South Korea's Patent-Approval Linkage System

Although South Korea's new Patent-Approval Linkage System will not be fully implemented until 2015, there is already keen interest from global pharmaceutical companies. Yet while the system should strengthen patent rights, it may also increase the number of disputes

By **Keum Nang Park, Hui Jin Yang** and **Eunkyoung Lyu**, Lee & Ko

After extensive negotiations between South Korea and the United States, the Korea-US Free Trade Agreement (FTA) was signed in 2007 and – after additional negotiations – became effective on March 15 2012. Among other significant impacts, the FTA introduced a major structural change to South Korea's pharmaceutical industry by creating a bridge between the drug approval system and the patent rights associated with drugs – the Patent-Approval Linkage System. Much like the system under the US Hatch-Waxman Act, South Korea has introduced a linkage system between the drug approval process at the Ministry of Food and Drug Safety and the bodies responsible for enforcing patent rights.

Article 18.9 of the FTA provides that:

- a patent owner shall be notified of any person that applies for a marketing approval (MA) from the relevant authorities during the term of a patent; and
- a system of measures shall be implemented in the MA process to prevent another person from marketing a product without the consent or acquiescence of the patent owner during the patent's term of a patent.

South Korea is undergoing legislative reform with regard to the Pharmaceutical Affairs Act to implement the Patent-Approval Linkage System. The first part of Article 18.9 was implemented as of March 15 2012, although implementation of the second part (ie, the system of measures under the marketing approval process) is on hold for three years. However, the government must amend all relevant statutes and complete the system's implementation by March 15 2015.

On March 21 2014 the Ministry of Food and Drug Safety announced a two-month period to receive comments to the Revised Draft of Pharmaceutical Affairs Act. The revised draft adopts various new systems, such as patent listing, marketing prevention (also referred to as the 'stay of MA process'), first-generic exclusivity and the Patent Approval Linkage Tribunal. More detailed criteria for these systems will be stipulated under the subordinate laws and regulations, which will be enacted and/or revised before the revised draft is implemented on March 15 2015. Until then, many uncertainties will remain and players in the pharmaceutical industry should keep themselves up to date on ongoing developments.

Current status of the Patent-Approval Linkage System

Drug MA approval and patent listing

Upon implementing the first part of the Patent-Approval Linkage System, the Ministry of Food and Drug Safety constructed a patent database called the Green List, similar to the Orange Book in the United States. Once a new drug is approved for marketing by the ministry, the MA holder can apply to list all patents associated with the drug under the Green List. Patents must be listed on the Green List in order to enjoy the protection offered

under the Patent-Approval Linkage System. For MA obtained before the FTA came into effect (ie, March 15 2012), the ministry allowed applicants a period of three months to submit an application to list the patents on the Green List (ending on June 14 2012). For MA approvals granted after the FTA came into effect, the MA holder must submit an application within 30 days to list the relevant patents on the Green List. Listing patents on the Green List does not happen automatically, but rather takes place under close scrutiny by patent attorneys at the ministry.

Generic MA application and notification to patentee

If a generic applicant submits a MA application relying on the safety and efficacy data of an approved drug, it must fall under one of six categories:

- The listed patent has expired;
- The drug will be marketed after the listed patent has expired;
- The patentee has agreed to waive receipt of notification (explained further below);
- There is a court ruling or a decision from the IP Tribunal that the drug falls outside the scope of the listed patent or that the listed patent is invalid;
- The drug is unrelated to the listed patent; or
- The listed patent is invalid or the drug does not infringe the listed patent.

In addition, the generic applicant must notify the MA holder and the patentee within seven days of filing the MA application. Under the current system, the applicant is required to send a notification only for an application made under the sixth category – that is, the MA application has been made on the ground that the drug does not infringe the listed patent or that the listed patent is invalid.

The revised draft stipulates that generic applicants under the second or third category are not required to notify the patentee. It is anticipated that the Ministry of Food and Drug Safety may require patentees to be notified under the fourth category as well. The specific categories will be stipulated under the ordinance of the prime minister, which is forthcoming.

Patent-Approval Linkage System under the revised draft

The revised draft introduces a new chapter which implements the Patent-Approval Linkage System. This includes provisions on patent listing on the Green List, notification, marketing prevention, first-generic exclusivity and the Patent-Approval Linkage Tribunal.

