

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,

Petitioner

v.

SOLENO THERAPEUTICS, INC.,

Patent Owner

Case No. PGR2026-00034

U.S. Patent No. 12,419,895

**PETITIONER'S OBJECTIONS TO PATENT OWNER'S EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64(b)(1)**

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Apotex Inc. (“Petitioner”) submits the following objections to the evidence relied on by Patent Owner Soleno Therapeutics, 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 (10) 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.

I. Objections to Exhibits 2002, 2004-2016, 2018-2024, 2029-2030, and 2032-2034

Petitioner objects to Exhibits 2002, 2004-2016, 2018-2024, 2029-2030, and 2032-2034 as inadmissible under Fed. R. Evid. 402 because none of these exhibits are relevant to any issue in this proceeding, or, alternatively, under Fed. R. Evid. 403 because any remaining probative value of these exhibits would be substantially outweighed by a danger of confusing the issues and wasting time.

These exhibits are not cited in Patent Owner’s Preliminary Response (Paper 8). Instead, Patent Owner cited these exhibits to support its arguments for discretionary denial. *See, e.g.*, Patent Owner’s Discretionary Denial Brief (Paper 6) at 7-8, 10-15, 17, 19-20. Director Squires denied Patent Owner’s discretionary denial request (Paper 9) and instituted this PGR (Paper 10). Therefore, Patent Owner’s

discretionary denial arguments are now moot, and these exhibits are no longer relevant to any issue in this proceeding.

II. Objections to Exhibit 2038

Petitioner objects to Exhibit 2038 as inadmissible under Fed. R. Evid. 402 because this exhibit is not relevant to any issue in this proceeding.

This exhibit is cited in the Declaration of Lynne M. Bird, M.D. in Support of Patent Owner's Preliminary Response in connection with its discussion of Cowen; however, Exhibit 2038 post-dates the earliest priority date of U.S. Patent No. 12,419,895 ("the '895 patent"), and therefore, is not relevant to any issue in this proceeding.

III. Objections to Exhibits 2025-2026, 2028, 2038, 2074-2075, and 2080-2089

Petitioner objects to Exhibits 2025-2026, 2028, 2038, 2074-2075, and 2080-2089 as inadmissible hearsay under Fed. R. Evid. 801 and 802 for which no exception has been established.

Moreover, to the extent Patent Owner offers any of Exhibits 2025-2026, 2028, 2038, 2074-2075, and 2080-2089 for any purpose other than as alleged objective indicia of nonobviousness, Petitioner objects under Fed. R. Evid. 402 because none of these exhibits are relevant to any issue in this proceeding. Each of these exhibits post-dates the earliest priority date of the '895 patent, and therefore, is not relevant

to any issue in this proceeding if offered for any purpose other than as alleged objective indicia of nonobviousness.

CERTIFICATE OF SERVICE

I hereby certify that the foregoing, Petitioner's Objections to Patent Owner's Evidence Pursuant to 37 C.F.R. § 42.64(b)(1), was served on October 21, 2026, via electronic mail at the following email addresses:

Inge A. Osman
inge.osman@lw.com

Michael A. Morin
michael.morin@lw.com

Marc N. Zubick
marc.zubick@lw.com

Dated: October 21, 2026

Respectfully submitted,

/s/ Sara M. Pistilli
Jitendra Malik (Reg. No. 55,823)
jitty.malik@katten.com
KATTEN MUCHIN ROSENMAN LLP
615 S. College Street, Ste. 1700
Charlotte, NC 28202-3354
Tel.: (704) 344-3185

Sara M. Pistilli (Reg. No. 82,287)
sara.pistilli@katten.com
KATTEN MUCHIN ROSENMAN LLP
525 W. Monroe Street
Chicago, IL 60661-3693
Tel.: (312) 902-5681

Counsel for Petitioner Apotex Inc.