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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 Legislative Yuan (equivalent to the Japanese national Diet) passed a proposal for the partial revision of the Pharmaceutical Affairs Law on December 29, 2017. The revision and newly established articles are 26 in all, and data protection for new indications and a patent linkage system were introduced in accordance with this revision proposal. Patent linkage is a system whereby a country links drug marketing approval of a generic drug to the status of the patents related to the originator's product.

The newly established patent linkage system in Taiwan is positioned to be a part of Taiwan's Trade and Investment Framework Agreement (TIFA) and the Trans-Pacific Partnership (TPP), and involves the disclosure and registration of patent information on new drugs, declaration and announcement by generic drug applicants, challenges to patent rights and related correspondence, temporary suspension of the issuance of generic drug licences, and market exclusivity of generic drug manufacturers who first obtained a drug license.

The following are brief comments on the aforementioned issues involving the new patent linkage system in Taiwan.

1. Disclosure and registration of patent information on new drugs

According to the provisions of Article 48-3 to Article 48-8 of the revised Pharmaceutical Affairs Law, the new drug license holder must disclose the information of the patent within 45 days from the date on which the license was obtained for substance patents, process patents and pharmaceutical patents for drug-related use. The patent information includes the patent certificate number, the term of the patent, the patent proprietor, and the name of the licensee, if any. In the case of pharmaceutical patents for drug-related use, it is also necessary to clearly disclose the claim number which protects the approved drug. On the other hand, if the registered patent information does not satisfy the statutory requirements or is registered erroneously, anyone can submit a request to delete or correct the registered patent information to the Taiwan Food and Drug Administration (TFDA) as long as the appropriate reasons and evidence are provided.

Our comment:

We believe that the patent linkage system was established so that research and development by other drug manufacturers does not fall within the scope of the patent due to the earlier disclosure of patent information on new drugs to the public. On the other hand, it is expected that generic drug manufacturers will be able to prepare their cases at an early stage by disclosing patent information. New drug license holders are obliged to disclose patent information, but the proposal explains that it is still possible to enforce patent rights against generic drug manufacturers for non-conformance with this obligation.

2. 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.

a. With respect to the new drug, whether no patent information has been registered,

b. Whether the patent rights on the new drug have already expired,

c. Whether the TFDA has issued an initial generic drug license before the patent rights on the new drug have expired, and
d. 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.
Our comment:
In order to reduce the risk of being unable to consistently supply drugs to patients once it becomes involved in a patent dispute, it is necessary for generic drug applicants to declare whether the generic drugs infringe the patent rights of the new drugs. With respect to the above a. and the above b., there is no risk of infringement of patent rights, so a license may be issued after completion of the examination under the Pharmaceutical Affairs Law by the TFDA. With respect to the above c., it is possible that there are two or more patent rights on one new drug, so if there is even one patent right whose patent term has not expired, the manufacture and sale of generic drugs can be an infringement of a patent right. Therefore, a generic drug license will be issued after all the patent rights have expired. With respect to the above d., the generic drug applicants must notify the new drug license holder and the TFDA in writing and provide reasons and evidence for invalidation and non-infringement. If the new drug license holder is different from the registered patent proprietor and exclusive licensee, those individuals should also be notified. The TFDA will check only the formal content of the notice but will not substantively examine the reasons and evidence that were submitted.

3. Challenges to patents and responses
The patent proprietor or exclusive licensee may file a patent infringement lawsuit within 45 days from the date on which a notice is received from the generic drug applicant. At the same time, the patent proprietor or exclusive licensee is required to notify the TFDA accordingly.
Our comment:
A practical way to challenge a patent right is to request a patent invalidation trial before the Taiwan Intellectual Property Office (TIPO). According to a report by the TIPO, the percentage of Taiwanese patent rights invalidated in recent years is about 44%, while the winning percentage of generic drug manufacturers is about 83.7% in patent infringement lawsuits between generic drug manufacturers and original drug manufacturers. Judging by such data, the environment in Taiwan seems to favor generic drug manufacturers.

