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TMI: Your Formulation is Showing



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A recent citizen petition provides a cautionary tale for those who might be tempted to include confidential information in a notice letter. On November 2, 2026, AstraZeneca submitted a citizen petition asking the FDA not to approve Cipla's ANDA for a generic olaparib product referencing Lynparza.[1] AstraZeneca appended two of Cipla's Paragraph IV ("PIV") notice letters as exhibits to its petition, which were then publicly posted on the Regulations.gov docket. The letters, marked "Highly Confidential," disclose certain details about Cipla's (allegedly noninfringing) formulation.

Pharmaceutical companies generally treat their formulations as closely guarded confidential information, the disclosure of which may invite serious consequences.[2] But content of a PIV notice letter is not necessarily protected from public disclosure.[3] ANDA filers are required under 21 U.S.C. § 355(j)(2)(B)(iv)(II) to articulate "the factual and legal basis" of their invalidity or noninfringement positions. But filers should carefully balance the notice requirements with the need to protect confidential business information such as proprietary formulations.

Here, Cipla's notice letter states that its ANDA formulation "does not contain copovidone." Another approach would be to combine multiple limitations in a way that protects sensitive information. For example, Cipla could have asserted that its formulation does not feature "a carrier phase comprising co-povidone [with a] weight ratio of [olaparib] to co-povidone [] from

1:2 to 1:4."[4] The details of the formulation can then remain shielded until a protective order is entered or an offer of confidential access is signed, thus mitigating the potential for public disclosure.

[1] AstraZeneca Pharms. LP, Citizen Petition, Docket No. FDA-2026-P-13537-0001 (Nov. 2, 2026), available at https://www.regulations.gov/document/FDA-2026-P-13537-0001.

[2] *See Supernus Pharms., Inc. v. TWi Pharms., Inc.*, No. 1:15-CV-00369-RMB-JS, 2019 WL 13043558, at *1 (D.N.J. July 17, 2019) (noting that disclosure may enable competitors to copy the formulation "and submit a competing ANDA without undertaking independent research and development.").

[3] *Nycomed U.S. Inc. v. Tolmar*, No. CIV.A. 10-2635 KSH, 2011 WL 1675027, at *8 (D.N.J. Apr. 28, 2011) (noting that the protections of an Offer of Confidential Access (OCA) apply to the ANDA, not the notice letter).

[4] U.S. Patent No. 8,475,842, claim 1.



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