



American Intellectual Property Law Association

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中华人民共和国

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IP Protection Division, Enforcement Guidance  
Department China National Intellectual Property  
Administration People's Republic of China, 100088

*via email zhifa@cnipa.gov.cn*

**Re: Comments regarding the CNIPA Administrative Adjudication Measures for Early Resolution Mechanism for Drug Patent Disputes 《药品专利纠纷早期解决机制行政裁决办法（征求意见稿）》**

Dear Sir or Madam,

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to comment on the Draft Implementation Rules of the Chinese Patent Law. Our detailed comments are described below.

AIPLA is a national bar association of approximately 8,500 members engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

AIPLA commends the China Intellectual Property Administration (CNIPA) on its efforts to provide the draft Administrative Adjudication Measures for Early Resolution Mechanism for Drug Patent Disputes (Draft Measures). AIPLA appreciates the opportunity to provide comments to the draft Implementation Rules. AIPLA would also welcome the opportunity to provide additional comments on any specific revisions to the language of the draft Implementation Rules that may be drafted and proposed in response to this initial round of comments.

The absence of comments on any part of the Draft Measures does not reflect support or lack of support of this part by AIPLA.

The current draft Measures relate to the Measures of Early Resolution Mechanism for Drug Patent Disputes (draft for comment) promulgated by the National Medical Products Administration (NMPA) and the CNIPA (NMPA/CNIPA Draft Resolution Mechanism). Therefore, the following comments also refer to the NMPA/CNIPA Draft Resolution Mechanism when appropriate.

## **1. AIPLA requests clarification of handling of patent invalidity challenges.**

AIPLA observes that substantial ambiguity remains concerning the handling of patent validity challenges in the NMPA/CNIPA Draft Resolution Mechanism Art. 4, Fourth Type Certification under NMPA/CNIPA Draft Resolution Mechanism. The Chinese Patent Law provides authority only to CNIPA to invalidate a granted patent. Specifically, CNIPA's Re-examination and Invalidation Department (RID) may do so only after careful reexamination. Civil courts and the administrative adjudication of infringement within the CNIPA does not consider validity issues. Article 76 of the Chinese Patent Law 2020 appears to comport with this bifurcation. It provides that linkage adjudication is limited to the question "...whether the technical solutions related to the drug applying for registration fall[s] within the protection scope of the other party's patent right." It does not specifically mention invalidity.

Article 16 of the CNIPA Draft Adjudication Measures provides that CNIPA's administrative adjudication is likewise limited to determining "... whether the technical solutions related to the drug applying for registration fall[s] within the protection scope of the other party's patent right." It too does not contemplate adjudicating invalidity. Article 12 of the CNIPA Draft Adjudication Measures provides that "if some of the involved claims of a patent at issue are declared invalid, the [CNIPA] will make administrative adjudication based on the claims that remain valid; if all of the involved claims of a patent at issue are declared invalid, the [CNIPA] will reject the request for administrative adjudication."

This provision does not require the linkage tribunal to rule on invalidity. Rather, it appears to provide that, if parallel invalidity proceedings conclude the patent claims are invalid, the invalidity determination will have immediate effect on the linkage proceeding. Provided this understanding is correct, CNIPA RID would remain the sole authority in China to rule on the issue of invalidity. If correct, these provisions could prevent gamesmanship by follow-on drug applicants. Otherwise, follow-on drug applicants may be able to avoid the obligation to resolve their Freedom to Operate. It would also preclude multiple parallel invalidity proceedings, which may result in inconsistent outcomes due to the compressed nature of linkage proceedings.

AIPLA recommends amending the Draft Measures to clarify whether patent validity in linkage adjudications is limited to promptly incorporating determinations of invalidity by CNIPA RID under the established regulations. If not, AIPLA requests that the Draft Measures specify precisely which tribunals are authorized to determine patent validity. In addition, AIPLA requests further clarification regarding precisely which tribunals are authorized to determine whether the proposed product falls within the scope of the claims remaining patentable. If any new linkage tribunals are to be so empowered, AIPLA suggests that further revisions may be

required in the Draft Measures to provide appropriate guidance and ensure consistency with the Reexamination and Invalidation Department decisions.

