

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner

v.

HALOZYME INC.,
Patent Owner

Case IPR2026-00314
U.S. Patent No. 11,066,656

**PATENT OWNER'S BRIEF REQUESTING
DISCRETIONARY DENIAL**

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U.S. Patent and Trademark Office
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PATENT OWNER'S EXHIBIT LIST

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2001	Merck & Co., Inc. Form 10-K, Securities and Exchange Commission, February 24, 2026
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
2005	Merck & Co., Inc. Form 10-Q, Securities and Exchange Commission, November 5, 2025
2006	Merck & Co. Inc. job posting for “Patent Counsel”
2007	Merck & Co. Inc. job posting for “Oncology Customer Team Leader”
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
2012	Minutes recorded in the public hearing of the Munch I Regional Court, December 4, 2025, Munich, Germany
2013	USPTO Office of Enrollment and Discipline Practitioner Search for “Merck,” February 15, 2026

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2014	“Executive team,” MSD, accessible at http://www.msd.com/company-overview/leadership/executive-team/ (last accessed January 5, 2026)
2015	“Executive team,” Merck, accessible at http://www.merck.com/company-overview/leadership/executive-team/ (last accessed January 5, 2026)
2016	Merck Sharp & Dohme LLC Entity Details, Division of Corporations, Florida Department of State
2017	Bratulic, A., “Merck & Co. signals confidence in defending Keytruda beyond 2028 cliff,” FirstWord Pharma, February 3, 2026
2018	Transcript of Merck & Co. Inc. Q4 2025 Earnings Call, February 3, 2026
2019	Complaint for Patent Infringement and Declaratory Judgment of Patent Infringement, Halozyme, Inc. v. Merck Sharp & Dohme Corp., Civil Action No. 2:25-cv-03179-ES (D.N.J.), filed April 24, 2025
2020	Kim, S., “Alteogen Finally Reveals Partner as MSD, Strikes Additional \$450M Deal for Keytruda SC,” BioSpectator, February 26, 2024
2021	Yeon-ho et al., “Alteogen anticipates record biotech exports for MSD deal,” Pulse by Maell Business News Korea, February 26, 2024
2022	Biologics License Application Letter regarding Keytruda Qlex to Merck Sharp & Dohme LLC, U.S. Food & Drug Administration, September 19, 2025
2023	Biologics License Application Letter regarding Opdivo Qvantig to Merck Sharp & Dohme LLC, U.S. Food & Drug Administration, December 27, 2024

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2024	Stipulation and (Proposed) Order, Halozyme, Inc. v. Merck Sharp and Dohme LLC, <i>Halozyme, Inc. v. Merck Sharp & Dohme Corp.</i> , Civil Action No. 2:25-cv-03179-ES (D.N.J.), filed October 14, 2025
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
2027	Transcript of the Deposition of Kelly Grez, in PGR2025-00003, -00004, -00006, -00009, -00017, -00033, -00039, -00046, -00024, -00030, -00052, -00042, -00050, and -00053, March 26, 2026 (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2028	Transcript of the Deposition of Michael Hecht, Ph.D., in PGR2025-00003, -00004, -00006, and -00009, August 26, 2025
2029	Petition for Post-Grant Review, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00003 (P.T.A.B.), November 12, 2024
2030	Declaration of Michael Hecht, Ph.D. (Exhibit 1003), <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00003 (P.T.A.B.), November 12, 2024
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2032	Institution Decision, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00003 (P.T.A.B.), June 2, 2025
2033	Patent Owner Response, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00003 (P.T.A.B.), September 23, 2025
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Cases

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I. INTRODUCTION

The Director should exercise his discretion and deny institution because Petitioner Merck Sharp & Dohme LLC (“MSD”) failed to identify all real parties in interest (“RPI”). The Petition identifies only MSD as an RPI. Pet., 5. But clear evidence shows that its parent, Merck & Co., Inc. (“MCI”), should have been identified. MSD’s omission violates 35 U.S.C. § 312(a)(2) and controlling Board precedent. *Corning Optical Comms. RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 at 24 (P.T.A.B. Aug. 18, 2015) (precedential) (“*Corning*”); *see also Yangtze Memory Techs., Ltd, v. Micron Tech., Inc.*, IPR2025-00098, Paper 38 at 6 (P.T.A.B. Jan. 15, 2026) (informative); *Aylo Freesites LTD v. Dish Techs. L.L.C.*, IPR2024-00940, Paper 75 at 2-4 (P.T.A.B. Feb. 3, 2026) (*sua sponte* Director Review). The Director should deny institution on this basis alone. *Id.*

