Taiwan Amendment and China Draft to Introduce the Patent Linkage

On December 29, 2017, Taiwan's Legislative Yuan (Taiwan's Congress) passed the Amendment to the Pharmaceutical Affairs Act ("Taiwan Amendment") to introduce the patent linkage system. Similarly, the China Food and Drug Administration ("CFDA") also released the draft "Relevant Policies on Encouraging Innovation in Drug and Medical Devices and Protecting the Rights and Interests of Innovators" to introduce the patent linkage system ("China Draft").

I. PATENT LISTING

According to the Taiwan Amendment, the owner of a drug permit license for a new drug ("Owner") can, by submitting the documents and information related to Listable Patents, request the Taiwan Food and Drug Administration ("TFDA") to list the relevant patents on the public database ("Listed Patents") to establish the patent linkage. The term "Listable Patents" refers to substance patents, composition or formulation patents, and medical usage patents. The Owner shall file the documents and information related to the Listable Patent to the TFDA within 45 days of the issuance of the drug permit license. If a Listable Patent is granted by the Taiwan Intellectual Property Office ("TIPO") after the issuance of the drug permit license, the Owner shall file the patent documents and information to the TFDA within 45 days of the grant of the patent. If the Owner is different from the patentee, the Owner shall first obtain the patentee's consent or the exclusive licensee's consent if the exclusive license of the patent is registered with the TIPO.

II. UPDATES or DELISTING

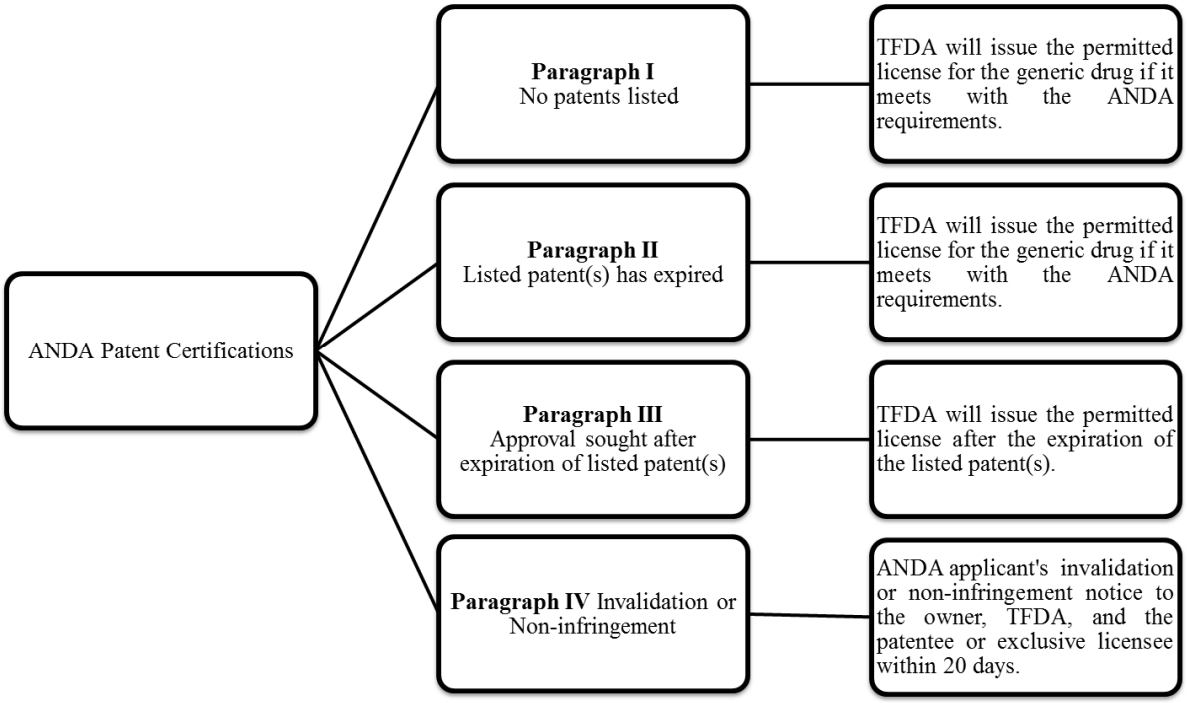
The Owner is obligated to update the Listed Patent information within 45 days of the effective date of the change of the Listed Patent.

