UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner

v.

HALOZYME, INC.,
Patent Owner

Case IPR2026-00313
U.S. Patent No. 11,041,149

PATENT OWNER PRELIMINARY RESPONSE
UNDER 37 C.F.R. § 42.107(a)

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2002	File History of U.S. Patent Application No. 19/346,638
2003	"Product Patents," Merck.com, accessible at https://www.merck.com/products/patent/ (last accessed February 20, 2026)
2004	Merck & Co., Inc. Form 10-Q, Securities and Exchange Commission, May 4, 2026
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2008	Schedule 14A Proxy Statement, Merck & Co., Inc., 2025
2009	By-Laws of Merck & Co., Inc., Effective as of November 19, 2024
2010	USPTO OED Practitioner Search - Mark J. Stewart, October 30, 2025
2011	USPTO Office of Enrollment and Discipline Practitioner Search for Mark J. Stewart, February 13, 2026
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2025	Letter to the Court on the Status of Post-Grant Review Proceedings, Halozyme, Inc. v. Merck Sharp and Dohme LLC, Civil Action No. 2:25-cv-03179-ES (D.N.J.), filed January 7, 2026
2026	E-mail Exchange Between Counsel for Halozyme and Merck regarding Meet and Confer, October 1 -9, 2025
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2028	Transcript of the Deposition of Michael Hecht, Ph.D., in PGR2025-00003, -00004, -00006, and -00009, August 26, 2025
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2030	Declaration of Michael Hecht, Ph.D. (Exhibit 1003), *Merck Sharp & Dohme LLC v. Halozyme Inc.*, Case No. PGR2025-00003 (P.T.A.B.), November 12, 2024
2031	Declaration of Dr. Sheldon Park (Exhibit 1004), *Merck Sharp & Dohme LLC v. Halozyme Inc.*, Case No. PGR2025-00003 (P.T.A.B.), November 12, 2024
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2035	Declaration of James Naismith. Ph.D. (Exhibit 1133), *Merck Sharp & Dohme LLC v. Halozyme Inc.*, Case No. PGR2025-00003 (P.T.A.B.), January 20, 2026
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I. INTRODUCTION

The totality of the circumstances here warrant denial of institution. Merck ("Petitioner") is using the AIA process to gain leverage in litigation and avoid liability for its infringement by engaging in a multi-stage campaign of gamesmanship against Halozyme's patents. From November 12, 2024, to March 23, 2026, Petitioner filed fifteen PGR petitions and three IPR petitions. The challenged patent issued on June 22, 2021, but Petitioner waited until March 23, 2026, on the eve of the one-year bar under 35 U.S.C. § 315(b) and nearly a year and a half from filing its first PGR, to file an IPR. Petitioner's delay was no accident—the IPR filing was timed to follow the oral hearing in the first set of PGRs, giving Petitioner a chance to switch its experts, develop new theories, and test them before the panel.

Notably, while Petitioner pursued obviousness challenges in the 15 PGRs, following skepticism from the Board at oral argument in the first set of PGRs, Petitioner ***dropped the obviousness challenges*** it asserted in its first PGRs which relied on prior art, choosing to rely only on alleged lack of § 112 support and then anticipation by Patent Owner's own earlier published patent application. Petitioner also relies on cherry-picked portions of prior AIA proceeding testimony from PO's experts while disregarding the same experts' testimony that the claims in those cases satisfy § 112.

Petitioner also declined to submit a *Sotera* stipulation, which preserves its ability to pursue overlapping invalidity theories in district court. Petitioner's decision confirms that this IPR is not a substitute for litigation but an additional forum for duplicative challenges.

Petitioner's delayed filing and selective use of the record from its previously filed PGRs reflect precisely the type of duplicative and inefficient practice the AIA was intended to discourage. Allowing institution on this record would therefore waste the Board's limited resources and disserve the public interest. *Magnolia Medical Technologies, Inc. v. Kurin, Inc*., IPR2026-00097, Paper 17 at 2 (P.T.A.B. May 14, 2026); *Sotera Wireless, Inc. v. Masimo Corporation*, IPR2020-01019, Paper 12 (P.T.A.B. Dec. 1, 2020) (precedential).

