

<p>¹Provisions 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)</p>	<p>Provisions of the Supreme People’s Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Patent right Disputes Related to Drug Registration Application Fa Shi [2021] No. 13 (Approved at the 1839th Meeting of the Judicial Committee of the Supreme People’s Court on May 24th, 2021, and to come into force since July 5, 2021)</p>
<p>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 <i>Patent Law of the People’s Republic of China</i>, the <i>Civil Procedure Law of the People’s Republic of China</i> and other relevant laws and regulations and in combination with the intellectual property trial practice.</p>	<p>For the purpose of proper trial of civil cases of patent disputes related to drug registration application, these Provisions are formulated in accordance with the related legal provision from the <i>Patent Law of the People’s Republic of China</i>, the <i>Civil Procedure Law of the People’s Republic of China</i> and in combination with the intellectual property trial practice.</p>
<p>Article 1 Patent civil cases of first instance involving the review and approval for drug marketing as stipulated in Article 76 of the <i>Patent Law</i> shall be under the jurisdiction of Beijing Intellectual Property Court.</p>	<p>Article 1 First instance case filed by a party concerned for a dispute over the determination of whether falling into the protection scope of the patent rights pursuant to the provisions of Article 76 of the <i>Patent Law</i> shall be under the jurisdiction of Beijing Intellectual Property Court.</p>
<p>Article 2 The related patent mentioned in Article 76 of the <i>Patent Law</i> 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.</p> <p>The interested parties mentioned in Article 76 of the <i>Patent Law</i> refer to a licensee of the related patent mentioned in the preceding paragraph and a</p>	<p>Article 2 The related patent mentioned in Article 76 of the <i>Patent Law</i> refers to the patent applicable to the specific the linkage measures on the resolution of patent disputes during the review and approval of drugs marketing authorization and the application of drug marketing authorization (hereinafter “the linkage measures”) from the relevant administrative departments of the State Council.</p>

¹ Courtesy Translation by GEN Law Firm. If any questions or suggested changes, contact: guxiaoman@genlaw.com; or hejing@genlaw.com

<p>holder of the marketing approval of the registered drug. The relevant parties refer to a holder of the related patent mentioned in the preceding paragraph, interested parties and a marketing approval applicant.</p>	<p>The interested parties mentioned in Article 76 of the <i>Patent Law</i> refer to a licensee of the patent mentioned in the preceding paragraph and relevant marketing authorization holders (“MAH”).</p>
<p>Article 3 Where a party brings an action mentioned in Article 76 of the <i>Patent Law</i>, it shall comply with the provisions of the <i>Civil Procedure Law</i> 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 protection scope 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 protection scope of the related patent right.</p> <p>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 protection scope of the related patent right.</p>	<p>Article 3 Where a patentee or an interested party files a lawsuit mentioned in Article 76 of the Patent Law, it shall submit the following materials according to Article 119 (3) of the <i>Civil Procedure Law</i>:</p> <p>(1) Information on the related patent, including but not limited to patent name, patent number, relevant claims, etc., registered on the platform set up by the relevant administrative department of the State Council in accordance with the linkage measures;</p> <p>(2) Related information on a drug for the application of registration that are publicized on the platform set up by the relevant administrative department of the State Council in accordance with the linkage measures, including the name of the drug, the type of drug, the category of registration and the correspondence between the drug applied for registration and the listed drug involved; and</p> <p>(3) Category four declaration and the basis for the declaration made by the drug marketing authorization applicant in accordance with the linkage measures.</p> <p>The marketing authorization applicant shall, within the time limit for answer in the first instance, submit to the People’s Court copies of the essential technical materials declared to the national drug evaluation agency and corresponding to the determination of whether falling within the protection scope of the related patent right.</p>
<p>Article 4 Where the claims as the basis of an action mentioned in Article 76</p>	<p>Article 4 Where a patentee or an interested party does not file a lawsuit at</p>

<p>of the <i>Patent Law</i> filed by a patentee 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.</p> <p>Where part of the claims as the basis of the action mentioned in Article 76 of the <i>Patent Law</i> brought by a patentee 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.</p>	<p>the People's Court within the period specified in the linkage measures, the drug marketing authorization applicant may file a lawsuit with the People's Court to request for confirmation that the drug applied for registration does not fall within the protection scope of the relevant patent rights.</p>
<p>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 patentee 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.</p>	<p>N/A</p>
<p>Article 6 Where a party, on the ground that the patent administration department of the State Council has accepted the application for administrative adjudication mentioned in Article 76 of the <i>Patent Law</i>, 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.</p>	<p>Article 5 Where a party, on the ground that the patent administration department of the State Council has accepted the request for administrative adjudication mentioned in Article 76 of the Patent Law, claims that the action mentioned in Article 76 of the <i>Patent Law</i> shall not be accepted or shall apply to suspend the action, the People's Court shall not support the party.</p>