Listing patents on the Green List

Pursuant to the current Pharmaceutical Affairs Act, an MA holder can apply for listing on the Green List regardless of the patent application date. However, under the revised draft, patents eligible for listing are limited to those filed prior to the MA approvals, the purpose of which is to offer protection only to those patents that have actually contributed to the development of the listed drugs.

Once an application for listing on the Green List satisfies the eligibility requirements, the Ministry of Food and Drug Safety shall publish it for comment. The applicant can file an amendment request with the ministry before any decision. In the event that the applicant amends the name of the drug and/or the patent registration number, or includes additional patent claims, the applicant must file the amendment request within 30 days of the date of the marketing approval or the date of the patent registration.

If any changes need to be made to the information about the listed drugs, the MA holder may request that the ministry delete or amend this. If such a request relates to the MA holder, patentee, expiration date of the patent or additional claims of the patent, it should be made within 30 days of the date that the changes were made. However, if the listed drug is the subject of any pending patent-related lawsuits, a deletion request is not permitted. This is to prevent patentees from deliberately deleting listed drugs that are the subject of a pending patent lawsuit by second movers claiming first-generic exclusivity.

If a patent for a drug listed in the Green List fails to satisfy the eligibility criteria (eg, the patent or the MA has expired), the Ministry of Food and Drug Safety can delete or amend, *ex officio*, the patent information of the listed drug in the Green List. This is to prevent a patent holder from delaying approval of generic drugs by registering a patent with little relevance.

Notification of MA application and marketing prevention

If an MA application relies on the safety and efficacy data of an approved drug, the generic applicant must notify the MA holder and the patentee within seven days of filing the MA application. The current Pharmaceutical Affairs Act does not specify situations where the applicant fails to do so. However, the revised draft sets out the

Keum Nang Park
Partner
Lee & Ko
South Korea
Tel: +82 2 2191 3036
Fax: +82 2 772 4001/2
keumnang.park@leeko.com

Keum Nang Park is a partner in Lee & Ko's healthcare and IP groups, as well as a leading expert in pharmaceutical affairs and IP law. She has represented many multinational companies in patent litigations covering pharmaceuticals, biotech drugs and chemicals.

Ms Park is a member of the Asia Patent Attorneys' Association Korea and of the Ministry of Health and Welfare Committee. She is a prolific speaker and writer on IP matters, with recent publications including "Patentability of Chemical and Pharmaceutical Inventions-Enantiomer Invention, Crystalline Invention, and Selection Invention", *Law & Technology*, 2013 and "Life Sciences – South Korea Part," *The Law and Leading Lawyers Worldwide*, 2011.

Hui Jin Yang
Associate
Lee & Ko
South Korea
Tel: +82 2 772 4984
Fax: +82 2 772 4001/2
huijin.yang@leeko.com

Hui Jin Yang is an associate in Lee & Ko's IP group. Before joining the firm in 2010, she served as a judge at both the Seoul Central and Seoul Western District Courts. Ms Yang's practice covers all the traditional IP practice areas, including patents, trademarks, trade secrets, copyright, unfair competition (in the context of domain names and e-commerce), and IP transfer and licensing matters. Her representation covers all major technical fields, including chemistry, medicine, biotechnology and food engineering.

Ms Yang holds a BS in biochemistry from Yonsei University and completed her legal training at the Judicial Research and Training Institute of the Supreme Court of Korea. She is admitted to the Korean Bar and the Korean Patent Bar.

> "The immediate effects of the Patent-Approval Linkage System may not be all positive for South Korean pharmaceutical companies as specific legal provisions on the relevant systems have not yet been enacted"

same obligation and also clearly states that if the applicant fails to notify the patentee within the prescribed period, the minister of food and drug safety may order the applicant to notify the patentee personally. Such notification is imperative because the first-generic exclusivity requirement is determined based on the actual date of the notification as it is deemed as the date of MA application, in case the applicant fails to notify within seven days.

The revised draft introduces the marketing prevention system based on the measures set out in Article 18.9(2) of the FTA. When a second mover submits an MA application relying on the safety and efficacy data of an approved drug, the listed drug's MA holder can apply for marketing prevention for a maximum of 12 months after commencing legal proceedings with respect to the relevant patents. The Ministry of Food and Drug Safety will then decide whether to stay the MA process, taking into account the scope of damages incurred by the patentee. However, the listed drug's MA holder cannot apply for such marketing prevention, only targeting specific patents of listed drugs for no justifiable reason. In other words, a selective marketing prevention is not permitted under the revised draft.