On the substance, Petitioner's claim construction is erroneous because Petitioner reads a "properly folded" requirement and a stability requirement into the claims, neither of which is reflected in the claim language or the specification. Petitioner instead relies on its expert testimony to import these limitations. Petitioner thus improperly relies on extrinsic evidence rather than the intrinsic record required under *Phillips v. AWH Corp*., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc).

Finally, Petitioner's new anticipation argument is inconsistent with its claim construction and with positions Petitioner has taken in the PGR proceedings.

Specifically, in arguing the challenged claims cannot claim priority due to an alleged lack of written description, Petitioner contends that the claims require a "properly folded" modified PH20. Pet., 19-20. Petitioner's expert Dr. Naismith testified that "properly folded" means "stably" folded, which he alleges involves exhibiting activity at ***8 hours***. EX2038, 138:6-141:19, 180:2-184:24, 190:9-19, 200:9-16, 250:17-25. In the PGR proceedings—where Petitioner did not make an anticipation argument—Dr. Naismith testified that the activity assay in the allegedly anticipatory priority document does not provide sufficient information to confirm that the tested modified PH20s meet his 8-hour stability requirement for "proper folding." Thus, Petitioner cannot show anticipation.

Separately, this Petition is defective because it fails to identify Merck & Co., Inc. ("MCI") as a real party-in-interest. The evidence shows that MCI has the ability to control the AIA challenges against Halozyme's MDASE (modified PH20 polypeptides) patents and stands to directly benefit from their outcome. This same omission recently warranted denial of institution in a closely related proceeding (PGR2025-00087), and the factual record here is identical. By failing to name MCI, Petitioner has not satisfied the statutory requirements of § 312(a)(2), rendering the Petition incomplete and providing a separate and sufficient basis to deny institution.

Given the totality of the circumstances, institution would be unwarranted

and counterproductive. Petitioner's conduct reflects a deliberate pattern of strategic delay and selective presentation of evidence, including waiting until long after the PGR window, and filing only at the eleventh hour of the § 315(b) bar after developing a complete record in related PGRs and failing to name all RPI. Trial should be denied.

II. THE DIRECTOR SHOULD DENY INSTITUTION BECAUSE THE PETITION REFLECTS STRATEGIC GAMESMANSHIP THAT UNDERMINES THE STATUTORY PURPOSE AND LIMITS OF *INTER PARTES* REVIEWS.

The Petition is not a good-faith invocation of *inter partes* review as a streamlined alternative to district court litigation. Instead, it reflects a pattern of strategic gamesmanship designed to avoid infringement liability.

As Director Squires explained in the recent precedential decision in *Magnolia*, "[t]he purpose of AIA reviews was, and is, to provide a *quick and cost effective alternative to district court patent litigation* for resolving disputes over patent validity." IPR2026-00017, Paper 17 at 2. Congress cautioned that such proceedings should not be used "for harassment or a means to prevent market entry through repeated litigation and administrative attacks," which would "frustrate the purpose" of providing "quick and cost effective alternatives to litigation." *Id.* (citing H.R. Rep. No. 112-98 at 48 (2011), S. Rep. No. 110-259 at 72 (2008)). Such misuse would divert resources away from innovation and undermine the constitutional purpose of the patent system. *Id.* (citing H.R. Rep. No. 112-98 at 48;

S. Rep. No. 110-259 at 72). And as Director Squires explained, "[t]he Office institutes review to reconsider its own decision and correct a possible error in the original patent grant—not to shield a particular petitioner from infringement liability." *Id.* at 6.

Petitioner is misusing the AIA practice to deny Patent Owner, an American company, its day in court by filing an endless series of spaced challenges under the AIA. Patent Owner filed an infringement action in April 2025, asserting 15 patents. Petitioner challenged 12 of those patents in PGRs; under § 321(c), the remaining three were no longer PGR-eligible. The parties and the District Court spent months negotiating a pause in the proceedings to account for the PGRs, with the understanding that the three patents no longer eligible for PGR would not be challenged. EX2001, 118/148. Petitioner waited nearly a year, until after the oral hearing in the first set of PGRs, to challenge the three PGR-time-barred patents through IPR.

