[1]Administrative Adjudication Measures for Early Resolution Mechanism for Drug Patent Disputes (Draft for Solicitation of Comments)	Administrative Adjudication Measures for Early Resolution Mechanism for Drug Patent Disputes No. 435 Published on July 5, 2021
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 on drug patent disputes**") in accordance with the *People's Republic of China Patent Law* and the relevant laws, regulations and rules, these Measures are hereby enacted.	**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 on Drug Patent Disputes**") in accordance with the *People's Republic of China Patent Law* (hereinafter referred to as the "***PRC Patent Law***") and the relevant laws, regulations and rules, these Measures are hereby enacted.
Article 2 The China National Intellectual Property Administration (hereinafter referred to as the "**CNIPA**") is responsible for the administrative adjudication tasks referred to in Article 76 of the PRC Patent Law.	**Article 2** The China National Intellectual Property Administration (hereinafter referred to as the "**CNIPA**") is responsible for the administrative adjudication tasks referred to in Article 76 of the *PRC Patent Law*. The CNIPA shall establish an administrative adjudication committee for the early resolution of drug patent disputes to organize and carry out administrative adjudication work related to the early resolution of drug patent disputes.
Article 3 If an officer involved in the proceedings ~~has a direct interest relationship with a party~~, he shall apply for voluntary withdrawal.	Article 3 The officer involved in the proceedings shall apply for voluntary withdrawal for the following circumstances:

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

The parties also have the right to apply for withdrawal of a certain officer involved in the proceedings. If a party applies for withdrawal, reasons therefor shall be given. The withdrawal of an officer involved in the proceedings shall be decided by ~~the person chiefly in charge of~~ the department dealing with the proceedings.	(1) He/she is a close relative of the parties concerned or their agents; (2) He/she has an interest relationship with the patent application or the patent right; (3) He/she has other relationships with the parties or their agents, which may affect the fair handling of the case. The parties also have the right to apply for withdrawal of a certain officer involved in the proceedings. If a party applies for withdrawal, reasons therefore shall be given. The withdrawal of an officer involved in the proceedings shall be decided by the department dealing with the proceedings.
Article 4 The party requesting the CNIPA for administrative adjudication on drug patent disputes shall meet the following conditions: (1) Where the claimant is the patentee or interested party of the ~~relevant patent and the applicant for drug marketing authorization~~ as referred to in Article 76 of the *PRC Patent Law*, where the interested party is the licensee of the relevant patent ~~and~~ the registered drug marketing authorization holder; (2) Where there is a definite respondent; (3) Where there are definite claims and specific facts and reasons; (4) Where relevant patent information has been ~~effectively~~ registered on the PRC Marketed Drug Patent Information Registration Platform and ~~the patent type~~ complies with the relevant provisions of the	**Article 4** The party requesting the CNIPA for administrative adjudication on drug patent disputes shall meet the following conditions: (1) Where the claimant is the drug marketing authorization applicant and the relevant patentee or interested party as referred to in Article 76 of the *PRC Patent Law*, where the interested party is the licensee of the relevant patent or the registered drug marketing authorization holder ("MAH"); (2) Where there is a definite respondent; (3) Where there are definite claims and specific facts and reasons; (4) Where relevant patent information has been registered on the PRC Marketed Drug Patent Information Registration Platform and complies with the relevant provisions of the *Implementing Measures*

Implementing Measures for Early Resolution Mechanism for Drug Patent Disputes; (5) Where ~~the parties~~ have not initiated litigation with the People's Court in respect of the disputes over the drug patent~~, or the case has not been accepted and filed by the People's Court before~~.	*for Early Resolution Mechanism for Drug Patent Disputes*; (5) Where the People's Court has not established the case; (6) Where the drug marketing authorization applicant has requested for administrative adjudication, the patentee or an interested party should have not filed a lawsuit in the People's Court or requested for administrative adjudication on the drug patent dispute within forty-five days from the publishing date of the application of the drug marketing authorization by the national drug review agency; (7) One request for an administrative adjudication shall be limited to the confirmation of whether one technical solution applied for drug marketing authorization falls within the protection scope of one certain patent right.
N/A	**Article 5** Where a patentee or an interested party requests for confirmation that the drug related technical solution applied for marketing authorization falls within the protection scope of the relevant patent right, the drug marketing authorization applicant shall be the respondent. If the patent right is jointly owned by more than one patentees, the request shall be made by all the patentees, unless some of the joint patentees expressly give up the relevant substantive rights. A MAH or an exclusive licensee of the exploitation license contract can make a request in his own name; a sole licensee of the exploitation license contract can make a request in his own name if the patentee does not make a request.