Further, the Taiwan Amendment also provides the delisting mechanism. Any person or entity may file a written notice to request for the delisting of a Listed Patent to the TFDA if any of the following situations exists: (1) the Listed Patent is irrelevant to the permitted drug; (2) the Listed Patent does not belong to the Listable Patents; (3) the Listed Patent information is inaccurate; or (4) the Owner fails to file the updates according to the foregoing stipulation. Upon receipt of such notice, TFDA shall forward such notice to the Owner within 20 days, and TFDA shall request the Owner to file its written response or update within 45 days upon the Owner's receipt of the notice. After receiving the written response or update from the

Owner, TFDA will list the contents of the notice and the Owner's response on the public database.

III. ANDA PATENT CERTIFICATIONS

Following regulations similar to those stipulated in the U.S. Hatch-Waxman Act, TFDA now requires the ANDA applicants for generic drug permit licenses to file one of the following certifications ("ANDA Patent Certifications") to TFDA:



IV. STAY OF APPROVAL

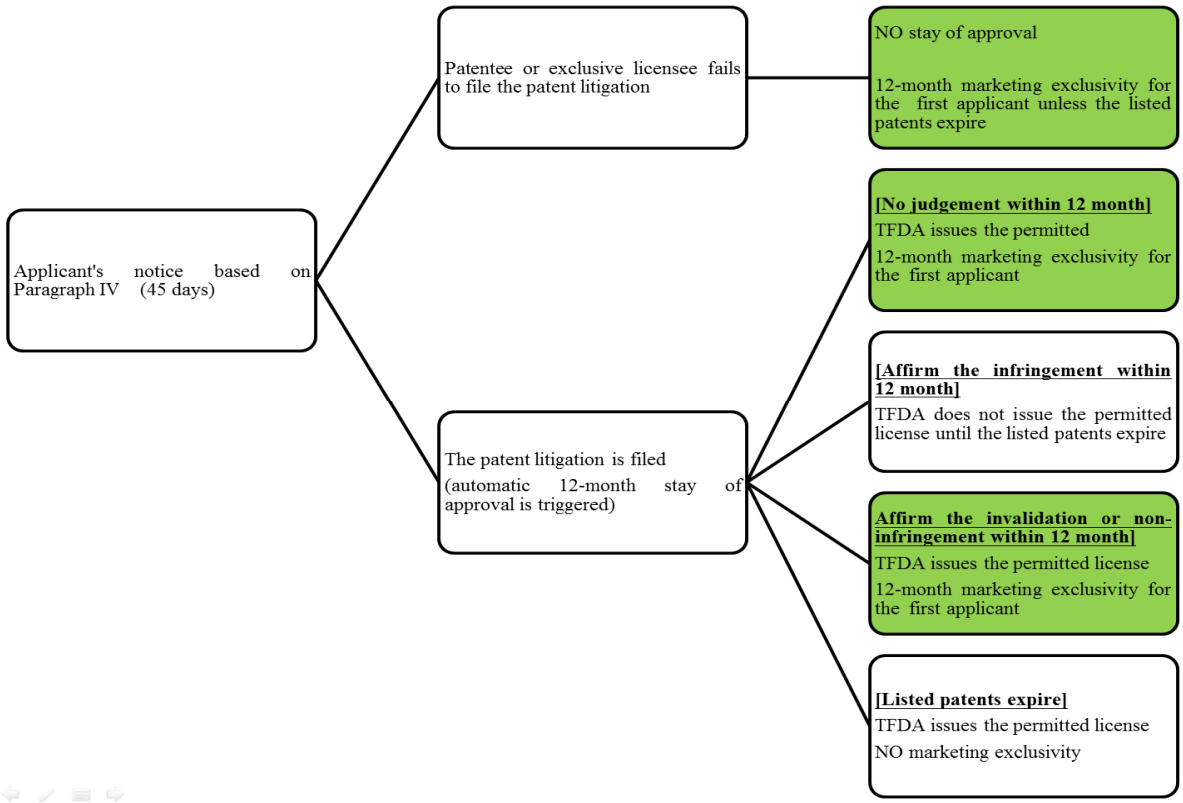
In accordance with Paragraph IV of ANDA Patent Certifications, the patentee or exclusive licensee may file for patent litigation based on the Listed Patent(s) against the ANDA applicant within 45 days of the receipt of the ANDA applicant's notice. If the patentee or exclusive licensee files for such patent litigation and notifies TFDA of the filing for the patent litigation, a 12-month stay of approval shall be triggered unless otherwise provided in the Taiwan Amendment. During the 12-month stay of approval, TFDA shall continue its review and evaluation of the application documentation and will issue a preliminary approval notice to the ANDA applicant if the application meets the ANDA requirements. The preliminary approval notice is not a permitted license, and thus the ANDA applicant cannot manufacture, sell or import the product in question. However, the ANDA applicant may apply to the National Health Insurance Administration for the product to be listed in the National Health