As explained above, the challenged patent issued in June 2021. Petitioner could have filed a PGR during the nine-month window for this patent and raised the § 112 arguments that it makes now. Or, Petitioner could have filed this IPR at any point from November 2024 through November 2025, when it filed its fifteen related PGRs. It did neither. Petitioner instead waited out the first four PGRs—through institution, full briefing, a developed evidentiary record, and oral argument

before the Board—and now relies on those proceedings as a roadmap to refine and recast its § 112 theories as a priority attack.

As further evidence of Petitioner's gamesmanship, Petitioner did not file a *Sotera* stipulation for any of the IPRs, instead preserving identical invalidity grounds in the parallel litigation. *Sotera Wireless, Inc.*, IPR2020-01019, Paper 12. As such, Petitioner has made this IPR not an "alternative," but rather an *additional* forum for duplicative challenges. That is not an efficient use of USPTO's resources—particularly where, as here, Petitioner relies on a host of material outside of prior art for its theories. It is gamesmanship, pure and simple.

The sole ground of the IPR, coupled with the evidence on which Petitioner relies, shows that Petitioner is using the IPR process as a litigation tactic. IPRs are limited to anticipation and obviousness based on patents or printed publications. 35 U.S.C. 311(b). Here, Petitioner's sole challenge is a Section 112-based priority attack coupled with an anticipation argument based on an earlier published patent application from the same family.

Notably, Petitioner had included an obviousness ground in thirteen of the fifteen PGRs, but following skepticism from the Board on institution and at oral argument, including a comment from Judge Fredman that "Your argument is somewhat inconsistent. You can see that I'm sure," (PGR2025-00003, Paper 127, 36:25-37:1), Petitioner removed that ground from its IPR petitions. Thus, in the

proceeding that should be limited to anticipation and obviousness, Petitioner no longer pursues an obviousness challenge. Instead, Petitioner focuses on alleged lack of priority through a new version of its enablement and written description arguments presented in the PGRs.

Petitioner and its expert also improperly rely on PGR-proceeding testimony from Patent Owner's experts Dr. Petsko and Dr. Simpson in an effort to support its arguments regarding the potential scope of the sequence-based feature in the claims. *See* Pet., 20 n.50 (Petsko); *id.* at 11 n.13, 23 n.55, 48 n.119, 70 n.186, 78 n.205 (Petsko); *id*. at 23 n.55 (Simpson). But this testimony was "not made for this trial" and is used to prove the truth of the matter asserted, so PO's expert testimony in this context is hearsay and should be excluded. *Unified Patents Inc. v. Sound View Innovations, LLC*, IPR2018-00599, Paper 50 at 50–51 (P.T.A.B. Sept. 9, 2019); *see also Google Inc. v. Intellectual Ventures II LLC*, IPR2014-00787, Paper 91 at 20–23 (P.T.A.B. July 24, 2020).

Petitioner also ignores Dr. Petsko's and Dr. Simpson's extensive testimony explaining the import of the teachings in the specification, including the disclosure of representative species, common structural features, and means of practicing the claimed invention using routine methods well known in the art. For example, Petitioner ignores Dr. Petsko's testimony that "[t]he information content of that particular set of substitutions is enormous. And when combined with the structural

information from modeling the PH20 structure, it allows you to visualize and make predictions about much more of the dataset than just what you see here." EX1131, 113:8-18. Petitioner ignores Dr. Petsko's testimony that "you could" "predict whether that mutated 15 or 20 residue-mutated PH20 will exhibit the activity that you are hoping to get." *Id.* at 111:9-19. And Petitioner ignores Dr. Simpson's testimony that a POSA "would have all the information they needed with respect to its activity to create a sequence that was 95% identical, that would either adopt the fold and be enzymatically active, or adopt the fold and not be enzymatically active, or not adopt the fold." EX1130, 99:5–10. And, egregiously, Petitioner relies on Dr. Petsko's PGR declaration in footnote 53 and lists it in the Exhibit List but does not include the declaration itself as an exhibit. Nor does Petitioner include Dr. Simpson's declaration.

