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.,
Petitioners,

v.

JANSSEN BIOTECH, INC.,
Patent Owner.

Case No. IPR2026-00257
Patent No. 11,041,020

PETITIONERS' OBJECTIONS TO PATENT OWNER'S EVIDENCE

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Accord Biopharma, Inc., Intas Pharmaceuticals Ltd., and Bio-thera Solutions, Ltd. ("Petitioner") submits the following objections to the evidence relied on by Patent Owner Janssen Biotech, Inc. ("Patent Owner"). Petitioner's objections apply equally to Patent Owner'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, Petitioner expressly reserves the right to rely on any evidence submitted by Patent Owner, including on the ground that such evidence constitutes a party admission.

Objections

Exhibit 2054

Petitioner 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.

Petitioner further objects to this exhibit as violating FRE 401, FRE 402, and FRE 403, which bar testimony that is confusing, unduly prejudicial, and/or irrelevant, and under FRE 703 for relying on improper bases.

Petitioner 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. Haroon's area of expertise or fails to properly provide the underlying facts, data, and other required disclosures.

Exhibit 2500

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

Petitioner 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 Ann Donlon's area of expertise or fails to provide the underlying facts, data, and other required disclosures.

Petitioner further objects to this exhibit as violating FRE 401, FRE 402, and FRE 403, which bar testimony that is confusing, unduly prejudicial, and/or irrelevant, and under FRE 703 for relying on improper bases.

Exhibit 2501

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

Petitioner 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. Brennan's area of expertise or fails to provide the underlying facts, data, and other required disclosures.

Petitioner further objects to this exhibit as violating FRE 401, FRE 402, and FRE 403, which bar testimony that is confusing, unduly prejudicial, and/or irrelevant, and under FRE 703 for relying on improper bases.

Exhibit 2502

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

Petitioner 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. Marzullo's area of expertise or fails to provide the underlying facts, data, and other required disclosures.

Petitioner further objects to this exhibit as violating FRE 401, FRE 402, and FRE 403, which bar testimony that is confusing, unduly prejudicial, and/or irrelevant, and under FRE 703 for relying on improper bases.

Exhibits 2012-2013, 2037, 2047, 2050, 2052, 2056

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 exhibits 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 2014

Petitioner objects to this exhibit as not relevant under FRE 401.

Respectfully submitted,

Dated: September 23, 2026

/ Lora M. Green /
Lora M. Green, Lead Counsel
Reg. No. 43,541

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 Objections to Patent Owner's Evidence by electronic mail on Patent Owner's lead and backup counsel at the following email addresses:

Inge A. Osman (Reg. No. 74,480)
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Respectfully submitted,

Dated: September 23, 2026

/ Lora M. Green /
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