

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MERCK SHARP & DOHME LLC,  
Petitioner

v.

HALOZYME, INC.,  
Patent Owner

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Case PGR2025-00087  
U.S. Patent No. 12,371,685

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**PATENT OWNER PRELIMINARY RESPONSE  
UNDER 37 C.F.R. § 42.207(a)**

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

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**PATENT OWNER'S UPDATED EXHIBIT LIST**

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                           |
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| <b>2001-2011</b>   | <i>Intentionally Left Blank</i>                                                                                                                                                                              |
| <b>2012</b>        | Complaint for Patent Infringement and Declaratory Judgment of Patent Infringement, <i>Halozyme, Inc. v. Merck Sharp &amp; Dohme Corp.</i> , Civil Action No. 2:25-cv-03179-ES (D.N.J.), filed April 24, 2025 |
| <b>2013-2399</b>   | <i>Intentionally Left Bblank</i>                                                                                                                                                                             |
| <b>2400</b>        | Merck & Co., Inc. Form 10-Q, Securities and Exchange Commission, November 5, 2025                                                                                                                            |
| <b>2401</b>        | E-mail Correspondence between Counsel for Petitioner and Patent Owner, January 6, 2026 (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                                            |
| <b>2402</b>        | MERCK_PGR00006 - 30November2023 Merck 031988 Master Agreement - executed 4932-6153-3216 1_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                                |
| <b>2403</b>        | MERCK_PGR00056 - MSA - Term 4 - Dechert LLP_Signed_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                                                                       |
| <b>2404</b>        | MERCK_PGR00467 - Mark Stewart Offer Letter_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                                                                               |
| <b>2405</b>        | MERCK_PGR00052 - Hecht Engagement Letter (7-19)_Signed (Redacted)_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                                                        |
| <b>2406</b>        | MERCK_PGR00086 - Park Engagement Letter with signature - sjp (redacted)_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                                                  |

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| <b>2407</b>        | “Executive team,” MSD, accessible at <a href="http://www.msd.com/company-overview/leadership/executive-team/">http://www.msd.com/company-overview/leadership/executive-team/</a> (last accessed January 5, 2026)                   |
| <b>2408</b>        | “Executive team,” Merck, accessible at <a href="http://www.merck.com/company-overview/leadership/executive-team/">http://www.merck.com/company-overview/leadership/executive-team/</a> (last accessed January 5, 2026)             |
| <b>2409</b>        | “Board of directors,” MSD, accessible at <a href="http://www.msd.com/company-overview/leadership/board-of-directors/">http://www.msd.com/company-overview/leadership/board-of-directors/</a> (last accessed January 5, 2026)       |
| <b>2410</b>        | “Board of directors,” Merck, accessible at <a href="http://www.merck.com/company-overview/leadership/board-of-directors/">http://www.merck.com/company-overview/leadership/board-of-directors/</a> (last accessed January 5, 2026) |
| <b>2411</b>        | “Contact us,” MSD, accessible at <a href="http://www.msd.com/contact-us/">http://www.msd.com/contact-us/</a> (last accessed January 5, 2026)                                                                                       |
| <b>2412</b>        | “Contact us,” Merck, accessible at <a href="http://www.merck.com/contact-us/">http://www.merck.com/contact-us/</a> (last accessed January 5, 2026)                                                                                 |
| <b>2413</b>        | “Who we are,” MSD, accessible at <a href="http://www.msd.com/company-overview/">http://www.msd.com/company-overview/</a> (last accessed January 5, 2026)                                                                           |
| <b>2414</b>        | “Who we are,” Merck, accessible at <a href="http://www.merck.com/company-overview/">http://www.merck.com/company-overview/</a> (last accessed January 5, 2026)                                                                     |
| <b>2415</b>        | Merck & Co., Inc. Form 10-K, Securities and Exchange Commission, February 25, 2025                                                                                                                                                 |
| <b>2416</b>        | USPTO OED Practitioner Search - Mark J. Stewart                                                                                                                                                                                    |
| <b>2417</b>        | Petition for <i>Inter Partes</i> Review, <i>Merck Sharp &amp; Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00240 (P.T.A.B.), November 30, 2023                                                                          |

