

# English Translation<sup>1</sup> of Provisions of the Supreme People's Court on Several Issues Concerning Application of Law to the Trial of Patent Civil Cases Involving the Review and Approval for Drug Marketing (Draft for Comment)

For the purpose of proper trial of patent civil cases involving the review and approval for drug marketing, these Provisions are formulated in accordance with the *Patent Law of the People's Republic of China*, the *Civil Procedure Law of the People's Republic of China* and other relevant laws and regulations and in combination with the intellectual property trial practice.

**Article 1** Patent civil cases of first instance involving the review and approval for drug marketing as stipulated in Article 76 of the *Patent Law* shall be under the jurisdiction of Beijing Intellectual Property Court.

**Article 2** The related patent mentioned in Article 76 of the *Patent Law* refers to the related patent registered on the China Patent Information Registration Platform for Listed Drugs for an original drug registered and marketed in China.

The interested parties mentioned in Article 76 of the *Patent Law* refer to a licensee of the related patent mentioned in the preceding paragraph and a holder of the marketing approval of the registered drug. The relevant parties refer to a holder of the related patent

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<sup>1</sup> THE USPTO IS PROVIDING THIS TRANSLATION SOLELY AS A CONVENIENCE TO THE ENGLISH-READING PUBLIC. WE HAVE ATTEMPTED TO PROVIDE AN ACCURATE ENGLISH TRANSLATION OF THE CHINESE DOCUMENT, BUT DUE TO THE NUANCES IN TRANSLATING FROM CHINESE TO ENGLISH, SLIGHT DIFFERENCES MAY EXIST. WE WILL MAKE EVERY EFFORT TO CORRECT ERRORS BROUGHT TO OUR ATTENTION.

mentioned in the preceding paragraph, interested parties and a marketing approval applicant.

**Article 3** Where a party brings an action mentioned in Article 76 of the *Patent Law*, it shall comply with the provisions of the *Civil Procedure Law* on the conditions for bringing an action, and submit the following evidence materials when bringing an action:

(1) Information on the related patent registered on the China Patent Information Registration Platform for Listed Drugs;

(2) Related information on a drug under application for registration and a statement on not falling within the scope of protection of the related patent right that are publicized on the information platform of the national drug evaluation agency;

(3) Preliminary evidence about whether the technical solution of the drug under application for registration falls within the scope of protection of the related patent right.

The marketing approval applicant shall, within the time limit for defense in the first instance, submit to the people's court copies of the technical materials declared to the national drug evaluation agency and corresponding to the determination of whether the drug falls within the scope of protection of the related patent right.

**Article 4** Where the claims as the basis of an action mentioned in Article 76 of the *Patent Law* filed by a patent holder or an interested party is beyond the patent types that can be registered for the declared drug on the China Patent Information Registration Platform for Listed Drugs, the people's court shall not accept the action; and where the action has been accepted, the people's court shall rule to dismiss the action.

Where part of the claims as the basis of the action mentioned in Article 76 of the *Patent Law* brought by a patent holder or an interested party falls under the circumstance as prescribed in the preceding paragraph, the people's court may decide not to accept the action against that part, and where the action has been accepted, the people's court shall not include it in the scope of the trial.

**Article 5** Where, after an action mentioned in Article 76 of the *Patent Law* has been brought by a party, another action mentioned in Article 76 of the *Patent Law* is brought by other parties for the same patent right and drug under application for registration, the people's court may combine the trial of the actions according to law. Where an application by a patent holder or an interested party to participate in the action as a third party

conforms to the relevant provisions of the *Civil Procedure Law*, the people's court shall give its permission.

**Article 6** Where a party, on the ground that the patent administration department of the State Council has accepted the application for administrative ruling mentioned in Article 76 of the *Patent Law*, claims that the action mentioned in Article 76 of the *Patent Law* shall not be accepted or applies to suspend the action, the people's court shall not support the party.

**Article 7** Where a party, on the ground that the patent administration department of the State Council has accepted the request for the related patent invalidation, applies to suspend the action mentioned in Article 76 of the *Patent Law*, the people's court generally will not support the party.

**Article 8** Where the claim as the basis of the action mentioned in Article 76 of the *Patent Law* filed by a party is declared invalid by the patent administration department of the State Council, or the administrative judgment of first instance ascertains that the claim falls under the circumstances where the claim shall be declared invalid, the people's court may dismiss the action brought by the patent holder or the interested party, or may adjudge that the technical solution of the drug under application for registration does not fall within the scope of protection of the related patent right upon the request of the marketing approval applicant.

