

Taiwan's Patent Linkage System Finally Comes into Effect

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On December 29, 2017, the Legislative Yuan of the Republic of China (Taiwan) passed an Amendment to the Pharmaceutical Affairs Act (PAA) establishing a patent linkage system. On August 20, 2019, Taiwan's long-awaited patent linkage system finally came into effect.

Beginning August 20, 2019, new drug marketing approval holders (new drug MA holder) are able to list any patents covering their products and assert those patents against generic drug applicants in patent litigation actions at first instance.

Skim Through the Patent Linkage System in Taiwan:

- Who is responsible for Patent Listings: Patent listings will be the responsibility of a new drug MA holder.
- Timing Frame for Listing: The time frame for listing any patents is as follows:
 1. A new drug MA holder must list any patents considered to cover a new drug within 45 days after the date marketing approval is received.
 2. Patents granted after marketing approval is received must be listed by a new drug MA holder within 45 days after issuance (e.g., the issue date).
- Types of Patents Eligible for Listing:
 1. The only patents eligible for listing are those that claim: (i) a substance ("substance" refers to the active ingredient(s) of a drug preparation, including inventions directed to different forms of polymorphs of a compound); (ii) compositions or formulation ("composition or formulation" refers to the combination or formulation of the active ingredient(s) of a drug preparations); and/or (iii) medical uses ("medical use" refers to the use corresponding to all or part of the indications identified on the drug permit methods of treatment).
 2. With respect to medical use patents, the new drug MA holder must not only specify the patent number, but, also the specific claims covered by the asserted medical use.
- Making Changes, Deletions, and Corrections to a Listing:
 1. In the event that any information included in a listing needs to be changed (such as, for

example, receipt of approval of a patent term extension for a listed patent, transfer or other assignment of a patent right, patent expiration, etc.), the new drug MA holder must proactively request a change or deletion of the information within 45 days after the date on which the change event occurred.

2. If the patent listed is unrelated to a new drug, is directed to ineligible subject matter (e.g., a method of manufacturing the new drug), or if the listing contains incorrect information, or if a change or correction of information is not timely made, any party may notify the Taiwan Food and Drug Administration (TFDA) with supplying a written explanation regarding the incorrectly listed information as well as any supporting evidence. Upon receipt of such written explanation, the TFDA will serve the new drug MA holder with a copy of the third party's written explanation and supporting evidence within 20 days of receipt of the written explanation. The new drug MA holder must file a written reply and, if necessary, make correction or deletion of the information with the TFDA within 45 days after receipt of the service.
3. The PPA does not provide any penalty in the event that a patent listing made by a new drug MA holder contains incorrect information. Nevertheless, if a new drug MA holder intentionally lists incorrect information that is deemed to be fraudulent, such actions may result in criminal liability for the MA holder.

- Required Certifications by a Generic Drug Applicants:

Under the new linkage system, generic drug applicants who submit a generic drug marketing application (GDMA) for review by the TFDA are required to state whether their proposed products will infringe any patents listed by a drug MA holder. Much like Hatch-Waxman in the United States (U.S.), generic drug applicants in Taiwan will be required to make one of the following certifications:

- (1) The drug has not been listed with patents;
- (2) The patent(s) has already expired;
- (3) The marketing approval for the proposed product will be issued by the TFDA after the patent has expired.
- (4) The patent is not infringed or is invalid.

Generic drug applicants that certify that any listed patents are not infringed or are invalid are required to notify the TFDA and the drug MA holder of the certification and provide evidence supporting their non-infringement or invalidity position within 20 days after the TFDA notifies the generic applicant that all the documents required for an application of drug permit have been duly prepared.

- Consequences of Certification:

1. For GDMA's that contain a certification under section (1) or (2), once the application is

examined and approved, marketing approval by the TFDA will be issued.

2. For GDMAAs that contain a certification under section (3), once the application is examined and approved, marketing approval will be withheld by the TFDA until the listed patent(s) expire.
3. For GDMAAs that contain a certification under section (4), the issuance of marketing approval will depend on the response of the patent owner of the listed patent(s). If the patent owner files a patent infringement action within 45 days after receipt of notification by the generic drug applicant, the TFDA will withhold marketing approval for up to 12 months after receipt of notification from the drug MA holder.

- Reward for Generic Drug Applicants Making a Certification Under Section (4):

1. The generic drug applicant with application documents duly prepared at the earliest and receive approval for a GDMA which contains a certification under section (4) within 12 months after the next day to the date that all the application documents are duly prepared will be rewarded with a 12-month marketing exclusivity period. (Note: the wording of this portion of the law is somewhat ambiguous and further confirmation from the TFDA will be required.)
2. The marketing exclusivity period will begin on the earliest actual sales date of the generic product. The first generic drug applicant is required to inform the TFDA of the earliest actual sales date and provide evidence thereof.
3. The first generic drug applicant is required to begin selling its product no later than 6 months after the date on which the generic drug marketing approval is received.
4. If there is more than one “first generic drug applicant” (first applicants), each of the first applicants will receive a 12-month marketing exclusivity period. However, the 12-month exclusivity period will start to run for all the first applicants beginning on the date that any of them begins to sell the approved product.

- Possible Competition Concerns:

The TFDA should be notified of any settlement agreement on patent linkage-related arrangements between the MA holder and the GDMA applicant or the first GDMA holder. The TFDA has established guidelines on the details of such notification. If the TFDA notices any potential anti-competition arrangements in such agreements, it will transfer the matter to the Taiwan Fair Trade Commission (TFTC) for handling.

- Brief Comparison of the U.S. Hatch-Waxman System and the Taiwan Patent Linkage System:

	U.S. Hatch-Waxman System	Taiwan Patent Linkage
Types of Medicinal products	Chemical (small molecule) drugs; protein drugs (biologics) are not included	Chemical drugs Protein drugs (biologics) are included
Eligible patents for listing	Substance (e.g., compound), composition, or formulation, and methods of treatment patents	Substance (e.g., compound), composition, or formulation, and medical use
Stay of generic drug marketing approval under section (4) (i.e., P4)	30 months	12 months
Marketing exclusivity for the first generic drug applicant	180 days	12 months

- What are the biggest patent litigation growth areas in your jurisdiction in terms of industry sector?

Overall, one of the biggest patent litigation growth areas in Taiwan in terms of industry sector is the biotechnology industry, including the pharmaceutical industry. This reflects the policy direction that the Taiwan government has actively promoted in recent years. As the industry continues to grow, more and more new drugs and new medical materials enter into market, local and global. Many international biotech companies have also developed patent portfolios in Taiwan. In addition, the patent linkage system in Taiwan came into effect on August 20, 2019, and the protein drugs (biosimilar) are also included. The main effects include the stay of the marketing approval for 12 months and the marketing exclusivity for the first generic drug applicant for 12 months. This situation has led to an increasing number of patent litigation disputes in terms of pharmaceuticals in Taiwan.

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