4. Temporary suspension of the issuance of generic drug licenses
According to the provision of Article 48-13 of the revised Pharmaceutical Affairs Law, 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. However, if the patent proprietor or exclusive licensee: 1) does not file a lawsuit within 45 days from the date on which the notification was received; 2) or if there is a valid judgment showing that the generic drug applicant did not infringe a patent right of the new drug, if the patent right is invalidated by the TIPO, if there is a settlement reached between the parties, or if the patent right became extinct; the TFDA must issue a generic drug license.
On the other hand, if the drug license is temporarily suspended and damage to the generic drug manufacturers was caused because of the illegal exercise of the patent right by the patent proprietor or the exclusive licensee, the patent proprietor or the exclusive licensee will be liable for damages.
Our comment:

If the patent proprietor or exclusive licensee files a patent infringement lawsuit, the TFDA will temporarily suspend the issuance of the drug license. Therefore, it is expected that a number of lawsuits will be filed by the original drug manufacturers. For this reason, the Taiwan Pharmaceutical Industry Association (TPMA), the Pharmaceutical Manufacture and Development Association (PMDA) and the Taiwan Generic Pharmaceutical Association (TGPA) submitted a joint statement stating that the patent proprietor or the exclusive licensee should prove that it would be possible to win a patent infringement lawsuit and provide a guaranty bond in order to prevent abuse of patent rights. If related laws and regulations are to be developed in the future, it is possible that such a suggestion will be taken into consideration.

5. The market exclusivity of generic drug manufacturers who first obtained a drug license

According to the provision of Article 48-16 of the revised Pharmaceutical Affairs Law, generic drug manufacturers who first obtained a drug license and successfully challenged the original manufacturer's patent rights will obtain a market exclusive period of 12 months. During this period, applications for identical items by other applicants will not be approved.

Our comment:

A market exclusivity period of 12 months is provided to generic drug manufacturers once they successfully challenge the original manufacturer's patent rights, even if they do not hold a patent. From this point of view, the patent linkage system has become very attractive to generic drug manufacturers.

6. Protection of data exclusivity and market exclusivity

According to the provisions of Article 40-2 and Article 40-3 of the revised Pharmaceutical Affairs Law, the five-year data protection period for new ingredient drugs has been shortened to three years, but the five-year market exclusivity period and the three-year data protection period for drugs that have been marketed abroad and contain new ingredient(s) have not been revised. In addition, the provision regarding a two-year data protection period and a three-year market exclusivity period for additional indication, a five-year data protection period and a three-year market exclusivity for newly-indicated drugs for which there is clinical data in Taiwan have been added.

In Taiwan, there are many who have criticized this provision for not taking into consideration the development status regarding generic drugs, especially where the temporary suspension of issuing licenses for generic drugs is concerned, and also because it prolongs the period of approval of generic drugs. However, when judging whether the patent linkage system is favorable or not, we should first consider one issue which is how to protect an original drug manufacturer who holds a patent. After a period of time elapses following the launch of a new drug, the patent term of 20 years expires due to research and development, clinical trials and approval procedure, and the drug is subject to threat from generic drugs.

Since the benefits of new drug manufacturers rest on the protection provided by patents, the patent linkage system plays a role in resolving conflicts by making use of its related benefits. In the end, the ultimate responsibility for the resolution lies with the TIPO and the IP Court in Taiwan, which are the arenas in which invalidation and patent infringement litigation take place. At the present time, the revised Pharmaceutical Affairs Law has been in force since January 31, 2018, which is the date on which the President issued the promulgation, but it is not yet clear when the Taiwan patent linkage system will be enforced. In addition, it will take time to prepare a database for disclosure and

registration of patent information on new drugs and to establish the other related laws and regulations, so we believe it will be necessary to carefully observe the future progress of this system.

Source:
Publication of the President of the Republic of Taiwan
https://www.fda.gov.tw/upload/133/20170523120331851 35.pdf

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Sonderhoff & Einsel Law and Patent Office
Shin-Marunouchi Center Bldg. 18/19F
1-6-2 Marunouchi, Chiyoda-ku
Tokyo 100-0005, Japan

tel +81-3-5220-6500
fax +81-3-5220-6556