In fact, MSD’s failure to identify all RPI here is the same defect the Director considered when denying institution in PGR2025-00087—a related case between the same parties involving the same patent family. There, Halozyme’s pre-institution briefing focused exclusively on MSD’s failure to name its parent, MCI, as an RPI—just as MSD failed to do here. *See* PGR2025-00087, Paper 10 (Patent Owner Preliminary Response), Paper 13 (Petitioner’s Preliminary Reply), Paper 16 (Patent Owner’s Preliminary Sur-Reply). The Director appropriately denied institution. *Id.*, Paper 22 (Director Discretionary Decision, May 15, 2026). Because

the same arguments and underlying evidence are at issue here, the Director should deny this Petition for the same reason. *Id.*

Independent of the fatal RPI defect, the Director should deny institution to deter the type of gamesmanship and abuse of AIA trials that MSD has engaged in here. The challenged patent is part of Halozyme's MDASE (modified PH20 polypeptides) portfolio. MSD has known of this patent family for at least six years, since it began developing the subcutaneous version of its cancer drug, KEYTRUDA (named KEYTRUDA QLEX). Indeed, MSD initially pursued a license from Halozyme (a U.S. company), but instead took its business overseas, partnering with the Korean company Alteogen to use its ALT-B4 hyaluronidase.

In November 2024, MSD began sequentially attacking Halozyme's MDASE patent family. It has since filed 18 AIA Petitions (15 PGRs and 3 IPRs). Critically, MSD deliberately delayed filing its three IPRs (including this one) until the PGRs were largely complete, allowing MSD to repackage and change its unpatentability challenges using the PGR record as a roadmap. MSD's strategic staging "using [Board] decisions as a roadmap" is "unfair to patent owners and is an inefficient use" of AIA trials. *General Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 17-18 (P.T.A.B. Sept. 6, 2017) (precedential).

Specifically, the Petition repackages recycled § 112 assertions from the PGRs as a priority challenge coupled with an "anticipation" ground to challenge

the PGR-ineligible¹ '656 patent. MSD cites no new prior art, relying instead on the '656 patent's own intervening published specification. At the same time, MSD abandons the obviousness grounds it advanced in the PGRs. Thus, the Petition is a thinly veiled § 112 challenge—outside the core purpose of IPRs—strategically recast from the near-complete PGR record. MSD's omission of its prior obviousness grounds and its complete reliance on a priority attack using Halozyme's own MDASE patent specification as “prior art” confirm an attempted end-run around the IPR statute.

MSD's gamesmanship does not stop there: it is using the AIA process to delay Halozyme's day in court—precisely the type of conduct warranting discretionary denial. Halozyme filed an infringement action in April 2025, asserting 15 MDASE patents. MSD challenged 12 of those patents in PGRs; the remaining three (the '656, '149, and '400 patents) were not PGR-eligible under § 321(c). In October 2025, the parties negotiated a litigation schedule with limited discovery and a pause pending the first Final Written Decisions in the PGRs, which the district court adopted. This agreement rested on the shared understanding that the PGR-ineligible '656, '149, and '400 patents would not be

¹ The '656 patent is time-barred from PGR challenge under 35 U.S.C. § 321(c).

challenged at the PTAB. MSD never suggested otherwise during the lengthy schedule negotiations. To the contrary, in February 2026, MSD's parent, MCI, told the SEC that the three remaining patents "*cannot* be challenged *using the PGR* process," but "*can* be challenged *in court proceedings* if required," with no mention of IPRs.² EX2001, 118/148. Both Halozyme and the court thus reasonably expected that litigation of the '656, '149, and '400 patents would proceed in district court once the pause was lifted. MSD waited until just before the § 315(b) statutory bar, over four years after the '656 patent issued, to file this IPR, upending settled expectations and seeking maximum delay in parallel litigation.

Institution in this case would further disrupt settled expectations built on Halozyme's decade-long investment of substantial resources to develop the claimed invention. In light of MSD's gamesmanship and abuse of the AIA process, the Director should deny institution.

