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Patents
Taiwan Seeks to Join TPP with Draft Pharma Law Amendments

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Taiwan has released a draft amendment to its Pharmaceutical Affairs Act in a bid to join the Trans-Pacific Strategic Economic Partnership Agreement (TPP).

Taiwan's laws are already mostly in line with the TPP's IP provisions. However, on measures relating to pharmaceutical products, there are discrepancies regarding patent linkage and data exclusivity for pharmaceuticals and biologics. Therefore, the Taiwan Food and Drug Administration (TFDA), the Central Competent Health Authority, has drafted amendments of the Pharmaceutical Affairs Act (PAA) and held public hearings on these proposed changes.

Data and Marketing Exclusivity.

Under current Article 40-2 of the PAA, only drugs containing a new active ingredient enjoy five-year data and marketing exclusivity. The TFDA amended the PAA by newly introducing Article 40-3 to confer data and marketing exclusivity for a drug with new indication (the first bill) and held a public hearing on November 17, 2015.

Under the newly added Article 40-3 of the first bill, within three years after the issuance date of a market approval for a drug with new indication, other applicants, without the approval holder's consent, shall not cite for the purpose of applying for a market approval the information submitted in the approval holder's application, and a generic version cannot be approved for five years.

However, the new Article 40-3 also sets a limitation to the application of exclusivity right. That is, if the applicant files a market approval for a drug with new indication in another country first, the applicant must file the application for the same drug with the new indication within two years in the Republic of China (Taiwan) after the issuance of the market approval in another country. The first bill was approved by the Cabinet on February 4, 2016 and has been submitted to the Parliament for legislation.

Patent Linkage.

Taiwan currently does not have a patent linkage system. To join the TPP, the TFDA drafted amendments to the PAA by adding Articles 48-2 to 48-21 (the second bill) and held a public hearing on January 27, 2016. These newly added articles concern patent listings, patent declarations certified by an applicant filing an Abbreviated New Drug Application (ANDA), notification of the ANDA filing to the New Drug Application (NDA) holder, stay of issuing market approval to the generics by the TFDA, and marketing exclusivity provision conferred to the first ANDA applicant who suc- cessfully defends a patent infringement suit. The second bill might be subject to further revisions by the TFDA.

Patent Listings

According to Article 48-2 of the second bill, an NDA holder must list patents and claims that cover the drug within 45 days of issuance of an NDA market approval. In addition to patent information (such as patent number, patent expiry date, patentee and exclusive licensee), the NDA applicant should specify claims relating to the drug. Generally speaking, drug substance patents, composition patents, formulation patents and medical use patents can be listed. It is not yet clear whether other types can be listed. According to our understanding, the TFDA will create guidelines on the listing details in the future.

Article 48-5 of the second bill provides that a third party who alleges that the listed patent information is incorrect can notify the TFDA with a written explanation and evidence attached. The TFDA will notify the NDA holder of the third party's notification and relevant documents within 20 days of receipt of the notification.

Patent Certifications Certified by ANDA Filer

According to Article 48-8 of the second bill, the ANDA applicant shall simultaneously or separately select the following as a declaration for each of the listed claims claimed by the NDA holder:

(i) No patent information has been listed for the new drug;
(ii) The patent corresponding to the new drug has extinguished;
(iii) The TFDA will issue the generic market approval after the extinguishment of the patent(s) corresponding to the new drug; and
(iv) The patent corresponding to the new drugs should be revoked or will not be infringed by the generic drugs for which market approval is sought.

Notifying NDA Holder and Staying Market Approval to Generics

According to Article 48-11 of the second bill, the ANDA applicant having a declaration of Item (iv) of Article 48-8 shall inform the NDA holder and the TFDA in writing no later than 20 days after the day that all the required documents required for filing the market approval have been completed and well-prepared. After the NDA holder, patentee or patent exclusive licensee receives the notification, it can file a patent infringement suit within 45 days after the receipt of the notification under Article 48-12 of the second bill.

Under the same Article, the TFDA shall stay the issuance of the market approval within 15 months after the patentee or patent exclusive licensee receives the notification and files a patent infringement suit. However, the stay can be lifted if the ANDA applicant obtains a judgment that the patent has not been infringed.

Marketing Exclusivity to First Successful ANDA Applicant

According to Article 48-16 of the second bill, the first ANDA holder who successfully defends a patent infringement suit is granted a twelve-month period of marketing exclusivity. The TFDA shall not issue a market approval to other applicants for generic market approval until the expiration of the aforementioned 12-month period.

However, under Article 48-18 of the second bill, if the first ANDA holder fails to market the drug within 180 days after issuance of market approval, it will forfeit the 12-month period of marketing exclusivity.

Article 48-19 of the second bill also states that the TFDA and the Taiwan Fair Trade Commission (TFTC) should be notified of any settlement agreement on patent linkage-related arrangements between the NDA holder and the ANDA applicant or the first ANDA holder to clear any pay-for-delay or other reverse payment concerns.

The TFDA and the TFTC should work together to establish guidelines on the details of such notification in the future. Parties who fail to notify the TFDA and the TFTC might be subject to certain administrative penalties according to Article 92-1 of the second bill.

Next Steps.

The TFDA drafted and proposed both bills. While the first bill has been approved by the Cabinet and has been submitted to the Parliament, the second bill is still under discussion, might be further amended by the TFDA, and has not yet been approved by the Cabinet.

After a bill was approved by the Cabinet and submitted to the Parliament, the Parliament will then undergo first to third readings of the bill. If complicated issues are involved in the bill, several meetings will be held for the legislators to discuss the contents. If the bill passes the third reading, the bill will be sent to the President for announcement.

As the bills move through the legislative process, we may see some opposition and amendments. Some of the provisions are controversial due to business conflict between the generic companies and originator pharmaceutical companies and there is a lot of opposition to the proposed changes. However, before the public hearing, the TFDA held several independent meetings with the generic companies and the originator pharmaceutical companies for discussions and negotiations. The main frame of the bills may not be changed.

Joining the TPP may also be a controversial topic in Taiwan and we cannot rule out the possibility that there will be public opposition.