N/A	**Article 6** Where a drug marketing authorization applicant requests for the confirmation that the drug related technical solution applied for the drug marketing authorization falls within the protection scope of the relevant patent right, the patentee shall be the respondent.
Article 5 Where a claimant requests the CNIPA for administrative adjudication on drug patent disputes, a statement of claims shall be submitted together with the following materials: (1) Certificate of incorporation; (2) Registration information of the patent on the PRC Marketed Drug Patent Information Registration Platform and application for drug marketing authorization and statement of not falling within the scope of protection of the relevant patent publicized on the information platform of the national drug review agency; (3) If the claimant is an applicant for drug marketing authorization, it shall also submit a technical proposal of the drug applied for registration; where such technical proposal involves confidential information, it shall be submitted separately together with a statement of such.	**Article 7** Where a claimant requests the CNIPA for administrative adjudication on drug patent disputes, a statement of claims shall be submitted together with the following materials: (1) Certificate of incorporation; (2) Registration information of the patent on the PRC Marketed Drug Patent Information Registration Platform, application for drug marketing authorization, and statement of not falling within the scope of protection of the relevant patent and the basis of the statement publicized on the information platform of the national drug review agency; (3) If the claimant is an applicant for drug marketing authorization, it shall also submit a technical proposal of the drug applied for registration; where such technical proposal involves confidential information, it shall be submitted separately together with a statement of such.
Article 6 The statement of claims shall contain the following information: (1) The name and address of the claimant, the name and telephone number of the legal representative or person chiefly in charge, and if an agent is appointed, the name of the agent and the name, address	**Article 8** The statement of claims shall contain the following information: (1) The name and address of the claimant, the name and telephone number of the legal representative or the person chiefly in charge, and if an agent is appointed, the name of the agent and the name, address

and telephone number of the agency; (2) The name and address of the claimant, the name, telephone number and so forth of legal representative; (3) Relevant patent information registered on the PRC Marketed Drug Patent Information Registration Platform, including patent number, patent type, patent status, patentee, expiry date of patent protection, and the specific claim that is requested to find whether it falls within the scope of protection; (4) Relevant information and type of statement of the drug applied for registration publicized on the information platform of the national drug review agency; (5) Reasons as to whether the technical proposal of the drug applied for registration falls within the scope of protection of the relevant patent; (6) List of evidentiary materials; (7) The signature (of a natural person) or seal (of a legal person or other entity) of the claimant or a ~~specially~~ authorised agent. The relevant evidence and supporting documents may be submitted in the form of an annex to the statement of claims .	and telephone number of the agency; (2) The name and address of the claimant, the name, telephone number and so forth of legal representative; (3) Relevant patent information registered on the PRC Marketed Drug Patent Information Registration Platform, including patent number, patent type, patent status, patentee, expiry date of patent protection, and the specific claim that is requested to find whether it falls within the scope of protection; (4) Relevant information and type of statement of the drug applied for registration publicized on the information platform of the national drug review agency; (5) Reasons as to whether the technical proposal of the drug applied for registration falls within the scope of protection of the relevant patent; (6) List of evidentiary materials; (7) The signature (of a natural person) or seal (of a legal person or other entity) of the claimant or an authorised agent. The relevant evidence and supporting documents may be submitted in the form of an annex to the statement of claims .
Article 7 Upon receipt of the statement of claims and supporting materials, the CNIPA shall register and review the statement of claims and supporting materials. If the statement of claims and supporting materials are incomplete, ~~the claimant shall be notified to submit supplementary materials within the prescribed time limit~~. A request for administrative adjudication on drug patent disputes is deemed not to have been made if the request falls into one of the following circumstances:	**Article 9** Upon receipt of the statement of claims and supporting materials, the CNIPA shall register and review the statement of claims and supporting materials. If the statement of claims and supporting materials are incomplete, the statement of claims does not use the prescribed format or the filling does not meet the requirements, the claimant shall be notified to make corrections within five working days. If the statement of claims is not corrected by the end of the time limit or the same defects still exist after correction, the request for