Insurance Pharmaceutical Benefits and Reimbursement Schedule.

V. MARKET EXCLUSIVITY

The first applicant among the ANDA applicants filing the Paragraph IV certification shall be granted the 12-month period of market exclusivity. The "first applicant" is determined by the date of the complete filing of all required ANDA documentation. If there are multiple first applicants meeting the statutory standard, the multiple first applicants shall jointly enjoy the 12-month period of market exclusivity. If any of the following events occurs, the first applicant shall lose its market exclusivity and shall be replaced by the next applicant: (1) the first applicant amends all of his/her Paragraph IV certifications; (2) the first applicant fails to obtain TFDA's preliminary approval notice within 12 months of the date of completion of the required ANDA documentation; (3) the court makes a favorable judgement to the patentee and the judgement becomes final within the 12-month stay of approval.

The first applicant shall launch the generic drug within 6 months of the date of receipt of the permitted license, and shall submit the evidence supporting the earliest launch date to TFDA within 20 days of the earliest launch day. TFDA will review the documentation and determine the 12-month period of market exclusivity starting from the earliest launch day. If the first applicant fails to launch the generic drug within 6 months, the market exclusivity will be automatically canceled.



*** The green sections refer to the scenario that will trigger the 12-month market exclusivity ***

VI. COMPARISON

The China Draft has yet to provide the details of the China patent linkage system. However, the China Draft has built in the Stay-of-Approval mechanism. According to the China Draft, there are two approaches to trigger the Stay-of-Approval:

1. Similar to the Paragraph IV of Taiwan ANDA Patent Certifications :

   If the ANDA applicant in China declared that the generic drug does not infringe the Listed Patents, and the patentee files for patent litigation based on the Listed Patent(s) against the ANDA applicant within 20 days of the receipt of the ANDA applicant's notice, the stay of approval no longer than 24 months would be triggered at CFDA's discretion.

   This is similar to the Paragraph IV of the Taiwan ANDA Patent Certifications. However, under the Taiwan Amendment, the ANDA applicant's invalidation notice (in addition to the non-infringement notice) can also trigger the stay of approval. Further, the Taiwan Amendment provides the statutory 12-month stay of approval. TFDA has no discretion on the length of the stay of approval.

2. In the event that ANDA applicant in China declared that this application does not involve any Listed Patents, if the patentee believes that such application infringes his/her patent and file the lawsuit, CFDA may, at its discretion, set a stay of approval upon its receipt of patentee's filing notice. It is worth noting that the China Draft does not provide a 24-month limitation to such stay of approval while the Taiwan Amendment does not provide such grounds to trigger the stay of approval.