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China's Draft Amendments to ANDA Rules Encourage Earlier Invalidity Challenges

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Patent and ITC Litigation

On October 31, 2022, the China National Intellectual Property Administration (the "**CNIPA**") issued the "Proposed Amendments to Guidelines for Patent Examination (Draft for Further Public Comments)" (the "**Third Draft**").[1] This is the third time since November 2020 that the CNIPA has solicited public comments on the amendments to the country's Patent Examination Guidelines.[2] Among all proposed amendments, the Third Draft added a new section titled "Special Provisions on Adjudicating Invalidity Petition Cases Concerning the Early Resolution Mechanism of Drug Patent Disputes", aiming to provide rules for invalidity petitions relating to ANDA challenges, which have long been absent from China's ANDA rules.

What's new for China's ANDA from the Third Draft?

"First-come-first-served" for Pursuing "First Generic Winner"

One of the most significant proposals in the Third Draft is that it would set rules to better secure the first challenger's advantage for pursuing the "first generic winner." Article 11 of "Implementation Measures for Early Resolution Mechanism for Drug Patent Disputes (Trial)" (the "**ANDA Implementation Measures**") grants a 12-month market exclusivity to the "first generic winner"— a chemical generic drug applicant that first successfully invalidates all corresponding innovator drug patent(s) listed on China's Orange Book[3] through an ANDA

[1] https://www.cnipa.gov.cn/art/2022/10/31/art_75_180016.html

[2] The CNIPA previously solicited public comments on draft amendments to the current version of "Patent Examination Guidelines" on November 10, 2020 and August 3, 2021.

[3] China's Orange Book is formally known as the Patent Information Registration Platform for Marketed Drugs.

challenge[4] as well as first obtains a generic approval.[5] However, an issue with the current rules is that the first challenger is not necessarily the "first generic winner" if a follow-on generic applicant files an invalidity petition later but manages to win its case earlier, which is sometimes unfair to the first challenger.

The Third Draft seeks to address this issue by providing an order for the proceeding of the cases when multiple ANDA-related invalidity petitions are filed against the same innovator drug, including but not limited to those petitions competing for the "first generic winner" exclusivity. Specifically, Part IV Chapter 3 Section 9.2 of the Third Draft proposes that where multiple ANDA-related invalidity petitions are filed, the proceedings of the petitions "shall be arranged by the order of the dates of these filings". That is, the Third Draft seeks to set a "first-come-first-served" rule for pursuing the "first generic winner," *i.e.*, the one who files an ANDA-related invalidity petition earlier will proceed the case earlier, and thus will be more likely to conclude the case earlier too.

Limited "Gun-Jumping" Strategy for Challenging Invalidity before ANDA Filing

Another notable proposed amendment in the Third Draft is an ANDA filing deadline for those ANDA challengers who "jump the gun", *i.e.*, file the invalidity petition before the ANDA filing to pursue an earlier win than other ANDA challengers. Specifically, China's current ANDA rules do not pose any limitation on when an ANDA-related invalidity petition should be filed. This allows challengers to "jump the gun" and kick start the invalidity petition ahead of the ANDA filing so they can stay ahead of other competitors in pursuing the "first generic winner" exclusivity, or at least clear the bar for generic approval in advance.

The Third Draft would impose time limitation for the "gun-jumping" strategy, limiting how early the invalidity petition could be filed in advance of the corresponding ANDA filing. In particular, Part IV, Chapter 3, Section 9.1 of the Third Draft proposes that to have an earlier-filed invalidity petition incorporated into a later-filed ANDA challenge, the generic challenger must submit evidence proving the invalidity petition is ANDA-related before the conclusion of the debate in the oral hearing of the invalidity proceeding, or before the decision on the validity is made if the case is proceeded without an oral hearing. It appears that this draft provision intends to set a hard cap for early filing of invalidity petitions, but the draft language only ambiguously states that "this section [for ANDA-related invalidity petitions] does not apply" to those petitions lacking timely-filed ANDA-relevancy evidence, without indicating what is the consequence of an invalidity petition not being "ANDA-related" under this provision. It is not yet known whether those who miss the deadline for submitting the ANDA-relevancy evidence will lose the qualification to become the "first generic winner" or just lose the "first-come-first-served" advantage.

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[4] Unlike in the U.S., China's ANDA rules do not award the "first generic winner" exclusivity to those win through non-infringement challenges. See Article 11.2 of the ANDA Implementation Measures ("A successful patent challenge means that the chemical generic drug applicant submits a Type IV Certification, and according to the invalidity petition raised by the generic drug applicant, the relevant patent right is declared as invalid, so that the generic drug can be approved for listing".)

[5] See Article 11 of the ANDA Implementation Measures. ("A chemical generic drug that is the very first one to successfully challenge the patent(s) and also the first one to be approved for listing" will enjoy a 12-month market exclusivity period).

What are the impacts on innovator drug companies?

If the proposed amendments are adopted, it is expected that some generic competitors may be motivated to reconsider their ANDA filing strategies and move forward the dates for filing corresponding invalidity petitions, to secure a better position vis-à-vis other generic applicants. Innovator drug companies may thus need to prepare for potential invalidity challenges earlier—sometimes even before any ANDA filings. Therefore, we suggest that innovator drug companies pay close attention to the progress of relevant legislations and get prepared for these potential changes in the ANDA rules as early as possible.

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Please note that the Third Draft includes other provisions that may be of significance to drug companies, including provisions on patent term compensation and the link between patent eligibility and compliance with the Human Genetic Resources Regulations.

If you have any questions concerning the material discussed in this Alert, please contact the following attorneys:

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