Filed on behalf of: Accord BioPharma, Inc.
By: Lora M. Green (lgreen@geminilaw.com)

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACCORD BIOPHARMA, INC., INTAS PHARMACEUTICALS LTD., AND BIO-THERA SOLUTIONS, LTD.,
Petitioner,

v.

JANSSEN BIOTECH, INC.,
Patent Owner.

Case No. IPR2026-00258
Patent No. 12,122,824

PETITIONER'S PRE-INSTITUTION REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE[1]

[1] Authorized by the Board via e-mail on July 7, 2026. *See* EX3102.

Patent Owner ("PO") contends that Petitioner failed to establish that *NCT673-V23* (EX1011) qualifies as a printed publication or was available in January 2016. POPR, 32-35. PO's arguments fail.

Wayback Machine: EX2059 and *Valve Corp.* do not bear on when *NCT673-V23* was publicly available, as "[t]he Wayback Machine does not contain copies of every page that ever existed on the Internet." https://archive.org/legal/faq. EX2059 acknowledges this: "This calendar view maps the number of times [NCT02181673] was crawled by the Wayback Machine, not how many times the site was actually updated." EX2059, 1. More pertinent: (1) *NCT673-V23* states "Last Update Posted 2016-01-11 [Estimated]" (EX1011, 3); (2) the "ClinicalTrials.gov" Press Release states that "[t]hrough this new database, NIH offers ***up-to-date information*** on promising patient-oriented research" (EX1052, 1); and (3) the Q&A Document accompanying the Press Release indicates that the database is updated regularly (*id.*, 2). As the Southern District of New York has acknowledged, clinical trial updates "are published by government sources from which the Court may appropriately take judicial notice." *Abely v. Aeterna Zentaris Inc.*, 2013 U.S. Dist. LEXIS 78388, *65 (SDNY May 29, 2013). Even PO's expert relies on the public availability of clinical trial postings. IPR2026-00256, EX2054 ¶80 (citing EX2059).

Search Capabilities: PO contends that "[p]resent-day search results do not establish what a POSA would have located using the search tools available before

the priority date." POPR, 34. But PO's own exhibit, a clinicaltrials.gov search page captured in November 2015, indicates that over 200,000 trials are listed and provides active links for "Advanced Search" and "Search Help" to facilitate searching. EX2060, 1. Clinicaltrials.gov is a "consumer-friendly database" intended to provide the public and health care professionals with easy access to clinical trial information, and searches can be conducted based on treatment, illness and/or condition. EX1052, 1, 2, 4. A POSA using the same search terms as Petitioner's expert—golimumab (a treatment) and psoriatic arthritis (PsA, an illness)—would have found *NCT673-V23*. EX1005 ¶161. Given the statutory purpose, searchability, and reliability of the clinicaltrials.gov website, the Board has held that the publication date listed on a clinicaltrials.gov record is a reliable indicator of its actual publication date. IPR2022-00578, Paper 78, 27-28 (search capabilities adequate in 2009); PGR2019-00003, Paper 22, 17 (clinicaltrials.gov has adequate indicia of publication).

Celltrion cannot be distinguished. POPR, 34-35. The *Celltrion* "subcutaneous tocilizumab" search is similar to the search by Petitioner's expert for golimumab and PsA (EX1005, ¶161), and golimumab was first approved in 2009 for treating PsA (EX1015, 1). While *Celltrion* included the number of search hits and time for review, the undisputed testimony of Petitioner's expert covered the same ground, verifying "that a POSA searching for studies on 'golimumab' and 'psoriatic arthritis' would have readily found, among other studies, NCT02181673." EX1005, ¶161.

Respectfully submitted,

Dated: July 10, 2026

/ Lora M. Green /
Lora M. Green, Lead Counsel
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e), this is to certify that I caused to be served a true and correct copy of the foregoing Petitioner's Pre-Institution Reply To Patent Owner's Preliminary Response by electronic mail on Patent Owner's lead and backup counsel at the following email addresses:

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Respectfully submitted,

Dated: June 10, 2026

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