Granting institution on this record would effectively extend the PGR window and permit relitigation of § 112 issues that should have been raised earlier. That result is inconsistent with the AIA's design as a streamlined alternative to litigation, not a vehicle for serial, piecemeal challenges. To be clear, Patent Owner does not contend that the Director should limit otherwise proper priority challenges or the use of intervening art in IPRs. Rather, the Director can deny institution here based on the particular circumstances, where Petitioner exploited the timing and structure of AIA proceedings through staggered filings, tactical delay, and reliance

on litigation-developed testimony from previous AIA proceedings brought by the same petitioner. Drawing that line preserves the availability of appropriate IPR challenges while preventing self-serving conduct that undermines efficiency and the integrity of the Board's processes. Because Petitioner's conduct undermines the efficiency, fairness, and purpose of AIA proceedings, the Director should deny institution under § 314(a).

III. PETITIONER'S ERRONEOUS CLAIM CONSTRUCTION SUPPORTS DENYING TRIAL.

Petitioner fails to satisfy its burden to present and justify a proper claim construction under *Phillips* and 37 C.F.R. § 42.104(b)(3). *Phillips*, 415 F.3d at 1314. Petitioner asserts that "PH20" and "modified PH20 polypeptide" are "expressly defined in the disclosure," and then concludes, without analysis, that PH20 must be folded and that modified PH20 polypeptides must also be properly folded because they exhibit increased hyaluronidase activity. Pet., 19-20. But the claims do not mention proper folding, and neither does the specification.

The claims instead are directed to "modified PH20 polypeptides" that exhibit increased hyaluronidase activity conferred by mutations at specific positions. "Modified PH20 polypeptide" is a defined term, and the definition says nothing about "folding." In fact, the words "folded," "properly folded" and "proper folding" do not appear in the specification. Petitioner itself has argued that the patent does not teach folding; in its PGR submission, Petitioner criticized the

specification for allegedly providing "no evidence of proteins in supernatants or their folded state." EX2034, 3.

Petitioner's "properly folded" claim construction is based solely on expert testimony that Petitioner provides. Pet., 19-20; EX1003, ¶¶203-206. Dr. Naismith opines that the claims require "properly folded" modified PH20s, which means that the PH20s are "stably folded." EX1003, ¶¶203-206. Dr. Naismith testified that modified PH20s must maintain activity following 8 hours of incubation to satisfy Petitioner's "properly folded" claim requirement. EX2038, 138:6-141:19, 180:2-184:24, 190:9-19, 200:9-16, 250:17-25. That is because, according to Dr. Naismith, "a POSA would not believe an enzyme had properly folded if it did not maintain activity over a meaningful period (*e.g.*, at least 8-12 hours after expression) or if it formed aggregates within a short period." EX1003, ¶110; EX2035, ¶59.

The activity assay in the patent tested for activity following 1.5 hours, not 8 hours. EX1001, Example 3. Thus, according to Dr. Naismith, the activity assay in the patent is not sufficient to establish "proper folding" because it tested for activity after 90 minutes. EX2038, 140:23-141:19; EX1003, ¶110. As a result, at least according to Petitioner, the exemplary modified PH20s disclosed in the specification do not meet Dr. Naismith's "properly folded" claim requirement, which itself shows that Petitioner's construction is wrong. *Verizon Services Corp.*

v. Vonage Holdings Corp., 503 F.3d 1295, 1305 (Fed. Cir. 2007) ("We normally do not interpret claim terms in a way that excludes disclosed examples in the specification.").

Contrary to basic tenants of claim construction, Petitioner relies on expert testimony to read a "proper folding" limitation into the claims that is reflected nowhere in the specification and in fact is inconsistent with the specification. The Federal Circuit made clear thirty years ago that expert testimony cannot be used to construe claims contrary to the intrinsic record. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996) ("Indeed, where the patent documents are unambiguous, expert testimony regarding the meaning of a claim is entitled to no weight."); *Phillips*, 415 F.3d at 1318 ("[A] court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'") Petitioner's claim construction is contrary to the intrinsic record and should be rejected.

IV. BY PETITIONER'S ADMISSION, THE DISCLOSED EMBODIMENTS DO NOT SATISFY PETITIONER'S CLAIM CONSTRUCTION AND THUS DO NOT ANTICIPATE.

Petitioner contends that various exemplary embodiments that are disclosed as having 120% or more activity and satisfy the sequence requirements meet the claims and thus their disclosure in the US-275 publication anticipates the claims.