## **2. Gaps between the Draft Measures and the NMPA/CNIPA Draft Resolution Mechanism may unduly prejudice patentees.**

Article 7 of the NMPA/CNIPA Draft Resolution Mechanism provides that a patentee may file a patent linkage complaint (under Art. 76 of the Chinese Patent Law 2020) against the generic applicant within 45 days after the generic application information is published on the patent platform (“the 45-days period”). Once the action is docketed or accepted in court or at CNIPA, NMPA’s administrative review will be stayed for 9 months after the acceptance date. NMPA’s technical review will not be stayed (see Art. 8 of the NMPA/CNIPA Draft Resolution Mechanism). Thus, filing a patent linkage complaint within this 45-days period is critical for the patentee to obtain a 9-month moratorium on generic approval. The current CNIPA Draft Adjudication Measures, however, do not specify the time required for the CNIPA to act on either docketing or accepting a patent linkage complaint.

The patentee is required to file a complaint with CNIPA with the required materials. AIPLA requests that the Draft Resolution Mechanism be further revised to provide the patentee an opportunity to correct any non-critical deficiencies in its complaint. These may include, for example, a clerical or formality error, such that the complaint could be accepted provided it is corrected. AIPLA requests that such non-critical amendments should not affect the moratorium on generic approval provided the patentee filed its original complaint within the 45-days period. Alternatively, AIPLA requests that the CNIPA Draft Adjudication Measures require that the CNIPA act promptly, e.g., within 5 days of receipt of the complaint, to notify the patentee whether a complaint is accepted such that the patentee could correct deficiencies and refile the complaint within the original 45-day period.

AIPLA is also concerned that no deadline is specified to complete the adjudication in the Draft Measures. AIPLA requests that the Draft Measures be revised to recite an 8-month deadline to complete the adjudication, from the date of acceptance of an adjudication case at the CNIPA. Article 8 of the NMPA/CNIPA Draft Resolution Mechanism specifies a 9-month moratorium on approval of generic drugs from the date of acceptance of an administrative adjudication case. An 8-month deadline for the validity determination would provide sufficient time to receive a judgement and file the judgement with the NMPA to meet the 9-month deadline in the NMPA/CNIPA Draft Resolution Mechanism.

AIPLA notes that Article 13 of the Draft Measures provides: “[i]f mediation fails, the China National Intellectual Property Administration will make administrative adjudication in a timely manner.” AIPLA requests a clear statement that such mediation will not delay the administrative adjudication and will proceed independently and concurrently with the administrative adjudication. Otherwise, mediation could delay the adjudication beyond the end of the 9-month moratorium provided by Article 8 of the NMPA/CNIPA Draft Resolution Mechanism.

**3. The short oral-hearing notification and appeal deadlines in the Draft Measures may be impractical.**

Article 11 provides a notice period of “at least 3 working days before the oral hearing.” AIPLA proposes that this time period is impractically short, particularly if any of the parties involved is a foreign entity. AIPLA suggests extending this period to at least 10 working days.

Article 17 provides: “15 days after receipt of the administrative adjudication decision” for filing an appeal to a court. AIPLA submits that this is impractically short, particularly if any of the parties involved is a foreign entity. In addition, foreign entities are required to satisfy substantial formalities to file an appeal. AIPLA proposes extending this period to 3 months, which would be comparable to the 3-month time to appeal a CNIPA re-examination or invalidation decision.

**4. The Draft Measures are ambiguous regarding a parallel court action.**

Article 4(5) provides that one of the conditions for the case to be accepted by the CNIPA is “(5) [t]he parties have not filed a lawsuit involving the present drug patent dispute in a people’s court, or such a case has not been accepted by a people’s court.” AIPLA requests that the Draft Measures include a corresponding provision providing that if a case has been accepted by either CNIPA or the People’s Court, any case subsequently filed in the other tribunal shall not be accepted on the same asserted claims. Thus, a party could file a case in either or both tribunals, and once the case is accepted by one or the other tribunal, the other will not accept a case relating to the same claims. AIPLA also requests that the Draft Measures provide that different claims, not asserted in the first accepted case, may be accepted in the second tribunal.

Article 8(5) provides that one of the conditions for CNIPA refusing to accept an administrative adjudication case is that “(4) [t]he involved claims of the patent at issue are declared invalid.” It is not clear whether “declared invalid,” involves resolution of any appeal from such a decision. AIPLA requests that all possible appeals have been resolved or the time within which to appeal has expired without an appeal being filed. AIPLA proposes revising this provision to read: “(4) The status of the involved claims of the patent at issue are recorded as invalid in CNIPA’s register” because the CNIPA register will only do so after a claim is declared invalid and all avenues of appeal have been exhausted.

We appreciate the opportunity to provide these comments on the Draft Measures, and are happy to answer any questions that our comments may raise.

Sincerely,



Joseph R. Re  
President  
American Intellectual Property Law Association