Published on *The National Law Review* https://natlawreview.com

China Releases Patent Linkage Implementation Measures

Article By:

Aaron Wininger

On July 4, 2021, the National Medical Products Administration (NMPA) in conjunction with the China National Intellectual Property Administration (CNIPA) released the Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial) (??????????????????)). The Measures set up a registration system, set up a dual mechanism (via Courts or via CNIPA) for preventing marketing approval of drugs based on registered patents, and provide an exclusivity period for generics that successfully challenge patents.

Registration Platform

Per Article 3, the National Drug Evaluation Agency is responsible for establishing and maintaining a patent information registration platform for listed drugs in China, and publicizing relevant patent information on drugs that have been approved for marketing. The registration platform is currently up and running here.

Per Article 4, the holder of a drug marketing license shall, within 30 days after obtaining a drug registration certificate, register the drug name, dosage form and specifications, the holder of the drug marketing license, the relevant patent number, patent name, patentee, patent licensee, date of patent granting, date of expiry of the protection period, patent status, patent type, relationship between the drug and the relevant patent claims, mailing address, contact person, contact information and other

contents. Where the relevant information is changed, the lister shall complete the update within 30 days after the information change takes effect.

Per Article 5, holders of chemical drug marketing authorizations may register patents for active ingredients of pharmaceuticals, patents for pharmaceutical compositions containing active ingredients, and patents for medical uses.

Generic Certifications

Per Article 6, when submitting an application for the drug marketing license, a chemical generic drug applicant needs to make one of four certifications:

1. There are no relevant patents registered on the platform;

2. The relevant patent has lapsed or was declared invalid or the generic applicant has a license;

3. This is a registered patent but the generic applicant will not sell the drug before expiration of the patent.

4. There is a registered patent on the platform, but it will be declared invalid or the generic is outside the scope of protection of the patent.

Within 10 working days after an application for generic drugs is accepted, the State Drug Evaluation Agency shall disclose the application information and corresponding declaration to the public on the platform. The generic drug applicant shall also notify the lister of the registered patent of the corresponding declaration and basis, and if the lister is not a patentee, the lister shall notify the patentee.

If the declaration is for Type 4 that it does not fall within the scope of protection of the relevant patent, the basis for the declaration shall include a comparison table between the generic drug technical solution and the relevant claims of the relevant patent and the relevant technical materials.

Response to Certification Statement

Per Article 7, if the patent lister or other interested party objects to any of the declarations, they may, within 45 days of the publication of the generic application, it may file a lawsuit with the Beijing Intellectual Property Court or request an administrative ruling from CNIPA. If a party is dissatisfied with a CNIPA ruling, it may sue in the Beijing IP Court.

Within 15 working days of receiving a Notice of Acceptance from the Court or CNIPA, the plaintiff should submit a duplicate of the Notice to the National Drug Evaluation Agency.

Per Article 8, submitting the Notice will generate a 9-month moratorium on drug marketing approval from the date of acceptance. However, the National Drug Evaluation Agency will not cease evaluation of the generic application. Note that the corresponding CNIPA and Supreme People's Court's regulations do not set a 9-month deadline to conclude cases so there is a possibility that the patent linkage system will be ineffective in practice due to the complexity of pharmaceutical patent litigation leading to longer litigation times, especially for foreign patentees.

Marketing Exclusivity

Per Article 11, the first generic applicant that successfully challenges patent validity will enjoy a 12-month exclusivity period. The term of market monopoly shall not exceed the original patent term of the challenged drug. During the period of monopolization, the National Drug Evaluation Agency shall not marketing authorization review of other generics.

Remedies

Per Article 14, after a generic drug is approved for marketing, a patentee may still sue a generic manufacturer for patent infringement. However, marketing authorization will not be withdrawn.

The full text of the Measures is available here: ??????????????????(Chinese only).

National Law Review, Volumess XI, Number 187