

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner

v.

HALOZYME, INC.,
Patent Owner

Case PGR2025-00003
U.S. Patent No. 11,952,600

**PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW OF THE
FINAL WRITTEN DECISION**

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Patent Trial and Appeal Board
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Halozyme, Inc. (“Patent Owner”) requests Director review of the Board’s Final Written Decision (Paper 128, “Final Written Decision”) that issued on May 12, 2026. Director Review is warranted because the Final Written Decision should not have issued. Specifically, the Board instituted and maintained trial based on a Petition that failed to name all real parties in interest (“RPI”). As a result, the Final Written Decision is premised on a petition that fails to comply with statutory and regulatory requirements and should be vacated.

The Director has previously exercised authority to address such threshold defects even after issuance of a final written decision. In *Aylo Freesites Ltd. v. DISH Techs. LLC*, IPR2024-00940, Paper 75 at 1–3 (Director Feb. 3, 2026), the Director *sua sponte* initiated review of a final written decision and ultimately dismissed the petition and terminated the proceeding in view of the petitioner’s failure to properly identify all RPIs, and vacated the Board’s final written decision. Consistent with that case, Director Review is appropriate here to correct the Board’s error in instituting and maintaining trial and issuing a final written decision on a petition that did not comply with statutory and regulatory requirements. *See* 35 U.S.C. § 312(a)(2); 37 C.F.R. § 42.8; *Corning Optical Communications RF, LLC v. PPC Broadband Inc.*, IPR2014-00440, Paper 68 (P.T.A.B. Aug. 18, 2015) (precedential except Section II.E.1).

Halozyme's May 26, 2026 Request for Director Review (Paper 140) sets forth in detail the basis for termination of this proceeding. Patent Owner notes that if the Director resolves Patent Owner's May 26, 2026 Director Review Request and terminates the proceeding, this request is moot and no further action by the Director on this request will be necessary.

As explained in that Request, Petitioner Merck Sharp & Dohme LLC ("MSD" or "Petitioner") improperly refused to name its corporate parent, Merck & Co., Inc. ("MCI"), as an RPI despite MCI's actual ability to control, direct, and fund these proceedings, as reflected in its own corporate documents, and despite MCI's clear benefit from the case. Paper 140 at 1. Similar to what the Director recently determined in *Sun Pharm.*, the Petitioner here likewise has failed to provide sufficient evidence that its parent company did not have the ability to control this proceeding and thus has failed to meet its burden to establish it has identified all RPIs. *Sun Pharm. Indus., Inc. v. Biofrontera Inc.*, PGR2026-00021, Paper 12 at 2-3 (Director Decision, May 26, 2026).

Notably, the Director has already addressed the same factual circumstances between these parties, denying institution in MSD's related petition (PGR2025-00087) after Halozyme raised MSD's failure to name all RPIs as the sole issue in its Preliminary Response. PGR2025-00087, Paper 22 (May 15, 2026). Indeed, MSD persisted in this fatal omission even after the Director underscored the

importance of proper RPI identification by designating *Corning Optical* precedential. *Corning Optical*, Paper 68 (precedential except Section II.E.1).

Under these circumstances and based on Petitioner's clear failures, the Board should have terminated this proceeding months ago, especially after receiving Patent Owner's Motion to Terminate (Paper 84, February 16, 2026) and related filings, and the Board should not have issued a final written decision at all.

Accordingly, Halozyme respectfully requests that the Director vacate the Final Written Decision, terminate this proceeding, dismiss the Petition, and vacate all post-institution decisions.

Separate from the issue of RPI, Patent Owner intends to appeal the panel's findings in its Final Written Decision should that decision be permitted to stand. It is Patent Owner's understanding, under applicable rules, that its previous May 26, 2026 Director Review Request on the panel's interlocutory decision on Patent Owner's Motion to Terminate resets the time for appeal. In particular, 37 C.F.R. § 42.75(d)(1) provides that a timely request for rehearing or Director Review prevents any decision from becoming the final agency decision. Under that reading, in view of Patent Owner's pending May 26, 2026 Director Review Request on the RPI issue, the Final Written Decision does not constitute a final agency decision for purposes of triggering the notice of appeal period. Indeed, it would make little sense to run the appeal period while Patent Owner's previous

request for Director Review is under consideration because once a Notice of Appeal is filed, jurisdiction over the proceeding transfers to the Court of Appeals of the Federal Circuit and the Office is divested of authority over matters on appeal. *See Loshbough v. Allen*, 359 F.2d 910, 912 (C.C.P.A. 1966); *Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2019-00991, Paper 53 at 2 (P.T.A.B. May 24, 2021).

Notwithstanding Patent Owner's understanding that the timing for filing any notice of appeal is already tolled, out of an abundance of caution, Patent Owner submits this Request for Director Review of the Final Written Decision to ensure that the notice of appeal deadline is unambiguously reset under 37 C.F.R. § 42.75(e)(3). This request is intended to ensure that the Director has the opportunity to address the threshold RPI defect indicating that institution was improper in this case.

For the foregoing reasons, including in view of the Director's recent decision denying institution in the -087 PGR (with same RPI briefing and underlying evidence as here) (PGR2025-00087, Paper 22 (May 15, 2026)) and for the reasons stated in Patent Owner's May 26 Director Review Request (Paper 140), Patent Owner respectfully requests that the Director grant this request for Director Review, vacate the Board's Final Written Decision, terminate this PGR, and vacate all post-institution decisions.

Respectfully submitted,

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Date: June 11, 2026

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

I certify that the above-captioned **PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW OF THE FINAL WRITTEN DECISION** was served in its entirety on June 11, 2026, upon the following parties via electronic mail:

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