The Measures for Administrative Adjudication of Early Settlement Mechanism for Drug Patent Disputes
(Consultation Paper)

Article 1 For the purpose of conducting administrative adjudication on patent disputes in the process of review and approval of drug marketing authorization (hereinafter referred to as "administrative adjudication of drug patent disputes"), these Measures are hereby enacted in accordance with the *Patent Law of the People's Republic of China* (hereinafter referred to as the "Patent Law") as well as relevant laws, regulations, and rules.

Article 2 The China National Intellectual Property Administration ("CNIPA") is responsible for the administrative adjudication referred to in Article 76 of the Patent Law.

Article 3 Where the case handling personnel have a direct interest relationship with the parties, such personnel shall apply for voluntary withdraw from that case. The parties also have the right to apply for withdrawal of such case handling personnel. Where a party applies for withdrawal of the case handling personnel, the party shall state the reasons. The withdrawal of any case handling personnel shall be decided by the person chiefly in charge of the case handling department.

Article 4 Where a party petitions the CNIPA for an administrative adjudication of a drug patent dispute, the following conditions shall be met:
(1) The petitioner is the patentee or an interested party of the relevant patent and the applicant of drug marketing authorization as referred to in Article 76 of the Patent Law, where an interested party refers to the licensee of the relevant patent and the registered drug marketing authorization holder;
(2) There is a definite respondent;
(3) There are definite claims and specific facts and reasons;
(4) The relevant patent information has been validly registered on China's Marketed Drug Patent Information Registration Platform, and the patent type complies with the relevant provisions of the *Implementation Measures for Early Settlement Mechanism for Drug Patent Disputes*;

(5) The parties have not filed a lawsuit with the people's court over the drug patent dispute previously, or the case has not been accepted and filed by the people's court.

Article 5 Where a party petitions the CNIPA for an administrative adjudication of a drug patent dispute, such party shall submit a petition and the following documents:
(1) Certificate of Incorporation;
(2) The relevant patent information registered on the Marketed Drug Patent Information Registration Platform, and the application for drug marketing authorization and the declaration of not falling within the scope of protection of the relevant patent published on the information platform of the national drug review agency;
(3) Where the petitioner is the applicant of drug marketing authorization, a technical solution for the relevant drug shall be submitted. If the technical solution involves confidential information, it shall be submitted separately together with a declaration thereof.

Article 6 The petition shall specify the following contents:
(1) The name and address of the petitioner, or the name and contact number of the legal representative or the person chiefly in charge, and, where an agent is appointed, the name, address, and contact number of the agent or agency;
(2) The name and address of the respondent, or the name, contact number, and other information of the legal representative;
(3) The relevant patent information registered on the Marketed Drug Patent Information Registration Platform, including the patent number, patent type, patent status, patentee, expiry date of patent protection, and the specific claims for determining whether the drug falls within the scope of protection of the patent;
(4) The relevant information and the type of declaration of the drug applied for registration published on the information platform of the national drug review agency;
(5) The reasons for whether the technical solution of the drug applied for registration falls within the scope of protection of the relevant patent;
(6) List of evidence materials;
(7) The signature (of a natural person) or seal (of a legal person or other entity) of the petitioner or the specially authorized agent. Relevant evidence and supporting materials may be submitted as attachments to the petition.

Article 7 Upon receiving the petition and related materials, the CNIPA shall register and review the petition and related materials. If the petition and related materials are incomplete, the petitioner shall be notified to submit supplementary materials within the prescribed time limit.

Under any of the following circumstances, a petition for administrative adjudication of a drug patent dispute shall be deemed to have not been submitted:

(1) The petition is not prepared or filled in as required;

(2) No evidence material is submitted as prescribed.

Article 8 Under any of the following circumstances, the CNIPA shall not accept the petition for administrative adjudication of a drug patent dispute and notify the petitioner accordingly:

(1) The petition lacks basic information such as the name or contact address of the petitioner, or the patent information;

(2) The respondent is undefined;

(3) The patent involved in the case does not fall into the types of patent registered on the Marketed Drug Patent Information Registration Platform, or is inconsistent with the patent specified in the relevant Category IV declaration;

(4) The claims of the patent involved have been declared invalid.

