

From: [Director Discretionary Decision](#)
To: [Lora Green](#); [Director Discretionary Decision](#)
Cc: [Inge Osman \(DC\)](#); [Kevin Zhang \(DC\)](#); [Michael Morin \(DC\)](#); [Michael Seringhaus \(Bay Area\)](#); [Roger Chin \(Bay Area\)](#); [Raghav Bajaj \(ATX\)](#); [#C-M SIMPONI - IPR - LW TEAM](#); [Michael Johnson](#); [Robert Cerwinski](#); [Keith Zullo](#); [Heather Schneider](#); [Mike Cottler](#)
Subject: RE: IPR2026-00256, -00257, -00258, -00259 - Petitioner's Request for Authorization for Reply to Patent Owner's Preliminary Response
Date: Tuesday, July 7, 2026 12:44:30 PM
Attachments: [image001.png](#)

Petitioner is authorized to file a 2-page reply to Patent Owner's Preliminary Response in IPR2026-00256, -00257, -00258, and -00259, due no later than Friday, July 10, 2026, limited to addressing the matters raised below. Patent Owner is authorized to file a 2-page sur-reply, due no later than Wednesday, July 15, 2026.

From: Lora Green <lgreen@geminilaw.com>
Sent: Monday, July 6, 2026 6:11 PM
To: Director_Discretionary_Decision <Director_Discretionary_Decision@uspto.gov>
Cc: Inge Osman (DC) <inge.osman@lw.com>; Kevin Zhang (DC) <kevin.n.zhang@lw.com>; Michael Morin (DC) <michael.morin@lw.com>; Michael Seringhaus (Bay Area) <michael.seringhaus@lw.com>; Roger Chin (Bay Area) <roger.chin@lw.com>; Raghav Bajaj (ATX) <raghav.bajaj@lw.com>; #C-M SIMPONI - IPR - LW TEAM <simponiipr.lwteam@lw.com>; Michael Johnson <mjohnson@geminilaw.com>; Robert Cerwinski <rcerwinski@geminilaw.com>; Keith Zullo <kzullo@geminilaw.com>; Heather Schneider <hschneider@geminilaw.com>; Mike Cottler <mcottler@geminilaw.com>
Subject: IPR2026-00256, -00257, -00258, -00259 - Petitioner's Request for Authorization for Reply to Patent Owner's Preliminary Response

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Dear Honorable Director,

Petitioner (Accord) respectfully requests authorization to file a two-page reply to Patent Owner's Preliminary Responses ("POPR") in IPR2026-00256, -257, -258, and -259 filed on June 29, 2026 (Paper 12 in each proceeding).

Accord seeks to address Patent Owner's misleading arguments regarding Wayback Machine evidence. Good cause exists as Accord could not have foreseen Patent Owner's reliance on Exhibit 2064 (with respect to IPR2026-00256 and -00259) and Exhibit 2059 (with respect to IPR2026-00257 and -00258) to support its argument that absence of a Wayback Machine archived version before the priority date means that the clinical trials relied upon in Accord's Petitions are not prior art. POPR §VII.A (in all proceedings). Exhibit 2064 (IPR2026-00256 and -00259) however, explains that the

calendar view shown merely "maps the number of times <https://clinicaltrials.gov/study/NCT02186873> was crawled by the Wayback Machine, not how many times the site was actually updated," i.e., it only shows when website snapshots were captured without addressing availability at other times. An analogous argument applies to Exhibit 2059 (IPR2026-00257 and -00258). Accord also could not have foreseen that Patent Owner would argue, based on Exhibit 2065 (IPR2026-00256 and -00259) and Exhibit 2060 (IPR2026-00257 and -00258), that clinicaltrials.gov was not searchable in 2015. POPR §VII.A (in all proceedings). Accord should be allowed to respond to Patent Owner's misleading arguments regarding the Wayback Machine.

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

Counsel for Accord and Patent Owner have conferred. Patent Owner opposes Petitioners' request for a two-page reply. Patent Owner stated its position as follows:

Janssen (Patent Owner) opposes Petitioners' request for a two-page reply, as Petitioners have not established that good cause exists for such a reply.

According to Patent Owner, Petitioners bear the burden of proving the challenged patents are invalid, including showing that their raised references were publicly available, in the Petition itself. Petitioners failed. The Director should not permit a reply that effectively seeks to backfill their Petition.

As to the Wayback Machine evidence, Petitioners have not shown that Janssen's arguments were unforeseeable. POPR §VII.A (in all proceedings). Every single ground of the Petitions affirmatively relies on clinical trial protocols as alleged prior art, purportedly from clinicaltrials.gov. Having chosen to base their challenges on the public availability of those protocols, Petitioners could have reasonably anticipated that Janssen would challenge whether those materials were, in fact, publicly accessible before the priority dates. Petitioners carry the burden to show the public availability of their references, and any challenge to public accessibility of Internet-based references is a routine and foreseeable argument in inter partes review.

The exhibits Petitioners discuss are the kind of Wayback Machine evidence routinely at issue in IPRs. Exhibit 2064 (with respect to IPR2026-00256 and -00259) and Exhibit 2059

(with respect to IPR2026-00257 and -00258) show the archival records of the clinical trial protocols raised by Petitioners. And Exhibit 2065 (IPR2026-00256 and -00259) and Exhibit 2060 (IPR2026-00257 and -00258) simply demonstrate what limited clinicaltrial.gov search functionalities were available to a POSA at the critical dates—directly rebutting Petitioners’ poorly supported assertion that a POSA would have been able to find the asserted references. These exhibits were entirely foreseeable, and do not provide good cause for a reply.

Moreover, Petitioners’ arguments do not rise to the level of good cause. Petitioners contend that Janssen’s characterization of the Wayback Machine evidence is “misleading,” but the exhibits speak for themselves. The Director is fully capable of reviewing the record and weighing the parties’ interpretations without additional briefing. Petitioners’ disagreement with Janssen’s characterization of record evidence does not constitute good cause.

To the extent that the Director authorizes Petitioners to file a two-page reply, Janssen requests a two-page sur-reply, due 5 business days after Petitioners file their reply.

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

Best Regards,
Lora M. Green
Lead Counsel for Petitioner

Lora M. Green J.D., Ph.D.



Gemini Law LLP

32 West 39th St., 15th Floor

New York, NY 10018

o +1.301.461.9580

lgreen@geminilaw.com | geminilaw.com