II. THE DIRECTOR SHOULD DENY INSTITUTION BECAUSE MSD FAILED TO IDENTIFY MCI AS A REAL PARTY IN INTEREST.

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

² Emphasis has been added throughout, unless stated otherwise.

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* at 24-25; 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.” *Corning* at 24-25. The Petition lists only MSD as the RPI. Pet., 5. But MSD’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 MSD’s corporate witness, Ms. Kelly Grez admitted, MCI and MSD “[a]re *not* independent parties.” EX2027, 85:17-23.

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

MSD’s own patent filings show that MCI has the authority to control MSD’s KEYTRUDA QLEX-related patent activities, including litigation. MSD 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, MSD 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 the 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 MSD’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 MSD’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 ’656,

'149, and '400 patents].” EX2004, 35/76). In the related PGRs, MSD 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]

[REDACTED]

[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 MSD 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 MSD’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 outcome 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 MSD further evince MCI's direction and control.

MSD 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, MSD’s Backup Counsel, Mark Stewart, identified his “Firm Name” to the USPTO’s OED as “Merck Sharp & Dohme, LLC *and Merck and Co.*” EX2010.³ Mr. Stewart also attended a German proceeding between MCI (not MSD) and Halozyme on behalf of “Merck,” *not* MSD. 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 MSD and 12 for MCI. EX2013; *see also* EX2006 at 7 and EX2007 at 9 (MCI job postings stating that MCI is “also known as” MSD); 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 MSD. As just two examples, Ms. Zachary serves as “Executive Vice President and General Counsel” for *both entities*; and MSD’s president, Dalton Smart, is also an MCI officer. EX2014;

³ Mr. Stewart apparently later modified his employer information with OED after Halozyme raised the issue. *Compare* EX2010 with EX2011.

EX2015; EX2016, 3; EX2027, 347:10-23, 348:18-23. Further, not only does MCI have the authority to appoint MSD's board of managers, MCI has appointed MCI officers to fill those roles: two of the three MSD managers are MCI officers. EX2027, 347:10-23, 348:18-23. And seven MSD officers 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 MSD is representing that interest.

MCI unquestionably has an interest in and stands to benefit from MSD's AIA actions, and MSD 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 MSD's PGR

and IPR campaign against Halozyme's MDASE patents. The underlying evidence and arguments here are substantially the same as those in PGR-087, where the Director denied institution after considering briefing and evidence that MSD failed to name all RPI. The Director should do the same here.

III. OTHER CONSIDERATIONS WARRANT DENIAL.

A. Halozyme is a U.S. biotechnology company that pioneered hyaluronidase technology to improve patient lives.

Halozyme, a U.S. biotech company, spent nearly 13 years and invested millions to develop, and now manufactures in the U.S., a modified human hyaluronidase (PH20) enzyme. This technology enables large-molecule therapies (e.g., antibodies) to be administered by simple injection rather than IV infusion. To protect this innovation, Halozyme began filing patent applications on PH20 technology in 2011 ("the MDASE patent family"). The '656 patent—the family's fourth-filed application—issued on July 20, 2021, nearly five years ago. As shown below, MSD's history with Halozyme and its prolonged delay in challenging the '656 patent only strengthened Halozyme's settled expectations in its patent rights.

B. MSD's delayed patent challenge upsets settled expectations.

MSD—a sophisticated large entity with experienced in-house IP counsel and major firms as outside counsel—undoubtedly knew of the '656 patent when it issued in 2021. At the time, MSD was developing a subcutaneous version of its 30-billion-dollar-a-year cancer drug, KEYTRUDA, then administered only via hours-

long IV infusion. It also knew KEYTRUDA IV's patent protection would expire in 2028 and was already planning a strategic "shift to QLEX," to transition KEYTRUDA IV patients to the subcutaneous "KEYTRUDA QLEX." EX2017, 2; EX2018, 10-11; EX2027, 157:3-16, 165:13-166:4, 175:7-181:15.

In fact, MSD engaged Halozyme in licensing discussions in 2009 and again in 2015 regarding Halozyme's portfolio. EX2019, 21. But instead of licensing from the U.S. company Halozyme, MSD elected to source foreign hyaluronidase from abroad. As early as June 2020, MSD entered a license with Alteogen (a Korean company) to use Alteogen's ALT-B4 hyaluronidase with KEYTRUDA. EX2020, 2; EX2021, 2.

