

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ASCENDIS PHARMA A/S,
Petitioner

v.

BIOMARIN PHARMACEUTICAL INC.,
Patent Owner

Case PGR2026-00013
U.S. Patent No. 12,233,106

PETITIONER'S OBJECTIONS TO EVIDENCE

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Petitioner Ascendis Pharma A/S (“Petitioner”) objects under the Federal Rules of Evidence (FRE) and 37 C.F.R. § 42.64(b)(1) to the admissibility of Exhibits 2012, 2013, and 2017 (the “Challenged Evidence”), filed by Patent Owner BioMarin Pharmaceutical Inc. (“Patent Owner”) on February 3, 2026, with Patent Owner’s Brief Requesting Discretionary Denial (Paper 6). Petitioner’s Objections are timely filed under 37 C.F.R. § 42.64(b)(1), within ten business days of the Director’s May 6, 2026, Decision on Institution (Paper 14). Petitioner files these Objections to provide notice to Patent Owner that Petitioner may move to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c).

I. IDENTIFICATION OF GROUNDS FOR OBJECTIONS

A. Exhibit 2012

Exhibit 2012 purports to be “FDA Guidance for Industry, General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products.” Petitioner objects to Exhibit 2012 under FRE 401–403 because Exhibit 2012 purports to have published in “July 2022,” and therefore lacks relevance to a POSA’s knowledge and understanding before the ’106 patent’s claimed July 2021 and June 2022 priority dates.

B. Exhibit 2013

Exhibit 2013 purports to be “Sian Gaze, Best Practice for Medicines Use in Neonates, Pharmaceutical Journal.” Petitioner objects to Exhibit 2013 under FRE 401–403 because Exhibit 2013 purports to have published on May 7, 2024, and

therefore lacks relevance to a POSA's knowledge and understanding before the '106 patent's claimed July 2021 and June 2022 priority dates.

Petitioner also objects to Exhibit 2013 under FRE 901–903 because Exhibit 2013 lacks authentication and is not self-authenticating under FRE 902.

C. Exhibit 2017

Exhibit 2017 purports to be “Savarirayan (2024), *Vosoritide therapy in children with achondroplasia aged 3-59 months: a multinational, randomised, double-blind, placebo-controlled, phase 2 trial*, Lancet Child Adolesc. Health, 8(1):40-50.” Petitioner objects to Exhibit 2017 under FRE 401–403 because Exhibit 2017 purports to have published online on November 17, 2023, and therefore lacks relevance to a POSA's knowledge and understanding before the '106 patent's claimed July 2021 and June 2022 priority dates.

Petitioner also objects to Exhibit 2017 under FRE 1002 and 1003 as being an incomplete document. Exhibit 2017 repeatedly refers to supplemental information in an online “appendix,” which is not provided in Exhibit 2017. *See e.g.*, EX2017, 41-48. Exhibit 2017 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

II. CONCLUSION

In view of the Objections set forth above, Petitioner may file a motion to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c).

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

/David H. Holman/

Date: May 20, 2026
1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600

David H. Holman, Ph.D.
Registration No. 61,205
Lead Attorney for Petitioner

CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

I certify that the above-captioned **PETITIONER'S OBJECTIONS TO EVIDENCE** was served in its entirety on May 20, 2026, upon the following parties via electronic mail:

Naveen Modi (Lead Counsel)
Eric Dittman (Back-up Counsel)
Chetan Bansal (Back-up Counsel)
PAUL HASTINGS LLP
PH-Ascendis-BioMarin-PGR@paulhastings.com

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

/David H. Holman/

David H. Holman, Ph.D.
Registration No. 61,205
Lead Attorney for Petitioner

Date: May 20, 2026

1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600