Pet., 85-87. But 120% activity is not sufficient to meet the claims under Petitioner's claim construction. According to Petitioner, the claims require proper folding, which according to Dr. Naismith requires activity following 8-12 hours of incubation. EX1003, ¶110; EX2035, ¶59. But the patent does not test for activity after 8 hours; it tests for activity after 90 minutes. EX1001, Example 3. Indeed, Petitioner has criticized the specification for allegedly providing "no evidence of proteins in supernatants or their folded state," and nowhere explains away the contradiction between that position and its new one. EX2034, 3. Under its own (erroneous) construction, Petitioner presents no evidence that the embodiments on which it relies for anticipation are active after 8 hours such that they satisfy the proper-folding requirement Petitioner has read into the claims. Tellingly, neither Petitioner nor Dr. Naismith address their "proper folding" limitation in their anticipation analysis. Petitioner has not satisfied its burden to show anticipation.

V. THE DIRECTOR SHOULD DENY INSTITUTION BECAUSE PETITIONER FAILED TO IDENTIFY MCI AS A REAL PARTY-IN-INTEREST.

In Petitioner's recently denied petition (PGR2025-00087), Halozyme raised **only** the RPI issue in its Preliminary Response, and the Director denied institution. *Id.* at Paper 22 (May 15, 2026) ("the -087 PGR"). The relationships among Petitioner, MCI, and this IPR Petition do not differ from those that resulted in the Director denying institution of the -087 PGR. The outcome in the -087 PGR thus

applies equally here. Accordingly, as in the -087 PGR, the Director should deny this IPR because the Petition fails to name all RPI. *See Corning Optical Comms. RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 at 24-25 (P.T.A.B. Aug. 18, 2015) (precedential) ("*Corning*"); 35 U.S.C. § 312(a)(2). Petitions that omit required RPI "have not met the requirements" of § 312(a)(2), and "are incomplete and cannot be considered." *Id.* at 24-25. The Petition lists only Petitioner as the RPI. Pet., 5. But Petitioner's parent, MCI, directs and controls—and funds—this IPR (or at least has the ability to do so) and will directly benefit from it. As Petitioner's corporate witness, Ms. Kelly Grez admitted, MCI and Petitioner "[a]re not independent parties." EX2027, 85:17-23.

A. MCI has the authority to control Petitioner's KEYTRUDA QLEX-related patent activities, including this IPR.

Petitioner's own patent filings show that MCI has the authority to control Petitioner's KEYTRUDA QLEX-related patent activities, including litigation. Petitioner is the applicant on U.S. Application No. 19/346,638 (the "'638 application"), a grandchild continuation of the KEYTRUDA QLEX "Product patent," U.S. Patent No. 11,633,476. EX2002, 37-38; EX2003, 3. When filing its Power of Attorney in the '638 application, Petitioner submitted MCI's "General Corporate Resolution #5 – Patent Matters," authorizing (among others) MCI CEO Robert M. Davis and General Counsel Jennifer Zachary to act "on behalf of Merck & Co., Inc. and its affiliates (including subsidiaries)" in executing powers of

attorney "relating to the prosecution or defense of patent rights before courts of law or other government tribunals, agencies or departments … and any other documents which are necessary and proper for the acquisition, registration, maintenance, litigation and protection of patent rights." EX2002, 22; EX2027, 241:20-246:18, 252:6-257:11, 258:18-259:4. This demonstrates that MCI is "an involved and controlling parent corporation" with actual authority—not merely theoretical—to direct Petitioner's patent activities. *Galderma S.A. v. Allergan Industrie, SAS*, IPR2014-01422, Paper 14 at 12 (P.T.A.B. Mar. 5, 2015) ("Galderma"). MCI's Corporate Resolution unequivocally grants power to MCI General Counsel Jennifer Zachary (and others) to act on MCI's behalf in this matter. MCI also appoints and removes Petitioner's managers at will. EX2027, 53:6-17, 55:6-25, 63:17-25, 65:8-67:12.