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                     |
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| <b>2418</b>        | Petition for <i>Inter Partes</i> Review, <i>Merck Sharp &amp; Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00622 (P.T.A.B.), March 4, 2024  |
| <b>2419</b>        | Petition for <i>Inter Partes</i> Review, <i>Merck Sharp &amp; Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00623 (P.T.A.B.), March 4, 2024  |
| <b>2420</b>        | Petition for <i>Inter Partes</i> Review, <i>Merck Sharp &amp; Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00624 (P.T.A.B.), March 4, 2024  |
| <b>2421</b>        | Petition for <i>Inter Partes</i> Review, <i>Merck Sharp &amp; Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00625 (P.T.A.B.), March 4, 2024  |
| <b>2422</b>        | Petition for <i>Inter Partes</i> Review, <i>Merck Sharp &amp; Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00647 (P.T.A.B.), March 13, 2024 |
| <b>2423</b>        | Petition for <i>Inter Partes</i> Review, <i>Merck Sharp &amp; Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00648 (P.T.A.B.), March 13, 2024 |
| <b>2424</b>        | Petition for <i>Inter Partes</i> Review, <i>Merck Sharp &amp; Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00649 (P.T.A.B.), March 13, 2024 |
| <b>2425</b>        | Petition for <i>Inter Partes</i> Review, <i>Merck Sharp &amp; Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00650 (P.T.A.B.), March 13, 2024 |
| <b>2426</b>        | MERCK_PGR00035 - 20250813 Payment Remittance_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                       |

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                          |
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| <b>2427</b>        | MERCK_PGR00042 - Dechert T360 Halozyme - 202500327_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                      |
| <b>2428</b>        | MERCK_PGR00045 - FW_Atn_Accounts Receivable Dept - PAYMENT REMITTANCE DETAIL (Nov 2025)_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL) |
| <b>2429</b>        | MERCK_PGR00049 - Halozyme - 202000447 - Invoices 5_1_2024-12_22_2025_1 of 3_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)             |
| <b>2430</b>        | MERCK_PGR00465 - Mark Stewart Payroll Statement for Dec 12 2025_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                         |
| <b>2431</b>        | MERCK_PGR00001 - Workday - Ginkel Organization Screen Shot (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                       |
| <b>2432</b>        | MERCK_PGR00002 - Workday - Lally Organization Screen Shot (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                        |
| <b>2433</b>        | MERCK_PGR00003 - Workday - Majchrzak Organization Screen Shot (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                    |
| <b>2434</b>        | MERCK_PGR00004 - Workday - Stewart Organization Screen Shot (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                      |
| <b>2435</b>        | MERCK_PGR00005 - Workday - Su Organization Screen Shot (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                           |
| <b>2436</b>        | MERCK_PGR00036 - 20250903 Payment Remittance_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                            |
| <b>2437</b>        | MERCK_PGR00037 - 20251001 Payment Remittance_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                            |

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                     |
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| <b>2438</b>        | MERCK_PGR00038 - 20251203 Payment Remittance_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                                                                                       |
| <b>2439</b>        | MERCK_PGR00040 - 20251215 Payment Remittance_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                                                                                       |
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| <b>2441</b>        | MERCK_PGR00047 - FW_Attn_Accounts Receivable Dept - PAYMENT REMITTANCE DETAIL (Sept 2025)_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                                          |
| <b>2442</b>        | MERCK_PGR00048 - Halozyme - 202000447 - Invoice IN00125072310 Review History (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                                                                |
| <b>2443</b>        | MERCK_PGR00050 - Halozyme - 202000447 - Invoices 5_1_2024-12_22_2025_2 of 3_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)                                                                                        |
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| <b>2445</b>        | By-Laws of Merck & Co., Inc., Effective as of November 19, 2024                                                                                                                                                        |
| <b>2446</b>        | U.S. Supreme Court Amicus Curiae Brief by the Intellectual Property Owners Association, <i>Jack Daniel's Properties, Inc. v. VIP Products LLC</i> , Case No. 22-148                                                    |
| <b>2447</b>        | Board of Directors – Intellectual Property Owners Association, accessible at <a href="https://ipo.org/index.php/board-of-directors">https://ipo.org/index.php/board-of-directors</a> (last accessed February 15, 2026) |
| <b>2448</b>        | ChIPs Speaker Bio Information                                                                                                                                                                                          |

