

From: [Director Discretionary Decision](#)
To: [Raghav Bajaj \(ATX\)](#); [Director Discretionary Decision](#)
Cc: [Roger Chin \(Bay Area\)](#); [Michael Morin \(DC\)](#); [Michael Seringhaus \(Bay Area\)](#); [David Frazier \(DC\)](#); [Inge Osman \(DC\)](#); [Cecilia Bain \(Bay Area\)](#); [Chaarur Deb \(Bay Area\)](#); [Kevin Zhang \(DC\)](#); [Lauren Rosen \(LA\)](#); [Sarah Propst \(DC\)](#); [Stacy Silver \(SD\)](#); [Lora Green](#); [Heather Schneider](#); [Keith Zullo](#); [Mike Cottler](#); [Michael Johnson](#); [Robert Cerwinski](#)
Subject: RE: IPR2026-00256, -00257, -00258, -00259 - Patent Owner's Request for Reply Authorization to Petitioners' Discretionary Denial Opposition
Date: Tuesday, July 7, 2026 12:43:44 PM

Patent Owner is authorized to file a 5-page reply to Petitioners' Opposition to PO's Request for Discretionary Denial in IPR2026-00256, -00257, -00258, and -00259, due no later than Friday, July 10, 2026, limited to addressing the matters raised below. Petitioner is authorized to file a 5-page sur-reply, due no later than Wednesday, July 15, 2026.

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Subject: IPR2026-00256, -00257, -00258, -00259 - Patent Owner's Request for Reply Authorization to Petitioners' Discretionary Denial Opposition

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Dear Honorable Director,

Patent Owner respectfully requests authorization to file a Reply to the Petitioners' Opposition to PO's Request for Discretionary Denial in IPR2026-00256, -257, -258, and -259 filed June 29, 2026 (Paper 13 in each proceeding, "Opposition"). Citations to the Opposition below are to Paper 13 filed in IPR2026-00256, but similar arguments are contained in the other proceedings.

Patent Owner seeks to address two aspects of the Opposition, as detailed below. For each item, good cause supports authorization of the requested reply because Patent

Owner could not have reasonably anticipated the Opposition's arguments and the arguments rely on new allegations and factual evidence.

1. Patent Owner seeks to address the Opposition's arguments regarding domestic manufacturing. Opposition at 14 ("Accord's competing manufacturing are equitable guidelines to be weighed with other factors."); *id.* at 16-17 ("Accord is a U.S. Company Driving Significant Investment in Domestic Manufacturing and Infrastructure"). See, e.g., Opposition at §§ V.C, V.E.
 - a. Good cause supports authorization for the requested Reply. Patent Owner could not have anticipated Petitioners' arguments, because those arguments are based on information solely within Petitioners' control and newly-presented, and are unrelated to the inquiry contemplated by Director Squires' March 11, 2026 Memorandum.
 - i. Petitioners' arguments rely on a declaration by Chrys Kokino, President of U.S. Specialty of Accord Healthcare, Inc and President of U.S. BioPharma at Accord BioPharma, Inc., Ex. 1053, which is new factual evidence Patent Owner could not have reasonably anticipated.
 - ii. Petitioners' arguments relate to domestic "commercial distribution" activities. Opposition at 14. Patent Owner could not have reasonably anticipated that Petitioners would rely upon such activities, given the Memorandum's reference to **manufacturing** of "products accused of infringement in a parallel proceeding" Director Squires' March 11, 2026 Memorandum at 2 (emphasis added). Petitioners do not contest, and therefore concede, that the biosimilar product at issue in the parties' litigation will be manufactured in China. See IPR2026-00256, Paper 11 at § III.B.
 - iii. Petitioners' arguments rely upon newly-introduced evidence of Intas' domestic activities relative to "Udenyca." Opposition at 16-17. Udenyca is unrelated to this matter or the parties' litigation. Patent Owner could not have reasonably anticipated that Petitioners would rely on activities that are not contemplated as relevant by Director Squires' Memorandum.
2. Patent Owner seeks to address the Opposition's arguments regarding real-parties-in-interest. See, e.g., Opposition at § VI.
 - a. Good cause exists at least because Petitioners bear the burden on this issue, and Patent Owner could not have anticipated that Petitioners would make an argument contrary to law and based on new evidence previously unavailable to Patent Owner.

- i. Petitioners allege Accord is the “primary Petitioner,” Opposition at 2, and “Accord controls this IPR and related district court litigation for Petitioners,” Ex. 1053 ¶15. However, the burden lies solely with Petitioners to establish that the Chinese government does not have the **ability** to control the proceeding. See, e.g., *Tianma Microelectronics Co. v. LG Display Co.*, IPR2025-01579, Paper 12 at 9-10 (P.T.A.B. Mar. 18, 2026) (precedential). Good cause exists for the requested Reply to permit Patent Owner to address Petitioners’ new arguments and evidence and establish why Petitioners’ arguments fall short of its required burden.
- ii. Petitioners’ arguments rely upon Ex. 1103, which is new evidence that was previously unavailable to Patent Owner. For multiple reasons, Ex. 1103 cannot support Petitioners’ burden on this issue, and good cause exists to permit Patent Owner to rebut Petitioners’ attempts to rely on this new evidence.

Given the discrete issues to address, Patent Owner respectfully seeks a five-page reply, due 5 business days after the requested authorization is granted. Patent Owner does not seek authorization to file new evidence.

Counsel for Patent Owner and Petitioner have conferred. Petitioner opposes Patent Owner’s request. Petitioner’s position is stated below.

We oppose Janssen’s request for a five-page reply, as Janssen has not established that good cause exists for such a reply.

As to domestic manufacturing, Janssen’s discretionary denial brief brought those arguments into play. Janssen chose to address only Bio-Thera in its domestic manufacturing arguments while essentially ignoring Accord. Janssen also asserts it could not have foreseen Accord filing a declaration from its President, but Janssen does not point to any non-public information in the declaration. With respect to Janssen’s suggestion that Accord presents arguments that are not consistent with the Director’s March 11, 2026 Memorandum, the Director can determine the weight to give those arguments.

Janssen’s arguments as to Bio-Thera’s alleged ties to the Chinese Government also do not rise to the level of good cause. Exhibit 1103 merely confirms what Janssen’s own

untranslated Exhibits 2015, 2017, 2019, 2021, and 2023 state—that the No. 3 Venture Capital Partnership is a “Domestic, non-state-owned legal person,” not a Chinese Government controlled entity as alleged by Janssen.

To the extent that the Director authorizes Janssen to file a five-page reply, Accord requests a [five-page](#) surreply, due 5 business days after Janssen files its reply.

The parties are available for a conference call to discuss Patent Owner’s request at the Director’s convenience.

Best regards,

Raghav Bajaj
Counsel for Patent Owner

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