The Office favors PGRs precisely "because they must be filed no later than nine months from the grant of the patent ... are close in time to examination, and occur before expectations in the patent rights are strongly settled." *Multi-Color Corp. v. Brook & Whittle Ltd.*, PGR2025-00025, Paper 10 at 2-3 (Acting Dir., July 16, 2025) (precedential). When the '656 patent issued in July 2021, MSD was actively developing KEYTRUDA QLEX and knew or should have known of the '656 patent. MSD could have asserted § 112 challenges during the '656 patent's 2021-2022 PGR window but chose not to—opting instead to file this IPR years later to upend settled expectations.

C. MSD manufactures the accused product abroad while Halozyme's product is manufactured by its licensee in the U.S.

As noted, instead of entering into a license with Halozyme for its U.S.-made hyaluronidase, MSD elected to go overseas to partner with the Korean company Alteogen for its hyaluronidase. MSD also decided not to manufacture KETYRUDA QLEX in the U.S., opting instead to manufacture in Italy. EX2022, 2. By contrast, Bristol Myers Squibb ("BMS") licensed Halozyme's hyaluronidase technology for its subcutaneous PD-1 inhibitor product, OPDIVO QVANTIG, which competes with KEYTRUDA QLEX. And BMS manufactures OPDIVO QVANTIG in the U.S. EX2023, 3. These facts further weigh in favor of discretionary denial. *See* Director Memorandum of March 11, 2026, at 2-3.

D. MSD delayed challenging the '656 patent until the PGRs were nearly over.

In November 2024, MSD launched a sequential PGR attack on Halozyme's MDASE portfolio, filing PGR petitions against 15 MDASE patents sharing a common specification. Pet., 5-6 (related proceedings). Three family members, including the '656 patent, were no longer PGR-eligible under § 321(c) and were not challenged. Each PGR asserts § 112 written description and enablement grounds based on the MDASE family's shared specification. Fourteen PGRs were instituted: four are fully briefed and argued (two with Final Written Decisions), and ten are fully briefed with oral argument set for July 23, 2026. As noted, the

Director denied institution of the fifteenth PGR, the -087 PGR.

Meanwhile, in parallel litigation, the parties *and the court* agreed to pause proceedings pending Final Written Decisions *in the first PGRs*—an agreement premised in part on the fact that the '656 patent was no longer PGR-eligible and had not been challenged at the PTAB, unlike the 12 other asserted patents in MSD's PGRs. In October 2025, the parties *jointly* stipulated that (i) "Merck has filed [PGRs] ... against 12 of the 15 Asserted Patents"; (ii) "the three unchallenged patents (['656, '149, and '400]) *are not eligible for PGR*"; (iii) the first Final Written Decision ("FWD") on the first instituted PGR will issue "*no later than June 2, 2026*;" (iv) "the FWD may impact the scope of the Litigation;" and (v) "in order to *conserve resources and promote efficiencies* ... until issuance of the FWD, the Parties have agreed to engage in limited discovery ... and otherwise stay this litigation *until after the issuance of the first FWD*." EX2024, 2-3; *see also*, EX2025, 3; EX2026, 2-3. Consistent with that understanding, in February 2026 MCI told the SEC the three remaining patents "*cannot* be challenged using *the PGR process*," but "*can* be challenged in *court proceedings* if required." EX2001, 118/148. Halozyme made clear to MSD during negotiations that because three asserted patents were PGR time-barred, the litigation would proceed irrespective of the outcome of the PGRs. At no point during negotiations did MSD ever suggest it would pursue IPRs. MSD's belated filing is a tactical effort to exploit the AIA

process and disrupt the agreed-upon litigation schedule.