(1) The prescribed format is not used, or the form is not filled in as required; (2) Failing to submit supporting documents as required.	administrative adjudication shall not be accepted.
Article 8 If a request for administrative adjudication on drug patent disputes falls into one of the following circumstances, the CNIPA will not accept the request and notify the claimant thereof: (1) Where basic information such as the name or address of the claimant, or patent right information is missing in the statement of claims; (2) Where the respondent is not named; (3) Where the patent in question does not belong to the type of patent subject matter registered on the PRC Marketed Drug Patent Information Registration Platform, or ~~the patent in question~~ is inconsistent with the patent set out in the Statement of Category IV; (4) The claim involved in the patent in question have been declared invalid.	**Article 10** If a request for administrative adjudication on drug patent disputes falls into one of the following circumstances, the CNIPA will not accept the request and notify the claimant thereof: (1) Where basic information such as the name or address of the claimant, or patent right information is missing in the statement of claims; (2) Where the respondent is not named; (3) The subject qualifications of the claimant and the respondent do not meet the relevant provisions of Articles 4, 5, and 6 of these Measures; (4) Where the patent in question does not belong to the type of patent subject matter registered on the PRC Marketed Drug Patent Information Registration Platform, or is inconsistent with the patent set out in the Statement of Category IV; (5) The claim involved in the patent in question have been declared invalid by the CNIPA. (6) Where the request does not specify the patent claims involved and the specific matters of the request for administrative adjudication; (7) Where the claimant fails to specify the reasons for the administrative adjudication or fails to specify the reasons for the administrative adjudication in combination with the evidence

	submitted; (8) Where a request for an administrative adjudication involves more than one drug technical solutions applied for marketing authorization or more than one patent rights; (9) The same drug patent dispute has been established by the People's Court.
Article 9 Where the request of a party meets ~~the conditions stipulated in~~ Article 4 of these Measures, the CNIPA shall file a case and notify the claimant and the respondent within ~~the prescribed time limit~~.	**Article 11** Where the request of a party complies with Article 4 of these Measures, the CNIPA shall file a case and notify the claimant and the respondent within 5 working days.
Article 10 The CNIPA may verify the relevant evidence with the drug administrative department as required in the proceedings.	**Article 12** The CNIPA may verify the relevant evidence with the drug administrative department, upon the parties requests, or as required in the case proceedings.
Article 11 The CNIPA may ~~decide to~~ hold a written hearing or an oral hearing as required by the parties based on the circumstances of the case. If the CNIPA decides to hold an oral hearing, it shall notify the parties of the time and place of the oral hearing at least ~~three~~ working days before the oral hearing. If the claimant refuses to attend without justifiable reasons or withdraws without permission, its request shall be deemed to be withdrawn; if the respondent refuses to attend without justifiable reasons or withdraws without permission, the hearing shall be held in absentia.	**Article 13** The CNIPA shall form a collegial panel to hear the case. The collegial panel may hold an oral or a written hearing as required by the parties and based on the circumstances of the case. Where the same party files multiple administrative adjudication requests for multiple patent rights related to the same drug, the CNIPA may conduct joint trials. If the CNIPA decides to hold an oral hearing, it shall notify the parties of the time and place of the oral hearing at least five working days before the oral hearing. If the claimant refuses to attend without justifiable reasons or withdraws without permission, its request shall be deemed to be withdrawn; if the respondent refuses to attend without justifiable reasons or withdraws without permission, the

	hearing shall be held in absentia.
Article 12 In the proceedings of administrative adjudication on drug patent disputes, if some of the claims involved in the patent in question is declared invalid, the CNIPA shall make administrative adjudication on the basis of maintaining the valid claims; if all the claims involved in the patent in question are declared invalid, the CNIPA shall reject the request for administrative adjudication.	**Article 14** In the proceedings of administrative adjudication on drug patent disputes, if some of the claims involved in the patent in question is declared invalid by the CNIPA, the administrative adjudication shall be made based on the maintained the valid claims; if all the claims involved in the patent in question are declared invalid by the CNIPA, the request for administrative adjudication shall be rejected.
Article 13 In the proceedings of administrative adjudication on drug patent disputes, the CNIPA may conduct mediation of the will of the parties. If, after mediation, the parties reach an agreement, the CNIPA may, at the request of the parties, produce a mediation letter. If mediation fails, the CNIPA ~~shall~~ make administrative adjudication in a timely manner.	**Article 15** In the proceedings of administrative adjudication on drug patent disputes, the CNIPA may conduct mediation of the will of the parties. If, after mediation, the parties reach an agreement, the CNIPA may, at the request of the parties, produce a mediation letter. If mediation fails, the CNIPA should make administrative adjudication in a timely manner.
Article 14 The parties may apply for stay of the proceedings, and the CNIPA may also decide ex officio to stay under any of the following circumstances: (1) Where a party is dead and needs to wait for the heirs to indicate whether they will participate in the proceedings; (2) Where a party has lost the capacity to request for administrative adjudication and has not yet identified a legal representative; (3) Where a legal person or other organization that is a party to the proceedings is terminated and an assignee of the rights and obligations has not yet been identified; (4) Where a party is unable to attend the hearing due to irresistible	**Article 16** The parties may apply for stay of the proceedings, and the CNIPA may also decide ex officio to stay under any of the following circumstances: (1) Where a party is dead and needs to wait for the heirs to indicate whether they will participate in the proceedings; (2) Where a party has lost the capacity to request for administrative adjudication and has not yet identified a legal representative; (3) Where a legal person or other organization that is a party to the proceedings is terminated and an assignee of the rights and obligations has not yet been identified; (4) Where a party is unable to attend the hearing due to irresistible