| <b>Exhibit No.</b> | <b>Description</b>                                                                                   |
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| <b>2449</b>        | LinkedIn Profile Page                                                                                |
| <b>2450</b>        | Form PTO-158, Office of Enrollment and Discipline, United States Patent & Trademark Office           |
| <b>2451</b>        | Jennifer Zachary's March 16, 2018 Job Offer Letter                                                   |
| <b>2452</b>        | Form 13F Cover Page, Merck & Co., Inc., September 2025                                               |
| <b>2453</b>        | Form 13F Cover Page, Merck Sharp & Dohme LLC, September 2025                                         |
| <b>2454</b>        | Form 10-Q, Merck & Co. Inc., Quarterly Report for Quarter Ended June 30, 2025                        |
| <b>2455</b>        | <i>Intentionally Left Blank</i>                                                                      |
| <b>2456</b>        | Exhibit 24.1 to Merck & Co. Inc.'s Form 10-K for the Fiscal Year Ended December 31, 2024             |
| <b>2457</b>        | Sarbanes-Oxley Act of 2002                                                                           |
| <b>2458</b>        | Jennifer Zachary Biography, Merck.com                                                                |
| <b>2459</b>        | Rules of Professional Conduct of the New Jersey Bar                                                  |
| <b>2460</b>        | Jennifer Zachary Biography, MSD.com                                                                  |
| <b>2461</b>        | USPTO Office of Enrollment and Discipline Practitioner Search for Mark J. Stewart, February 13, 2026 |
| <b>2462</b>        | Schedule 13D, Harpoon Therapeutics, Inc., January 17, 2024                                           |
| <b>2463</b>        | Schedule 14A Proxy Statement, Merck & Co., Inc., 2025                                                |

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                                                               |
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| <b>2464</b>        | Form 13F, Information Required of Institutional Investment Managers Pursuant to Section 13(f) of the Securities Exchange Act of 1934 and Rules Thereunder, accessible at <a href="https://www.sec.gov/pdf/form13f.pdf">https://www.sec.gov/pdf/form13f.pdf</a> (last accessed February 15, 2026) |
| <b>2465</b>        | USPTO Office of Enrollment and Discipline Practitioner Search for “Merck,” February 15, 2026                                                                                                                                                                                                     |
| <b>2466</b>        | Form 8-K, Merck & Co. Inc., February 3, 2026                                                                                                                                                                                                                                                     |
| <b>2467</b>        | Exhibit 99.1 to Form 8-K, Merck & Co. Inc., February 3, 2026                                                                                                                                                                                                                                     |
| <b>2468</b>        | Exhibit 99.2 to Form 8-K, Merck & Co. Inc., February 3, 2026                                                                                                                                                                                                                                     |
| <b>2469</b>        | ICANN LOOKUP search results for “ <a href="http://www.msd.com">www.msd.com</a> ,” available at <a href="https://lookup.icann.org/en/lookup">https://lookup.icann.org/en/lookup</a> , last accessed February 19, 2026                                                                             |
| <b>2470</b>        | ICANN LOOKUP search results for “ <a href="http://www.merck.com">www.merck.com</a> ,” available at <a href="https://lookup.icann.org/en/lookup">https://lookup.icann.org/en/lookup</a> , last accessed February 19, 2026                                                                         |
| <b>2471</b>        | December 15, 2025 email from Jeffrey Kushan to Trey Powers                                                                                                                                                                                                                                       |
| <b>2472</b>        | Merck Press Release, “Merck Announces Settlement and License Agreement Resolving KEYTRUDA® (pembrolizumab) Patent Litigation,” (January 20, 2017)                                                                                                                                                |
| <b>2473</b>        | File History of U.S. Patent Application No. 19/346,638                                                                                                                                                                                                                                           |
| <b>2474</b>        | “Product Patents,” Merck.com, accessible at <a href="https://www.merck.com/products/patent/">https://www.merck.com/products/patent/</a> (last accessed February 20, 2026)                                                                                                                        |

