

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
Patent No. 12,233,106 B2

**AUTHORIZED REPLY IN SUPPORT OF
REQUEST FOR DISCRETIONARY DENIAL**

LIST OF EXHIBITS

Exhibit No.	Description	Previously Submitted
2001	USITC Inv. No. 337-TA-1447, Order No. 25: Amending Procedural Schedule (December 16, 2025), EDIS Doc. ID. 866614	X
2002	USITC Investigations Database System, Status of Investigation 337-1447, https://ids.usitc.gov/case/8276/investigation/8728 (last accessed January 20, 2026)	X
2003	RESERVED	
2004	U.S. Reissue Patent No. 48,267	X
2005	USITC Inv. No. 337-TA-1447, Amended Complaint (August 22, 2025), EDIS Doc. ID. 860269	X
2006	USITC Inv. No. 337-TA-1447, Disputed and Agreed Claim Constructions (September 23, 2025), EDIS Doc. ID 862675	X
2007	USITC Inv. No. 337-TA-1447, Respondents' Opening Claim Construction Brief (publicly available Feb. 5, 2026) (EDIS Doc No. 871764)	
2008	USITC Inv. No. 337-TA-1447, Respondents' Reply Claim Construction Brief (publicly available Feb. 5, 2026) (EDIS Doc. ID No. 871767)	
2009	RESERVED	
2010	RESERVED	
2011	USITC Inv. No. 337-TA-1447, Order No. 15: Initial Determination Granting Complainant's (1) Motion to Declassify and (2) Motion to Amend the Complaint and Notice of Investigation (August 14, 2025), EDIS Doc. ID. 861044	X
2012	FDA Guidance for Industry, General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products (July 2022) at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-clinical-pharmacology-considerations-neonatal-studies-drugs-and-biological-products-guidance , and	X

	https://www.fda.gov/media/129532/download (last accessed January 27, 2026)	
2013	Sian Gaze, Best Practice for Medicines Use in Neonates, Pharmaceutical Journal (May 7, 2024) at https://pharmaceutical-journal.com/article/ld/best-practice-for-medicines-use-in-neonates (last accessed January 27, 2026)	X
2014	March 31, 2025 Ascendis Press Release at https://investors.ascendispharma.com/news-releases/news-release-details/ascendis-submits-us-nda-transcon-cnp-navepegritide-treatment (last accessed January 27, 2026)	X
2015	November 25, 2025 Ascendis Press Release at https://investors.ascendispharma.com/news-releases/news-release-details/ascendis-announces-extension-fda-review-period-transcon-cnp (last accessed January 27, 2026)	X
2016	Clinical Trial NCT06079398 (ASND0030) at https://clinicaltrials.gov/study/NCT06079398 (last accessed January 27, 2026)	X
2017	Savarirayan (2024), <i>Vosoritide therapy in children with achondroplasia aged 3-59 months: a multinational, randomised, double-blind, placebo-controlled, phase 2 trial</i> , Lancet Child Adolesc. Health, 8(1):40-50	X
2018	USITC Inv. No. 337-TA-1447, Commission Investigative Staff's Claim Construction Brief (December 1, 2025), EDIS Doc. ID. 866257	X

In the ITC investigation concerning Ascendis' importation of drug products containing CNP variants, Ascendis argues that "[t]he term 'CNP variant' does *not* have a plain or established meaning in the art" such that "[i]t is *important* to determine what *exactly* a 'CNP variant' is" (Ex. 2007, 15 (emphases added).) There, Ascendis argued against adopting BioMarin's proposed ordinary meaning (Ex. 2006, Appendix A) because it purportedly "ignores the function of the CNP variant in the context of the claimed invention." (Ex. 2008, 2-3.) Yet, in this PGR, Ascendis contends that the term "CNP variant" has a plain and ordinary meaning (see Petition, 23-25; Opp. (Paper 8), 6) and fails to engage in the same exercise of determining the meaning of "CNP variant" that it believed was required in the ITC. Ascendis' material inconsistency cannot be excused by its erroneous assertion that the '106 patent is "unrelated to" RE48,267, at issue in the ITC. (Opp., 2-5.) It is *undisputed* that both patents disclose the use of CNP variants to treat the same disorder (skeletal dysplasia), and the '106 patent recites the *same* CNP variants as claim 15 of RE48,267. (DD Req., 4.) With its inconsistency exposed, Ascendis offers a purported "ordinary and customary meaning" (Opp., 5-7), which it argued in the ITC never existed. This belated construction, however, supports a discretionary denial because it is absent from the Petition in violation of 37 C.F.R. 42.204(b)(3), and was never applied in the Petition's obviousness analysis, as confirmed by Ascendis' limited citations to the Petition's background. (Opp., 6-7.)

Dated: March 12, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that I caused to be served on the counsel identified below a true and correct copy of the foregoing Reply in Support of Request for Discretionary Denial by electronic means on March 12, 2026:

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