Patent linkage in China

Contents:

China's patent linkage system became fully operational on July 5, 2021, as the relevant rules came into effect. Presented below are the key features of this system.

Mechanism of patent linkage in China

(1) **Patent listing**: A platform for listing patents of the originator drugs has been established on the website of the Center for Drug Evaluation, NMPA. Patents eligible for listing on the platform are (a) patents for active pharmaceutical ingredient compound, patents for pharmaceutical compositions comprising the active ingredient, and patents for medical use for small molecule chemical drugs, and (b) patents for sequence structure of the active ingredient and patents for medical use for biological products. But patents for intermediates, metabolites, crystal forms, preparation methods, and detection methods are excluded from listing.

The marketing authorization holder (MAH) shall register the patent information of the approved drug within 30 days from approval of the drug, and where related patent information changes, update the patent information within 30 days after the information change takes effect. Patents that are not listed on the platform are not qualified for patent linkage in China.

We are pleased to announce that we are able to prepare and submit patent information for MAH on the platform. Should you have any questions or need further information regarding patent listing, please do not hesitate to contact us.

(2) **Patent certifications**: Generic applicants must submit one of the following 4 types of certifications for each patent listed and provide the MAH with a hard copy of the certification and the basis of the certification and send an electronic copy to the email address registered by the MAH on the platform:

(i) No patents listed;
(ii) Patent term terminated or patent invalidated;
(iii) The generic will not be marketed until expiration of patents; and

(iv) Patent should be declared invalid, or does not cover the generic drug.
Generic drug application (ANDA) and certification shall be publicized on the above-mentioned platform.

(3) **Right to sue**: The patentee or interested party may take legal action before a court (civil action route) or request an administrative adjudication with CNIPA (administrative adjudication route) against the type (iv) certification within 45 days from the date when NMPA publicizes the ANDA. After the case is accepted, the patentee must submit the receipt to NMPA within 15 working days and notify the generic applicant.

(4) **9-month waiting period**, which is triggered only once, by the receipt of the case, and during which period the ANDA cannot be approved but technical review is not suspended.

(5) **Suspension to approve ANDA**: Where an effective judgement or an administrative adjudication decision holds that the generic is covered by a listed patent, the ANDA shall not be transferred to the administrative examination and approval step until the patent is close to expiration. Otherwise, in cases of no infringement, invalid patent or no timely judgement/decision available, ANDA can be approved.

(6) **Market exclusivity**: The first successful patent challenger/approved ANDA applicant is rewarded with a market exclusivity of 12 months.

(7) **Biological products**: Biologics differ from small molecule drugs in that biologics are not entitled to 9-month waiting period. If the patentee files a lawsuit or requests administrative adjudication and an effective judgement or an administrative adjudication decision holds that the biosimilar is covered by a patent, the biosimilar application will be approved but on the condition that the biosimilar must not be marketed until expiration of the patent. In addition, a market exclusivity of 12 months is not available to biosimilars.

Litigation under the patent linkage: Civil action route

(1) **Jurisdiction**: Beijing IP Court has the exclusive jurisdiction over the first instance of patent linkage civil actions.

(2) **Patents**: Patent linkage civil actions can only be based on the patents listable on the China's platform.

(3) **Parties and case types**: Patentee, licensee and brand-name drug MAH (collectively "patentee" hereinafter) as well as generic drug (or biosimilar) applicant may take legal

action before a court or file a request for administrative adjudication with CNIPA, which means that the patentee may file a ANDA patent infringement action, and the generic drug applicant may file a declaratory judgement action.

(4) **Evidence to initiate civil actions**: The patentee shall submit the patent information and drug information listed on the platform, as well as type IV certification; and in reply, the generic drug applicant shall file copies of technical materials submitted with NMPA that can determine infringement or non-infringement.

(5) **Parallel proceedings**: Successful filing of administrative adjudication case with CNIPA cannot preclude from filing or stay the civil action.

(6) **Relation with invalidation**: filing of invalidation request with CNIPA generally cannot stay the patent linkage civil action.

(7) **Defense**: Defense can be (i) prior art defense, and (ii) prior use defense.

(8) **Preliminary injunction**: Preliminary injunction is available to stop the act of infringement, which covers making, using, selling, offering to sell and importing, but not the act of filing, review and approval of ANDA application.

(9) **Abuse of rights**: The generic drug applicant can sue for damages if the patentee knew or ought to have known that the patent in suit should be invalidated or the generic drug does not fall within the patent scope.

Litigation under the patent linkage: Administrative Adjudication route

(1) **Jurisdiction**: CNIPA has the exclusive jurisdiction over the administrative adjudication of disputes connected to patent linkage.

(2) **Parties**: The Patentee, licensee and brand-name drug MAH as well as the applicant for generic drug (or biosimilar) marketing authorization may file a request for administrative adjudication with CNIPA.

(3) **Patents**: Administrative adjudication can only be based on the patents listed and qualified on the China's platform.

(4) **Parallel proceedings**: No (successful) prior lodging of a civil action before a court is one of the conditions for filing a request for administrative adjudication with CNIPA. Please note, however, that successful filing of administrative adjudication case with CNIPA can neither preclude from filing nor stay the civil action according to the rules of the Supreme People's Court.

(5) **Relation with invalidation**: All the claim(s) in suit of the patent being invalidated, either before or during the administrative adjudication, can be a ground for dismissal of the administrative adjudication; in case of a part of the claims in suit of the patent being invalidated, the administrative adjudication will be based on claims in suit that are maintained valid.

(6) **Examination of the request**: The examination of the request for administrative adjudication may be conducted via a written trial or an oral trial at the CNIPA's discretion taking account of the parties' request and in case of oral trial, CNIPA shall notify the parties at least five working days beforehand.

(7) **Decision**: In the decision of the administrative adjudication, CNIPA shall determine whether the technical solution of the generic drug (or biosimilar) falls within the protection scope of the relevant patent and such decision shall be published. The decision can be appealed to the court.

(8) **Trade secret**: The parties as well as staff of CNIPA are obliged to keep confidential the trade secrets they learned from the administrative case.