<p>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 <i>Patent Law</i>, the People's Court generally will not support the party.</p>	<p>Article 6 After a party files a lawsuit in accordance with Article 76 of the <i>Patent Law</i>, applies to suspend the action on the ground that the patent administration department of the State Council has accepted the request for the related patent invalidation, the People's Court generally will not support the party.</p>
<p>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 patentee or the interested party, or may adjudge that the technical solution of the drug under application for registration does not fall within the protection scope of the related patent right upon the request of the marketing approval applicant.</p>	<p>N/A</p>
<p>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 patentee 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 protection scope of the related patent right upon the request of the market approval applicant.</p> <p>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</p>	<p>Article 7 Where a drug marketing authorization applicant claims that there are circumstances under Article 67 and Article 75(2) of the <i>Patent Law</i>, etc., the People's Court may, upon examination and verification, adjudge that the technical solution of the drug under application for registration does not fall within the protection scope of the related patent right.</p>

<p>the patentee 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 protection scope of the related patent right upon the request of the market approval applicant.</p>	
<p>Article 10 Where a patentee or an interested party applies, in the action mentioned in Article 76 of the <i>Patent Law</i>, 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.</p> <p>Where a patentee or an interested party applies, in the action mentioned in Article 76 of the <i>Patent Law</i>, 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.</p>	N/A
<p>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 <i>Civil Procedure Law</i>, 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.</p>	<p>Article 8 A party shall have the obligation to keep confidential any trade secrets obtained in the lawsuit or other business information that is required to be kept confidential, and shall bear civil liability according to law if it discloses such trade secrets without authorization, or uses or allows others to use for other purposes beyond the action without authorization. Where such act constitutes the circumstances prescribed in Article 111 of the <i>Civil Procedure Law</i>, the People's Court shall handle it according to the law.</p>
<p>Article 12 Where some part of the technical solution of a drug under application for registration falls within the protection scope of the related</p>	

<p>patent right while other parts not, the people's court shall make the determination respectively in the judgment text.</p>	
<p>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 <i>Civil Procedure Law</i>, deal with it on the basis of the circumstances.</p>	<p>Article 9 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 authorization applicant and the technical materials submitted to the national drug evaluation agency obstructs the People's Court to hear the case, the People's Court shall deal with it in accordance with Article 111 of the <i>Civil Procedure Law</i>.</p>
<p>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 <i>Patent Law</i>, the case shall be transferred to the Beijing Intellectual Property Court, and otherwise the case shall not be transferred.</p> <p>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.</p>	<p>Article 10 Where a patentee or an interested party applies for behavior preservation in the lawsuit referred to in Article 76 of the <i>Patent Law</i>, requesting that the marketing authorization applicant be prohibited from implementing the acts specified in Article 11 of the <i>Patent Law</i> during the validity term of the relevant patent rights, the People's Court shall deal with it in accordance with relevant provisions in the <i>Patent Law</i> and <i>Civil Procedure Law</i>; The People's Court will not support the request to prohibit the act of drug marketing application or review and approval.</p>
<p>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 <i>Patent Law</i> makes an effective judgement determining that the technical solution of the drug under application for registration falls within the protection scope of the related patent right, and the patentee or the interested party may separately file a lawsuit for the</p>	

<p>infringement by the party upon the related patent right.</p>	
<p>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 protection scope of the patent right shall be determined based on an effective judgement of the action mentioned in Article 76 of the <i>Patent Law</i>, 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.</p>	<p>Article 11 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 involved drug falls within the protection scope of the patent right shall be determined based on an effective judgement of the action mentioned in Article 76 of the <i>Patent Law</i>, 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.</p>
<p>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 patentee or an interested party abuses its right to bring an action mentioned in Article 76 of the <i>Patent Law</i> 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.</p>	<p>Article 12 When a patentee or an interested party knows or should know that the patent right he claims should be declared invalid or that the technical solution related to the drug applied for registration does not fall within the scope of patent protection, but still brings an action mentioned in Article 76 of the <i>Patent Law</i>, or requests for administrative adjudications, the marketing authorization applicant may file a lawsuit for damages with the Beijing Intellectual Property Court.</p>
<p>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.</p>	<p>Article 13 The service made by the People's Court to the contact person, mailing address or E-mail published on the platform set up by the relevant administrative department of the State Council in accordance with the linkage measures 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 can also serve any document at the address specified in the confirmation.</p>
<p>Article 19 These Provisions shall enter into force as of June 1, 2021. In case</p>	<p>Article 14 These Provisions shall enter into force as of July 5, 2021. In case</p>

of any inconsistency between the relevant judicial interpretations issued by this Court and these Provisions, these Provisions shall prevail.

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