If granted, the marketing prevention will expire 12 months after the date of notification from the MA applicant, upon a court ruling or decision of invalidation or non-infringement action, or when the parties settle the matter through conciliation, mediation or arbitration. If the MA holder (or patentee) and the MA applicant relying on the safety and efficacy data of an approved drug enter into an agreement in relation to dismissing pending patent-related legal proceedings and/or first-generic exclusivity, they must submit this to the ministry and the Korean Fair Trade Commission within 15 days of the date of the agreement.

First generic exclusivity

A one-year exclusive marketing right is conferred on the first applicant for MA approval relying on the safety and efficacy data of an approved drug, which has successfully challenged a patent of an original drug in either an invalidation action or non-infringement action. During that period, other generic drugs which have equivalent formulation, composition, amount and efficacy of active ingredients of the drug that has been granted exclusivity are prohibited from entering the market.

This system has been adopted to encourage drug development and R&D investment, and to facilitate the efficient and successful market entry of second movers.

First-generic exclusivity may be revoked if one of the following occurs:

- The MA of the exclusive right holder expires;
- The patent period of a listed drug expires (excluding situations where such a patent was invalidated by the exclusive rights holder);
- The exclusive right holder is not granted MA approval within 12 months of the date of filing;
- Marketing is delayed with no justifiable reason for over two

months from the possible marketing date;
- A court or the Fair Trade Commission finds that the exclusivity rights are in violation of the Monopoly Regulation and the Fair Trade Act;
- the exclusive rights holder has behaved illegally (eg, by submitting falsified documentation when applying for approval);
- The courts render judgments reversing the above-mentioned successful decision; or
- The marketing prevention adversely affects the public interest.

Any interested third party can provide the Ministry of Food and Drug Safety with information in relation to any of the above events.

Patent-Approval Linkage Tribunal

The Ministry of Food and Drug Safety will establish the Patent-Approval Linkage Tribunal, comprising professionals from the medical, pharmaceutical, patent and legal sectors. The tribunal administers a separate appeals process which will allow a review to be requested with respect to a decision issued by the ministry or in connection with a dispute between interested parties. A party may then seek to appeal the matter further to the Korean Patent Court. The ministry anticipates that the tribunal will provide swifter and more technically sound and professional decisions, while simultaneously safeguarding the rights of interested third parties.

Conclusion

The keen interest taken by pharmaceutical companies in the United States and Europe in the South Korean pharmaceutical market is likely to increase as the Patent-Approval Linkage System strengthens the rights of patentees. As a consequence, the number of patent disputes is also likely to increase as patentees seek to prevent second movers from entering the market. However, the system is also designed to encourage drug development and R&D investment in order to facilitate South Korean companies to gain a foothold in the world market. Challenges by manufacturers of generic drugs have already begun as the costs and barriers associated with such challenges are relatively lower in South Korea compared to those in the United States and Europe. As such, the importance of patents in the marketing strategies of pharmaceutical companies cannot be over-emphasised.

Be that as it may, the immediate effects of the Patent-Approval Linkage System may not be all positive for South Korean pharmaceutical companies, as specific legal provisions on the relevant systems have not yet been enacted. Consequently, there is still much work necessary to complete this picture, such as establishing a special tribunal to resolve conflicts between manufacturers of original drugs and generic drugs, and implementing relevant subordinate laws and regulations. At the same time, the pharmaceutical industry must prepare itself to embrace all the changes and challenges in time to implement the revised draft on March 15 2015. ■

Lee & Ko
Hanjin Building, 63 Namdaemun-ro,
Jung-gu, Seoul 100-770, Korea
Tel: +82 2 772 4000
Fax: +82 2 772 4001
www.leeko.com

Eun Kyoung Lyu
Associate
Lee & Ko
South Korea
Tel: +82 2 2191 3206
Fax: +82 2 772 4001/2
eunkyoung.lyu@leeko.com

Eunkyoung Lyu is an associate at Lee & Ko. Previously, she served as a patent examiner at the Korean Intellectual Property Office for six years from 2005. Having examined and reviewed a broad range of patent applications for fine chemicals, electronic materials, biocide, biotechnology and pharmaceuticals, she has a vast knowledge of IP rights, especially in the chemical sector. Based on her extensive experience as a patent examiner, Ms Lyu now works primarily on the enforcement of IP rights, covering patents, trademarks, copyright, designs, trade secrets, unfair competition and work-made-for-hire inventions.