causes; (5) Other circumstances where the proceedings ~~shall~~ be stayed.	causes; (5) Other circumstances where the proceedings need to be stayed. Where the parties request for invalidation of the involved patent, the CNIPA may not stay (the adjudication of) the case.
Article 15 The claimant may withdraw the request before the CNIPA renders its administrative ruling. ~~If the claimant withdraws its request after the conclusion of the administrative ruling has been announced or the written ruling has been issued, the validity of the administrative ruling shall not be impaired.~~ If the claimant withdraws its request or if its request is deemed to be withdrawn, the proceedings for the administrative adjudication on drug patent disputes are terminated.	**Article 17** The claimant may withdraw the request before the CNIPA renders its administrative ruling. If the claimant withdraws its request or if its request is deemed to be withdrawn, the proceedings for the administrative adjudication on drug patent disputes are terminated. Where the claimant withdraws its request after the administrative adjudication has came into conclusions, the effectiveness of the administrative ruling shall not be affected.
Article 16 In the administrative ruling rendered, the CNIPA shall determine whether the technical proposal of the drug applied for marketing falls within the scope of protection of the relevant patent, and provide with reasons and grounds. The administrative ruling shall, upon being rendered, be made public in accordance with the relevant requirements.	Article 18 Where the CNIPA renders the administrative adjudication, 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 provide with reasons and grounds. The administrative ruling shall, upon being rendered, be served to the parties and copied to the national drug administrative departments, and made public in accordance with the *Decree of Government Information Openness* and relevant provisions. When an administrative ruling is made public, information involving trade secrets should be deleted.
Article 17 Where the parties are not satisfied with the administrative	**Article 19** Where the parties are not satisfied with the administrative

ruling rendered by the CNIPA on drug patent disputes, they may initiate litigation with the People's Court ~~within fifteen days from the date of receipt of the administrative ruling~~.	ruling rendered by the CNIPA on drug patent disputes, they may initiate litigation with the People's Court according to law.
Article 18 The parties are responsible for the authenticity of the evidence or supporting materials they provide. The parties are obliged to keep confidential trade secrets that come to their knowledge during the proceedings of the administrative adjudication and shall bear legal liability for disclosing, using, or allowing to use such trade secrets without permission.	**Article 20** The parties are responsible for the authenticity of the evidence or supporting materials they provide. The parties are obliged to keep confidential trade secrets that come to their knowledge during the proceedings of the administrative adjudication and shall bear corresponding legal liability for disclosing, using, or allowing to use such trade secrets without permission.
Article 19 Where the officer and other employees conducting the administrative adjudication on drug patent disputes abuse their powers, neglect their duties, show favoritism or disclose the trade secrets known in the proceedings, if such act does not constitute an offense, administrative penalties shall be imposed in accordance with law; if an offense is suspected, such officer or employee shall be transferred to the judicial authority.	**Article 21** Where the officer and other employees conducting the administrative adjudication on drug patent disputes abuse their powers, neglect their duties, show favoritism or disclose the trade secrets known in the proceedings, if such act does not constitute an offense, administrative penalties shall be imposed in accordance with law; if an offense is suspected, such officer or employee shall be transferred to the judicial authority.
Article 20 For matters not provided in these Measures, the *Measures for Administrative Enforcement of Patents* and the relevant provisions of the CNIPA on the administrative adjudication of patent infringement disputes.	**Article 22** For matters not provided in these Measures, the *Measures for Administrative Enforcement of Patents* and the relevant provisions of the CNIPA on the administrative adjudication of patent infringement disputes.
Article 21 The CNIPA is responsible for the construction of these Measures.	**Article 21** The CNIPA is responsible for the construction of these Measures.
Article 22 These Measures shall come into force ~~on 1 June 2021~~.	**Article 22** These Measures shall come into force from the date of promulgation.