Article 9 Where a party's petition meets the conditions specified in Article 4 of these Measures, the CNIPA shall accept the case within the prescribed time limit and notify the petitioner and the respondent.

Article 10 The CNIPA may verify the relevant evidence with the drug supervision and administration department where necessary.

Article 11 The CNIPA may, based on the request of the parties and the circumstances of the case, decide to conduct a written hearing or an oral hearing.

Where the CNIPA decides to conduct an oral hearing, it shall notify the parties of the time and place of the oral hearing at least three working days in advance. Where the petitioner refuses to participate in the hearing without justified reasons or quits midway without permission, the petition shall be deemed to have been withdrawn; where the respondent refuses to participate in the hearing without justified reasons or

quits midway without permission, the case shall be deemed to be subject to default hearing.

Article 12 Where some of the claims of the patent involved are declared invalid during the administrative adjudication proceedings of a drug patent dispute, the CNIPA will make an administrative adjudication on the basis of the valid claims; where all the claims involved in the patent are declared invalid, the CNIPA will reject the petition for administrative adjudication.

Article 13 The CNIPA may conduct mediation upon the request of the parties during the administrative adjudication proceedings of a drug patent dispute. Where the parties reach a consensus through mediation, the CNIPA may prepare a statement of mediation at the request of the parties. Where no consensus is reached through mediation, the CNIPA shall make an administrative adjudication in a timely manner.

Article 14 Under any of the following circumstances, a party may apply for suspension of the proceedings, and the CNIPA may also decide ex officio to suspend the proceedings:

(1) A party has died and it takes time for the successor of the party to decide whether to participate in the proceedings;

(2) A party has lost the capacity to petition for an administrative adjudication, and the legal representative of the party remains undetermined;

(3) The legal person or other entity of a party has terminated, and the successor to its rights and obligations remains undetermined;

(4) A party is unable to participate in the hearing due to force majeure;

(5) Other circumstances where the proceedings should be suspended.

Article 15 The petitioner may withdraw the petition before the CNIPA makes an administrative adjudication. Where the petitioner withdraws the petition after the administrative ruling has been announced or the written administrative ruling has been issued, the validity of the administrative adjudication shall not be affected.

Where the petitioner withdraws the petition or the petition is deemed to have been withdrawn, the administrative adjudication proceedings of the drug patent dispute shall be terminated.

Article 16 The administrative ruling made by the CNIPA shall determine whether the technical solution of the drug applied for marketing falls within the scope of protection of the relevant patent, and state the reasons and grounds.
After an administrative ruling is made, it shall be disclosed to the public in accordance with relevant regulations.

Article 17 Where a party is dissatisfied with the administrative adjudication of the pharmaceutical patent dispute made by the CNIPA, the party may file a lawsuit with the people's court within 15 days from the date of receipt of the administrative ruling.

Article 18 The parties shall respectively be responsible for the authenticity of the evidence or materials they provide.
The parties are obliged to keep confidential the trade secrets that they learn during the administrative adjudication proceedings, and shall assume corresponding legal liabilities if they disclose, use, or allow others to use the trade secrets without authorization.

Article 19 Where the personnel conducting the administrative adjudication proceedings of a drug patent dispute or other relevant staff abuse their powers, neglect their duties, practice favoritism, or disclose trade secrets that they have learned during the proceedings, if the circumstances do not constitute a crime, administrative penalties shall be given to such personnel or staff; if the circumstances constitute a crime, such personnel or staff shall be transferred to judicial authorities to face judgment.

Article 20 Matters not provided for in these Measures shall be handled in accordance with the *Measures for Patent Administrative Law Enforcement* and the relevant provisions of the CNIPA on administrative adjudication of patent infringement disputes.

Article 21 The CNIPA is responsible for the interpretation of these Measures.

Article 22 These Measures shall come into force on June 1, 2021.