MCI's own SEC filings confirm that it directed the AIA Petitions against Halozyme's MDASE portfolio, including this IPR. In its FY2025 Annual Report (filed by its General Counsel, Jennifer Zachary), MCI defines "Merck & Co., Inc." as "Merck or the Company." EX2001, 3/148; *see also* EX2004 (MCI's Q12026 Quarterly Report), 7/76; EX2005, 6/53. Those same filings state that, "[i]n November 2024, the Company [i.e., MCI] began filing a series of post grant review (PGR) petitions" challenging Halozyme's MDASE patents. EX2001, 118/148; EX2004, 35/76; EX2005, 25/53. MCI likewise reported that "[i]n March 2026, the

Company [i.e., MCI] filed inter partes review (IPR) petitions against [the '400, '149, and '656 patents]." EX2004, 35/76. In the related PGRs, Petitioner argued that the term "Company" in its SEC filings refers to MCI and its subsidiaries, relying on an independent audit letter from an outside accounting firm (PWC), attached to the end of one of the SEC filings. EX2001, 137/148. But that letter reflects PWC's definition—not MCI's. *Id.* Where MCI defines itself as "the Company," it unequivocally does not include subsidiaries. EX2001, 3/148; EX2004, 7/76; EX2005, 6/53.

Notably, Jennifer Zachary signed these SEC filings "on [MCI's] behalf" as its "Executive Vice President and General Counsel." EX2001, 148/148; EX2004, 76/76; EX2005, 53/53. [redacted] Ms. Zachary thus has the authority to direct these AIA challenges on MCI's behalf and publicly represented to the SEC that MCI filed and controls them.

Further, MCI's strategic oversight of Petitioner encompasses decisions concerning protection, enforcement, and defense of core assets, including patent disputes involving key products. For example, a subcommittee on MCI's Board makes "recommendations … [on] strategies and operations" critical to "drug and vaccine discovery, licensing and development"—areas directly tied to this IPR.

EX2008, 19/116; EX2027, 131:14-135:6, 138:19-140. And MCI's own By-Laws indemnify each "Director, officer or employee" of MCI or its subsidiaries from "any and all liabilities" connected to any proceeding. EX2009, 17-18.

B. MCI funds Petitioner's PGR campaign and its belated IPR filings.

MCI's SEC filings also confirm that it funds the Halozyme litigation matters, including this IPR. In the "Contingencies" section addressing "Patent Litigation," MCI describes these matters as involving "the Company," i.e., MCI. EX2001, 116/148-118/148; EX2005, 24/53-26/53. It specifically references litigation concerning "the Company's subcutaneous pembrolizumab product" (KEYTRUDA QLEX) and the MDASE PGR and IPR Petitions. EX2001, 118/148; EX2005, 25/53. As noted above, MCI expressly represents to the SEC that it (the "Company") filed the Halozyme AIA Petitions.

In its "Legal Defense Reserves" disclosures, MCI confirms it funds and directs litigation strategy including the Halozyme AIA proceedings. MCI states that expected legal defense costs encompass "actual costs incurred," development of "legal defense strategy and structure," and "the costs and outcomes of completed trials." EX2001, 118/148-119/148; EX2005, 26/53. It further reports reserves of approximately $245M (2025) and $225M (2024), "the Company's best estimate" of minimum defense costs for its outstanding litigation. EX2001, 119/148; EX2005, 26/53. In short, MCI told the SEC it funds and directs the

strategy for its litigation matters, including the Halozyme AIA challenges.

C. Blurred corporate lines between MCI and Petitioner further evince MCI's direction and control.

Petitioner and MCI are "so intertwined that it is difficult for both insiders and outsiders to determine precisely where one ends and another begins." *Atlanta Gas Light Co. v. Bennett Regulator Guards, Inc.*, IPR2013-00453, Paper 88 at 2-6, 11 (P.T.A.B. Jan. 6, 2015) ("*Atlanta Gas*"). For example, Petitioner's Backup Counsel, Mark Stewart, identified his "Firm Name" to the USPTO's OED as "Merck Sharp & Dohme, LLC [and] Merck and Co." EX2010. Mr. Stewart also attended a German proceeding between MCI (not Petitioner) and Halozyme on behalf of "Merck," not Petitioner. EX2012, 2; EX2027, 205:18-210:17. Likewise, an OED register search for "Merck" in the "business/firm" field yields only four employee entries for Petitioner and 12 for MCI. EX2013; *see also* EX2006, 7; EX2007, 9 (MCI job postings stating that MCI is "also known as" Merck Sharp & Dohme); EX2027, 334:17-337:2, 337:13-339:16, 358:25-360:7, 363:20-364:3.