E. MSD delayed filing this IPR Petition so it could inappropriately and unfairly use the prior PGRs as a roadmap.

Flouting the agreed-upon basis for pausing the litigation, and with the PGRs largely complete, MSD filed this IPR at the eleventh hour, just before the § 315(b) deadline.⁴ MSD bypassed its 2021-2022 PGR window and, at a minimum, could have filed this IPR in 2024 when it launched its PGR campaign, but instead waited to use PGR institution decisions, briefing, and evidence as a roadmap to refine and repackage its § 112 theories. Although the PGRs did not target the '656 patent, *General Plastic* applies with full force: these closely related MDASE patents share a common specification, MSD advances similar § 112 grounds, and it has benefited from iterative road-mapping as the PGRs near resolution. As discussed below, *General Plastic* Factors 2-6 strongly favor denial, while Factors 1 and 7 are neutral.

Factor 2 (whether at the time of filing the earlier PGR petitions MSD knew of the art later asserted in this IPR Petition) squarely favors denial. MSD knew of the Petition's asserted "art" US-275—the 2013 publication of the '656 patent's parent '731 application—well before this Petition. MSD acknowledged the

⁴ MSD's § 315(b) statutory deadline to challenge the '400 patent expired April 29, 2026. EX2019.

“ultimate parent ’731 Application” and the MDASE patents’ “shared disclosure” when it launched its 2024 PGR campaign. *See, e.g.*, EX2029, 1, 6 n.6. MSD likewise knew or should have known of US-275 when it began developing subcutaneous KEYTRUDA in 2020. *See Dabico Airport Solutions Inc. v. AXA Power ApS*, IPR2025-00408, Paper 21 at 3 (Acting Dir., June 18, 2025) (informative) (“actual notice of a patent or of possible infringement is not necessary to create settled expectations.”).

Factors 4 and 5 (the length of time between the earlier-filed PGRs and later-filed IPRs, and MSD’s explanation, if any, of the elapsed time) also favor denial. Despite long-standing knowledge of US-275, MSD waited years to file this IPR (**factor 4**)—doing so only after the related PGRs were largely complete and the § 315(b) bar was imminent. This mirrors the delay condemned in *Videndum Prod. Sols., Inc. v. Rotolight Ltd.*, IPR2023-01219, Paper 9 at 14-16 (P.T.A.B. Jan. 24, 2024), where the Board denied institution because “Petitioner waited over 19 months to file its second Petition [close to the § 315(b) statutory bar] based on art that it was aware of when it filed its first petition.” There, the petitioner’s strategy “implicate[d] the efficiency concerns underpinning *General Plastic*.” *Id.* The same inefficiencies are present here. MSD also offers *no explanation* for its delay (**factor 5**), and none exists. *General Plastic* at 16. The record instead reflects pure gamesmanship, evident from MSD’s road-mapping, strategic delay, and litigation

stalling.

Factor 3 (whether at the time of filing its later IPR Petition, MSD had already received briefing and Board decisions from the earlier PGRs) clearly favors denial because the Petition relies on cherry-picked PGR testimony and exploits the near-complete PGRs as a roadmap to refine its § 112 challenge. *General Plastic* at 17-18. The Petition repeatedly relies on declaration and deposition excerpts from Halozyme’s PGR experts, Drs. Petsko and Simpson, to fill in gaps in the art. *See* Pet., 20 n.50 (Petsko); *id.* at 10 n.13, 22 n.55, 42 n.109, 65 n.182, 73 n.201 (Petsko); *id.* at 22 n.55 (Simpson). For example, in asserting that “modified PH20 polypeptides” must be “properly folded,” the IPR Petition cites Dr. Petsko’s PGR declaration (referring to “PH20 as a folded protein”) yet notably omits his declaration from the record. Pet., 20 n.50. MSD’s own expert, Naismith, likewise concedes that his opinions are informed by “testimony submitted by Michael Hecht, Ph.D. and Sheldon Park, Ph.D.” and “testimony of Patent Owner’s experts” (Petsko and Simpson) from “*several PGR proceedings.*” EX1003, ¶20. None of those witnesses have testified in this proceeding, and neither the Petsko nor Simpson testimony would have been available for MSD to roadmap had it filed an earlier, timely AIA challenge. MSD’s road-mapping here is akin to that in *ResMed Corp. v. Cleveland Med. Devices, Inc.*, IPR2025-00157, Paper 10 at 11 (P.T.A.B. June 10, 2025), where “Petitioner and its declarants

expressly cite[d] and rel[ied] on alleged admissions Patent Owner made in [a previous PGR]”

