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Update of Patent Linkage System for Pharmaceutical Products in Taiwan

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Update of Patent Linkage System for Pharmaceutical Products in Taiwan

The patent linkage system for pharmaceutical products, which was added in response to the revised Taiwanese Pharmaceutical Affairs Law, has officially gone into effect. In addition, the enforcement rules and detailed procedures for implementing the patent linkage system have also been implemented. The latest information is explained below.

1. The Pharmaceutical Affairs Law

According to Decree No. 1080025868 dated August 6, 2019, the Executive Yuan officially decided to enforce the provisions relating to the patent linkage system for pharmaceutical products (Chapter 4-1, Articles 92-1, 100 and 100-1 of the Pharmaceutical Affairs Law) from August 20, 2019.

For example, the newly established patent linkage system for pharmaceutical products is defined as follows.

a. Rules for disclosure and registration of patent information on new drugs

The new drug license holder must disclose the content of the patent within 45 days from the date on which the license was obtained for substance patents, composition or formulation patents and pharmaceutical patents for drug-related use.

In addition, according to Article 48-21 of the revised Pharmaceutical Affairs Law, if the patent right is related to a patent right that satisfies the content disclosure provisions of Article 48-3, Paragraph 2 before the enforcement of the provisions related to the patent linkage system and the patent right has not expired, the new drug license holder can submit the patent information within three months after the enforcement of the revised provisions.

b. Rules for declaration and announcement by generic drug applicant

According to the provisions of Article 48-9 of the revised Pharmaceutical Affairs Law, generic drug applicants must declare the following items.

(1) With respect to the new drug, whether no patent information has been registered,

(2) Whether the patent rights on the new drug have already expired,

(3) Whether the Food and Drug Administration of Taiwan ("TFDA") has issued an initial generic drug license before the patent rights on the new drug have expired, and

(4) Whether the patent rights on the new drug should be invalidated or the generic drug for which a license has been applied for does not infringe the patent rights of the new drug.

c. Challenges to patents and responses

The patentee or exclusive licensee may file a patent infringement lawsuit within 45 days from the date on which a notification of "Whether the patent rights on the new drug should be invalidated or the generic drug for which a license has been applied for does not infringe the patent rights of the new drug" is received from the generic drug applicant. The patentee or exclusive licensee is required to simultaneously notify the TFDA.

d. Rules for temporary suspension of generic drug license issuance

The TFDA must temporarily suspend the issuance of a generic drug license within 12 months from the date on which the new drug license holder received notification from the generic drug applicant and filed a patent infringement lawsuit.

Please refer to our February 2018 newsletter regarding the Patent Linkage System for Pharmaceutical Products in Taiwan.

(https://se1910.com/en/newsletters-ja/taiwan-ip-newsletter-february-2018/)

2. “Regulations for the Notification of Pharmaceuticals Patent Linkage Agreements”

According to Decree No. 1080025868, the “Regulations for the Notification of Pharmaceuticals Patent Linkage Agreements” published on March 6, 2019 was also implemented from August 20, 2019.

According to Articles 48-19 and 92-1 of the revised Pharmaceutical Affairs Law, if settlement agreements or other agreements concluded between the applicants for new drug licenses, holders of new drug licenses, applicants for generic drug licenses, holders of generic drug licenses, the patentee or the exclusive licensee of the drug are related to the manufacture, sale and sales period of exclusive manufacturing of the drug, both parties must notify the TFDA within 20 days from the day after the settlement is made, and in the case of a reverse payment agreement, both parties must notify the Fair Trade Commission. Otherwise, a fine of NT $ 30,000 to NT $ 2 million will be imposed.

Regulations for the Notification of Pharmaceuticals Patent Linkage Agreements stipulates the method of notification, content, date of calculation of the period, processing method of the TFDA for the notification, etc.

These provisions are considered to be a system which is in place to avoid the lack of equity and maintain fair and reasonable market transactions.

3. “Enforcement Rules of Patent Linkage System for Pharmaceutical Products”

After the draft of the “Enforcement Rules of Patent Linkage System for Pharmaceutical Products”, which prescribes the details of the patent linkage system for pharmaceutical products, was announced on September 11, 2018 and January 30, 2019 for public opinion, it was finally officially announced by the TFDA on July 1, 2019 (hereinafter “Enforcement Rules”).

There are a total of 18 Enforcement Rules. These rules cover the method, content, changes or deletions, registration and disclosure of patent information on drugs (Enforcement Rules 5 and 6), statements, notification from applicants for generic drug licenses, the procedures for examination of applications and issuance of drug licenses (Enforcement Rules 8-11, 13 and 14), notification from new drug license holders on patent infringement lawsuits filed by patentees or the exclusive licensee (Enforcement Rule 12), and related information

The following are some of the points of particular interest to the pharmaceutical industry.

a. Polymorphs

The scope of patents disclosed is defined as a substance, composition or formulation, or pharmaceutical patents for drug-related use (Article 48-3 of the Pharmaceutical Affairs Law). However, if the substance invention is the polymorphs of the active ingredients contained in the pharmaceutical formulation, the issue of whether polymorphs patents should be disclosed was particularly discussed when the draft proposal for the Enforcement Rules was written.

In general, the term “polymorphs” encompasses the following types: crystalline, amorphous, hydrate, and solvated. In response to a generic drug manufacturer's opinion that

the scope of substance patents disclosed should not be extended to polymorphs not approved in new drug licenses, but instead only to the extent approved in new drug licenses, pharmaceutical manufacturers argued that since different polymorphs are included in the scopes of substance patents listed in countries with patent linkage systems, such as the United States, South Korea, and Canada, that polymorphs should fall within the scope of patents disclosed.

In response to these opinions, the TFDA held a hearing in November 27, 2018, and clarified that the scope of substance patents disclosed includes different polymorphs of the same ingredient, but if the substance invention is the polymorphs of the active ingredients contained in the pharmaceutical formulation, there should be test data in the drug registration application proving that pharmaceutical preparations containing the polymorph as an active ingredient have similar therapeutic effects.

b. Biosimilar

In addition, the TFDA expressed the opinion that the holder of a biological drug license can disclose patents related to the biological drug, but that since biosimilar drugs are not generic drugs, the linkage system will not be applied to biosimilar drugs. The above was determined at a hearing held on November 27, 2018.

However, during further amendment of the Enforcement Rules, the following opinion was reiterated: "If a patent related to a biological drug is disclosed, the TFDA must temporarily suspend the issuance of a generic drug license within 12 months from the date on which the new drug license holder received notification from the generic drug applicant and filed a patent infringement lawsuit". Furthermore, publicized Rule 16 of the Enforcement Rules states that applicability of the provisions governing the drug approval application for generic drugs to biosimilar drugs protects patents regarding biologics. The Enforcement Rules also stipulate a transitional clause stating that the relevant provisions of the chapter of the patent linkage system shall not apply to biosimilar drugs for which official approval for clinical trials has been issued by the central competent authority before the patent linkage is officially implemented.

Therefore, it is certain that Taiwan will actively promote the patent linkage system for drugs. Whether the role of the system can be fully demonstrated will need to be determined from a deep understanding of how it is being used and further development of and changes to the system.

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