And numerous individuals hold dual leadership roles with MCI and Petitioner. As just two examples, Ms. Zachary serves as "Executive Vice President and General Counsel" for both entities; and Petitioner's president, Dalton Smart, is also an MCI officer. EX2014; EX2015; EX2016, 3; EX2027, 347:10-23, 348:18-23. Similarly, Mary Morry has identified herself as "Legal Director, Global IP Litigation & Patents" for "Merck Sharp & Dohme LLC (Merck & Co., Inc.),"

including at the American Conference Institute for Biosimilars and Innovator Biologics (June 2-3, 2026). EX2036, 3; *see also* EX2037, 3 (Lisa Jakob identifying herself as "Executive Director, Intellectual Property" at "Merck"). Further, not only does MCI have the authority to appoint Petitioner's board of managers, MCI has appointed MCI officers to fill those roles: two of the three managers of Petitioner are MCI officers. EX2027, 347:10-23, 348:18-23. And seven officers of Petitioner hold dual roles as officers of MCI. EX2027, 54:10-54:17, 348:3-365:15. *See Atlanta Gas* at 11; *Galderma* at 12.

D. MCI has a large interest in and benefits from the Halozyme AIA proceedings—and Petitioner is representing that interest.

MCI unquestionably has an interest in and stands to benefit from Petitioner's AIA actions, and Petitioner represents that interest. *Applications in Internet Time, LLC v. RPX Corp*., 897 F.3d 1336, 1353 (Fed. Cir. 2018). MCI directly benefits from sales of KEYTRUDA QLEX—the accused product in the MDASE patent litigation—and reports its sales and revenue of the same. EX2001, 91/148; EX2005, 8/53. Its SEC filings further analyze how related litigation and AIA proceedings affect the "Company," including expected outcomes and attendant risks and benefits to MCI. EX2001, 112/148; EX2005, 21/53.

In sum, "RPIs are not limited to entities that are actually funding and controlling the proceeding, but include entities that have the ability to control the proceeding." *Sun Pharm. Indus., Inc. v. Biofrontera Inc*., PGR2026-00021, Paper

12 at 2-3 (Director Decision, May 26, 2026). The evidence shows that MCI is an RPI with actual (not theoretical) ability to direct, control, and fund Petitioner's PGR and IPR campaign against Halozyme's MDASE patents. The underlying evidence and arguments here are substantially the same as those in PGR2026-00087, where the Director denied institution after considering briefing and evidence that Petitioner failed to name all RPI.

In fact, denying institution here is even more warranted than in PGR2025-00087. Petitioner delayed filing even longer in this case—by approximately four and a half months—while engaging in extensive, self-serving gamesmanship. As discussed above, rather than timely presenting its § 112 theories, Petitioner waited to mine the PGR record, selectively excerpting and mischaracterizing testimony to construct a refined priority attack as an end-run around the IPR statute. This strategic delay and reliance on cherry-picked, misleading testimony further support denial of institution.

VI. CONCLUSION

Institution should be denied because allowing this Petition to proceed would countenance Petitioner's inefficient and delayed filing strategy, impose unnecessary burdens on the Board's limited resources, and undermine the public interest in streamlined and fair proceedings. That result is inconsistent with the AIA's purpose, especially given Petitioner's refusal to submit a *Sotera* stipulation.

Respectfully submitted,

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CERTIFICATE OF WORD COUNT (37 C.F.R. § 42.24(d))

1. This Patent Owner Preliminary Response complies with the type-volume limitation of 14,000 words, comprising 4,268 words, excluding the parts exempted by 37 C.F.R. § 42.24(a)(1).

2. This Patent Owner Preliminary Response complies with the general format requirements of 37 C.F.R. § 42.6(a) and has been prepared using Microsoft® Word in 14-point Times New Roman font.

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

I certify that the above-captioned **PATENT OWNER PRELIMINARY RESPONSE UNDER 37 C.F.R. § 42.107(a)** and associated Exhibits 2034-2038 were served in their entireties on June 29, 2026, upon the following parties via electronic mail:

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

I certify that the above-captioned **PATENT OWNER'S PRELIMINARY RESPONSE UNDER 37 C.F.R. § 42.107(a)** was served in its entirety on August 14, 2026, upon the following parties via electronic mail:

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