MSD likewise “took advantage of [the full PGR records] to *revise* invalidity challenges in the instant Petition.” *Metall Zug AG v. Carl Zeiss Meditec AG*, IPR2020-01074, Paper 8 at 8 (P.T.A.B. Jan. 5, 2021) (emphasis added; internal quotations omitted); *General Plastic* at 17-18. In its PGRs, MSD argued that “modified PH20 polypeptide” was limited to “active mutants.” EX2029, 22, 25. After that position collapsed during discovery (EX2028, 189:1-192:16), MSD abandoned it and now recasts active polypeptides as a “subset” of modified PH20 polypeptides. Pet., 22; EX1003, ¶152. Similarly, in the PGRs, MSD’s expert Hecht limited his § 112 analysis to knowledge in the art “before December 29, 2011.” EX2030, ¶11. Halozyme showed that Hecht failed to assess § 112 by the correct December 28, 2012 filing date. EX2033, 45 n.13. Now, MSD’s new expert Naismith claims to have “considered *both dates* in forming [his] opinions.” EX1003, ¶15.

MSD also jettisoned arguments that previously forced it to take inconsistent positions. In the PGRs, MSD’s expert Park argued that “homology models” were a well-known “accurate computational method to generate reliable structural [protein] models.” EX2031, ¶36. Halozyme demonstrated that a POSA would have used that same routine modeling, together with the MDASE patent specification, to

readily predict PH20 polypeptide enzymatic activity. MSD has now dropped that argument from this IPR Petition. Likewise, MSD dropped the § 103 grounds it advanced in its PGRs, after learning the Board found them unpersuasive. EX2031, 60; EX2029, 84-112. **Factor 3** clearly warrants denial. *General Plastic* at 17; *ResMed Corp.* at 11.

Factor 6, the finite resources of the Board, also favors denial. Instituting this IPR would force the Board to adjudicate an entire new trial and waste Board resources because the Petition is based on a new record with a different expert (Naismith replacing Hecht and Park). And the Board already streamlined the PGRs into two consolidated oral hearings. MSD could have filed this Petition alongside its PGRs in 2024, which would have permitted consolidated scheduling and efficient adjudication. Instituting this IPR now would squander Board resources. MSD also did not file a *Sotera* stipulation. *Sotera Wireless, Inc. v. Masimo Corporation*, IPR2020-01019, Paper 12 (P.T.A.B. Dec. 1, 2020) (precedential).

Factors 1 and 7 are neutral or weigh in favor of denial. Although MSD has not previously challenged the '656 patent, it is the same Petitioner who sequentially filed 15 PGR petitions against this same patent family (**factor 1**). And had MSD filed earlier, the Board could have resolved the IPR within one year instead of extending proceedings well beyond the PGRs' conclusions (**factor 7**). Instituting now would waste Board resources and risk duplicative proceedings with

the district court.

Given that all of the challenged patents in the related PGRs share the same specification with the '656 patent, and all of the PGRs raise § 112 challenges based on that same specification, the cumulative rationales against serial petitions in *General Plastic* weigh heavily in favor of denial.

F. The Petition's § 112 challenge and reliance solely on US-275 as intervening art are an attempted end-run around the IPR statute.

MSD's road-mapping confirms this Petition is an improper attempt to circumvent the IPR statute by importing § 112 challenges. Its sole "ground" asserts lack of § 112 support in the parent '731 application and treats the '731 application's published specification—identical to the '656 patent—as anticipatory. Pet., 1. The Petition alleges neither new matter added in the '656 patent nor any prior art beyond Halozyne's own specification. MSD also abandoned the prior art-based § 103 grounds it asserted in its PGRs. EX2029, 84-112; EX2032, 60. The Petition's "priority attack" is simply a repackaged § 112 challenge. In fact, the Petition expressly argues that "[t]he claims ... independently violate the written description requirement ... and are unpatentable." *Id.* at 57; see also *id.* at 24 n.57, and 59. The totality of the circumstances warrants denial.

IV. CONCLUSION

Given the totality of facts summarized above, the Director should exercise his discretion and deny institution.

Respectfully submitted,

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

I certify that the above-captioned **PATENT OWNER'S BRIEF ON DISCRETIONARY DENIAL** and associated Exhibits 2001-2033 were served in their entireties on May 27, 2026, upon the following parties via electronic mail:

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