

Filed on behalf of: Janssen Biotech, Inc.

Entered: September 23, 2026

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.

IPR2026-00259
Patent No. 12,291,566

PATENT OWNER'S OBJECTIONS TO PETITIONER'S EVIDENCE

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Janssen Biotech, Inc. ("Patent Owner") submits the following objections to the evidence relied on by Petitioner Accord BioPharma, Inc., Intas Pharmaceuticals Ltd., and Bio-Thera Solutions, Ltd. ("Petitioner"). Patent Owner's objections apply equally to Petitioner's reliance on this evidence in any subsequently filed documents or further proceedings in this matter. These objections are timely, having been filed and served within ten business days of institution of trial. Notwithstanding these objections, Patent Owner expressly reserves the right to rely on any evidence submitted by Petitioner, including on the ground that such evidence constitutes a party admission.

Objections

Exhibit 1005

Patent Owner objects to this exhibit as inadmissible hearsay under FRE 801 and 802 not falling under any exception, and as improper expert testimony under FRE 702 and 703, to the extent it impermissibly acts as a conduit for hearsay, including the hearsay objected to herein, and does not rely on the kinds of facts or data that experts in the relevant fields would reasonably rely on in forming an opinion on the subject without providing the underlying facts, data, and other required disclosures.

Patent Owner further objects to this exhibit for lack of foundation and lack of personal knowledge under FRE 602, and as improper lay testimony under FRE 701,

to the extent it offers testimony in areas outside of Dr. Fleischmann's area of expertise or fails to properly provide the underlying facts, data, and other required disclosures.

Exhibit 1053

Patent Owner objects to this exhibit as inadmissible hearsay under FRE 801 and 802 not falling under any exception.

Patent Owner further objects to this exhibit for lack of foundation and lack of personal knowledge under FRE 602, and as improper lay testimony under FRE 701, to the extent it offers testimony in areas outside of Mr. Kokino's area of expertise or fails to properly provide the underlying facts, data, and other required disclosures.

Exhibits 1011-1019, 1022, 1026-1030, 1032-1035, 1038-1044, 1050-1052, 1054, 1056-1065, 1107-1116

Petitioner objects to these exhibits as not properly authenticated under FRE 901 because Patent Owner has not presented sufficient evidence to show that they are authentic or self-authenticating under FRE 902. To the extent Patent Owner relies on these documents for the truth of the matter asserted, Petitioner objects to these exhibit as inadmissible hearsay under FRE 801 and 802 that do not fall under any exceptions, including those of FRE 803, 804, 805, or 807.

Exhibit 1088

Patent Owner objects to this exhibit as misleading, raising a likelihood of confusion, and unduly prejudicial under FRE 403 because the exhibit encompasses material that differs from Petitioner's representation of the exhibit.

Respectfully submitted,

Dated: September 23, 2026

By: / Raghav Bajaj /

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*Counsel for Patent Owner
Janssen Biotech, Inc.*

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 23rd day of September, 2026, a true and correct copy of the foregoing **Patent Owner's Objections to Petitioner's Evidence** was served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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