT."
- A "prohibition of infringement with a court".

This means that a patent holder of a listed drug cannot apply for marketing prevention where they only passively respond to a claim with the KIPT, or a court seeking patent invalidation, or a negative scope confirmation of the patent rights raised by the applicant of generic drug approval. Since the KIPT proceedings for positive scope confirmation of patent rights take less time than patent infringement litigation, a patent holder of a listed drug who wishes to obtain a quick decision on whether its patent has been infringed, is likely to file a claim for positive scope confirmation of patent rights with the KIPT, and a patent holder of a listed drug who hopes to delay generic drug approval as much as possible is likely to initiate a patent infringement lawsuit in court.

If a listed drug's patent holder and marketing approval holder are different, they should jointly apply for marketing prevention. For example, in the case of a multinational company which has a local subsidiary in South Korea, it is typical for the parent company to hold a patent while the South Korean subsidiary holds the approval. In such a case, the parent company and the South Korean subsidiary should jointly apply for marketing prevention.

In the US, if a patent holder of an original drug files for a patent infringement lawsuit within 45 days of receiving notice of an application for generic drug approval, issuance of approval for a generic drug is automatically stayed by the USFDA for 30 months. In comparison, the MFDS determines whether to approve marketing prevention after actually examining the application, and if the MFDS decides to approve the application for marketing prevention, the generic drug is stayed from marketing for a maximum of 12 months from the date of the marketing prevention application. The reason behind the decision to set the stay period as 12 months is because it generally takes less than 12 months for the KIPT or a court to reach a conclusion on a patent dispute.

In rendering its decision on the application for marketing prevention, the MFDS considers:

- The obviousness of patent infringement.
- The similarity between a listed drug and an applied drug.
- Whether irrecoverable damage would occur.
- An assessment of the benefits between a patent holder and the applicant for generic drug approval.
- The public benefit.

If the MFDS completes the substantive examination of an application for generic drug approval during the marketing suspension period, conditional approval is given. However, such approval is not issued where a generic drug is deemed to have infringed the patent of a listed drug.

The marketing prevention measures will be suspended if one of the following events occurs:

- A related patent dispute is concluded.
- The patent period of a listed drug expires.
- The approval of a listed drug is discharged.
- An improper act, such as collusion between a patent holder and an applicant for generic drug approval, occurs.

The applicant for generic drug approval may obtain approval without providing notification of its application for approval by choosing patent relationship number four and if:

- The applicant's claim for patent invalidation is granted.
- A negative scope confirmation of patent rights is filed against a patent holder.
- The applicant applies for generic drug approval after the expiry of the post marketing surveillance period (PMS), which is the de facto exclusivity period.

This means that the marketing prevention measures will not be applied. Therefore, applicants for generic drug approval are expected to file their claim for patent invalidation or negative scope confirmation of patent rights prior to applying for generic drug approval, to avoid marketing prevention measures.

**THE EXCLUSIVE MARKETING RIGHT OF THE FIRST GENERIC DRUG APPLICANT**

A one-year exclusive marketing right is conferred to "the first applicant for generic drug approval who has successfully challenged a patent of an original drug". This starts from the date the marketing becomes feasible, in consideration of factors such as
the substitutability of a drug, generic drug market share and industry practices. Although there have been controversies over whether to grant exclusive marketing rights to the first generic drug applicant as they are granted in the US, it was determined that exclusive marketing rights would be granted to “the first applicant for generic drug approval who has successfully challenged a patent of an original drug”, taking into consideration:

- The balance of interest between a patent holder and a generic drug applicant.
- The fact that it is in the public’s interest to encourage and reward challenges to the patent of an original drug.

Compared to the six-month exclusive marketing period of the US, the exclusive marketing period in South Korea was determined to be one year. This was because of the specific national circumstances, where hospitals typically decide to purchase drugs through yearly biddings; a shorter exclusive marketing period would render the exclusive marketing rights to become practically useless.

The exclusive marketing rights may be revoked if one of the following events occurs:

- Marketing is delayed without a justifiable reason.
- The approval of the generic drug with the exclusive marketing rights is cancelled.
- The patent period of a listed drug in the Green List, of which the safety and efficacy information are relied upon by the exclusive marketing rights holder, expires.
- There has been collusion between an exclusive marketing rights holder and a third party.

- The exclusive marketing rights holder has submitted falsified documentation when applying for approval.

The exclusive marketing rights can be transferred to a third party. Considering that drug approval is transferable, it appears to be reasonable to allow a transfer of the exclusive marketing rights. The MFDS is examining whether to impose the obligation to give notice of the transfer of exclusive marketing rights to the relevant authorities, or the obligation to obtain approval of those rights.

Although the MFDS announced that it would prepare detailed criteria by preparing subordinate laws and regulations, there are ambiguities even in the current tentative pronouncement. Ambiguities include the meaning of “first applicant who has successfully challenged a patent of an original drug” and the “date when the marketing becomes feasible”, which refers to the commencement date for the exercise of exclusive marketing rights. Problems may also arise when multiple persons have challenged the patent of an original drug, or when multiple patents are registered in connection with the same listed drug, or when a decision of a patent dispute is reversed. However, no specific guidelines have been determined at the time of writing.