**Article 9** Where the marketing approval applicant claims the prior art defense in the action mentioned in Article 76 of the *Patent Law* or claims that there are statutory circumstances that shall not be deemed an infringement upon a patent right, the people's court may dismiss the claims of the patent holder or the interested party upon examination and verification, or may adjudge that the technical solution of the drug under application for registration does not fall within the scope of protection of the related patent right upon the request of the market approval applicant.

Where the marketing approval applicant claims in defense that the related patent right obviously falls under the circumstances where the related patent right shall be declared invalid, the people's court may dismiss the claims of the patent holder or the interested party upon examination and verification, or may adjudge that the technical solution of the drug under application for registration does not fall within the scope of protection of the related patent right upon the request of the market approval applicant.

**Article 10** Where a patent holder or an interested party applies, in the action mentioned in Article 76 of the *Patent Law*, for act preservation not allowing the marketing approval applicant to carry out or be about to carry out the acts of manufacturing, using, offering for sale, sale or import for the purposes of production and business within the term of the related patent right, a guarantee shall be provided; and where it fails to provide the guarantee, the application shall be rejected.

Where a patent holder or an interested party applies, in the action mentioned in Article 76 of the *Patent Law*, for act preservation not allowing the acts of drug marketing application or review and approval, the people's court shall not support the act preservation application.

**Article 11** A party shall have the obligation to keep confidential any trade secrets obtained from other parties in the action, and shall bear civil liability according to law if it discloses such trade secrets without authorization, or uses or allows others to use such trade secrets for other purposes beyond the action without authorization. Where such act constitutes the circumstances prescribed in Article 111 of the *Civil Procedure Law*, the people's court may take compulsory measures according to law. Where such act constitutes a crime, criminal liability shall be investigated according to law.

**Article 12** Where some part of the technical solution of a drug under application for registration falls within the scope of protection of the related patent right while other parts not, the people's court shall make the determination respectively in the judgment text.

**Article 13** Where an obvious discrepancy between the technical solution of a drug under application for registration that is submitted to the people's court by the marketing approval applicant and the technical materials submitted to the national drug evaluation agency is significant enough to affect the normal trial of the case, the people's court may, in accordance with Article 111 of the *Civil Procedure Law*, deal with it on the basis of the circumstances.

**Article 14** Prior to the marketing approval of a drug related to a patent right, where with respect to the same patent right and drug under application for registration, an action brought by a party for patent infringement or confirmation of non-infringement is filed after the action mentioned in Article 76 of the *Patent Law*, the case shall be transferred to the Beijing Intellectual Property Court, and otherwise the case shall not be transferred.

Where a party, after a drug under application for registration has been approved according to law by the drug administration department under the State Council, brings an action for patent infringement or confirmation of non-infringement, the case shall not be transferred.

**Article 15** Where after a drug under application for registration is approved for marketing according to law, the people's court hearing the action mentioned in Article 76 of the *Patent Law* makes an effective judgement determining that the technical solution of the drug under application for registration falls within the scope of protection of the related patent right, and the patent holder or the interested party may separately file a lawsuit for the infringement by the party upon the related patent right.

**Article 16** Where a party, in an action for infringement upon the same patent right or confirmation of non-infringement for the same drug under application for registration, claims that whether the technical solution of the drug allegedly infringing the patent right falls within the scope of protection of the patent right shall be determined based on an effective judgement of the action mentioned in Article 76 of the *Patent Law*, the people's court will generally support the party, except that there is evidence that the technical solution of the allegedly infringing drug is inconsistent with that of the drug under application for registration, or a cause for a new claim is established.

**Article 17** Where the marketing approval applicant sues for compensation for the loss caused by the suspension of the drug marketing approval and for reasonable expenses incurred in the action when a patent holder or an interested party abuses its right to bring an action mentioned in Article 76 of the *Patent Law* and withdraw such an action without justification, or fails to gain support for all the claims, the people's court may accept the case according to law. The above case of first instance shall be under the jurisdiction of the Beijing Intellectual Property Court.

**Article 18** The service made by the people's court to the contact person, mailing address or E-mail published on the China Patent Information Registration Platform for Listed Drugs or the information platform of the national drug evaluation agency shall be deemed as effective service. After a party submits to the people's court a confirmation of the address for service, the people's court shall serve any document at the address specified in the confirmation.

**Article 19** These Provisions shall enter into force as of June 1, 2021. In case of any inconsistency between the relevant judicial interpretations issued by this Court and these Provisions, these Provisions shall prevail.