**APPEALS PROCESS**

The MFDS plans to prepare a separate appeals process by establishing the Drug Approval and Patent Adjudication Committee. This process will allow a review to be requested with respect to a decision of the MFDS, or in connection with a dispute between interested parties. Such plans take into account the difficulty in resolving what can be technical disputes over drug approval and patents, through ordinary administrative proceedings.

The types of adjudication requested and the claimants and respondents of the respective types are:

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<thead>
<tr>
<th>Type of adjudication</th>
<th>Claimant</th>
<th>Respondent</th>
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<tbody>
<tr>
<td>Revocation of rejection of registration</td>
<td>Applicant for registration</td>
<td>MFDS</td>
</tr>
<tr>
<td>Invalidation of a disposition of registration</td>
<td>Interested party concerned</td>
<td>Applicant for registration</td>
</tr>
<tr>
<td>Revocation of rejection of marketing prevention</td>
<td>Patent holder.</td>
<td>Applicant for generic drug approval</td>
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<tr>
<td>Revocation of a disposition of marketing prevention</td>
<td>Applicant for generic drug approval</td>
<td>Patent holder, etc.</td>
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<tr>
<td>Rejection of grant of exclusive marketing</td>
<td>Applicant for generic drug approval</td>
<td>MFDS</td>
</tr>
<tr>
<td>Revocation of grant of exclusive marketing</td>
<td>Party concerned</td>
<td>Applicant for generic drug approval</td>
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(This table is adapted from the MFDS presentation material for the patent approval linkage system briefing held on 29 November 2013.)

Except for adjudication for an invalidation of a disposition of registration, other types of adjudication can be requested up to 30 days after a disposition has been issued. The adjudication for an invalidation of a disposition of registration can be applied for at any time.

The patent court will have exclusive jurisdiction over any appeals against decisions made by the Drug Approval and Patent Adjudication Committee.

**MEASURES TO REGULATE ABUSE OF RIGHTS AND BREACH OF OBLIGATIONS**

To prevent an abuse of rights and a breach of obligations by patent holders and applicants for generic drug approval, MFDS plans to impose fees when the following scenarios occur:

- Applying for a registration in the Green List.
- Applying for a prevention of marketing approval proceedings.
- Applying for a grant of exclusive marketing rights.

In addition, the MFDS plans to prepare sanctions, such as the imposition of an administrative fine or penalty, in case of a breach of obligations or an abuse of rights.

**Recovery of unjust enrichment of a patent holder**

The MFDS is also planning to implement a process to recover funds from patent holders of listed drugs who are enriched from a delay in the marketing of a generic drug when the patent holder loses in a patent litigation. In other words, if a patent holder has unjustly earned money because the approval of a generic drug was stayed as a result of marketing prevention measures, and the price of its listed drug has not declined as a result of the non-marketing of the generic drug, such gains will be recovered.

However, the MFDS has not announced how it would deal with the situation where damage is caused to a patent holder of a listed drug. This damage could be the result of the generic drug company earning money from the marketing of the generic drug, and the
listed drug’s price going down. The damage could also follow on from an adjudication that the generic drug company has infringed the patent of the listed drug.

It has also been discussed whether it is necessary to protect applicants for generic drug approval, and encourage challenges against patents by limiting the liability of an applicant for generic drug approval. This might be done by holding an applicant for generic drug approval liable only for the revenue from the sale of the generic drug and not for the damage caused to a patent holder.

**ISSUES TO CONSIDER**

Various problems occurred in the US after the Hatch-Waxman Act was enacted. This included the misuse of the patent-approval linkage system where, for example, patent holders overused patent litigations, or unfair agreements, such as reverse payments, occurred between patent holders and the first applicants for generic drug approval.

It is necessary for South Korea to establish a unique patent-approval linkage system, incorporating the lessons from such precedents and considering the balance of the benefits between patent holders and generic drug producers. This is to prevent the misuse of the patent-approval linkage system, while taking into account South Korea’s unique patent litigation system, drug pricing system, and the special characteristics of the sales environment.

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**Recent transactions**

- Advising multinational pharmaceutical companies on corporate and regulatory issues, including listing a drug on Korea’s health insurance system.
- Advised multinational pharmaceutical company on listing a drug patent on the Green List under the patent-approval linkage system.
- Advising multinational medical device companies on regulatory issues including obtaining import license from the Ministry of Food and Drug Safety.
- Advising foreign and Korean companies, including pharmaceutical companies, on cross-border M&A’s and joint ventures.

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**Recent transactions**

- Advising multinational and Korean pharmaceutical companies on regulatory issues, including listing a drug on Korea’s health insurance system.
- Advised multinational pharmaceutical company on listing a drug patent on the Green List under the patent-approval linkage system.
- Advising multinational and Korean pharmaceutical companies on regulatory issues, including obtaining pre-marketing approvals, labeling and advertising, formulating marketing strategies, addressing consumer complaints, product recalls, licensing, and compliance with pharmaceutical affairs law and fair trade regulations.