## **TABLE OF AUTHORITIES**

### **Cases**

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| <i>Adello Biologics LLC v. Amgen Inc.</i> ,<br>PGR2019-00001, Paper 11 (P.T.A.B. Feb. 14, 2019) .....                    | 7, 8, 29      |
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| <i>Atlanta Gas Light Co. v. Bennett Regulator Giards, Inc.</i> ,<br>IPR2013-00453, Paper 88 (P.T.A.B. Jan. 6, 2015)..... | 10, 19        |
| <i>Aylo Freesites LTD v. Dish Techs. L.L.C.</i> ,<br>IPR2024-00940, Paper 75 (P.T.A.B. Feb. 3, 2026).....                | 2, 7, 8, 29   |
| <i>Corning Optical Comms. RF, LLC v. PPC Broadband, Inc.</i> ,<br>IPR2014-00440, Paper 68 (P.T.A.B. Aug. 18, 2015).....  | passim        |
| <i>Galderma S.A. v. Allergan Industrie, SAS</i> ,<br>IPR2014-01422, Paper 14 (P.T.A.B. Mar. 5, 2015) .....               | 5, 26, 27     |
| <i>Gonzalez v. Banco Cent. Corp.</i> ,<br>27 F.3d 751 (1st Cir. 1994).....                                               | 27            |
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| <i>SharkNinja Operating LLC v. iRobot Corp.</i> ,<br>IPR2020-00734, Paper 11 (P.T.A.B. Oct. 6, 2020) .....               | 30            |
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| <i>Yangtze Memory Techs., Ltd, v. Micron Tech., Inc.</i> ,<br>IPR2025-00098, Paper 38 (P.T.A.B. Jan. 15, 2026).....      | 2, 5, 6, 29   |
| <i>Zoll Lifecor Corp. v. Philips Elec. N. Am. Corp.</i> ,<br>IPR2013-00606, Paper 13 (P.T.A.B. Mar. 20, 2014) .....      | 4, 15, 21, 26 |

### **Statutes**

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| 37 C.F.R. § 42.8(b)(1)..... | 9    |

**Other Authorities**

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| 77 Fed. Reg. 48,756 (Aug. 14, 2012)..... | 10 |
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Patent Owner Halozyme, Inc. asks the Director to deny Petitioner Merck Sharp & Dohme LLC's ("MSD" or "Petitioner") petition for post-grant review for failure to identify all real parties in interest ("RPI").

## **I. INTRODUCTION**

Petitioner has serially filed 15 petitions for post-grant review ("the Halozyme PGRs"), challenging 15 related patents owned by Patent Owner. All 15 Petitions<sup>1</sup>, including this one, identify Petitioner MSD as the *sole* RPI. *See, e.g.*, Pet. at 6. Clear evidence establishes, however, that Merck & Co., Inc. ("Merck & Co."), MSD's corporate parent, should have been named as an RPI. Petitioner's failure to identify all RPI is in direct contravention with 35 U.S.C. § 322(a)(2) and the Board's precedential decision in *Corning Optical Comms. RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 at 24 (P.T.A.B. Aug. 18, 2015) (precedential); *see also Yangtze Memory Techs., Ltd. v. Micron Tech., Inc.*,

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<sup>1</sup> *See e.g.*, PGR2025-00003, Paper 1 at 6; PGR2025-00004, Paper 3 at 6; PGR2025-00006, Paper 1 at 6; PGR2025-00009, Paper 1 at 6; PGR2025-00017, Paper 1 at 6; PGR2025-00024, Paper 1 at 6; PGR2025-00030, Paper 1 at 6; PGR2025-00033, Paper 1 at 6; PGR2025-00039, Paper 1 at 7; PGR2025-00042, Paper 1 at 6; PGR2025-00046, Paper 1 at 6; PGR2025-00050, Paper 1 at 6; PGR2025-00052, Paper 1 at 6; PGR2025-00053, Paper 1 at 6.

IPR2025-00098, Paper 38 at 6 (P.T.A.B. Jan. 15, 2026) (designated informative Jan. 16, 2026); *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 decision). The Director should reject the petition and deny institution on this basis alone. *Id.*

As shown in this Preliminary Response, Merck & Co. not only directs and funds the Halozyme PGRs, but controls or has the opportunity to control them. EX2400 at 25-26; *see also id.* at 6 (1st ¶), 21 (1st ¶) (pages as designated in document). For example, Merck & Co.’s Securities and Exchange Commission (“SEC”) Form 10-Q filed on Nov. 5, 2025, shows that Merck & Co. *itself* directs, controls, and funds the Halozyme PGRs, or at minimum has the unmistakable opportunity to do so. EX2400 at 25-26, *see also* 6 (1st ¶), 21 (1st ¶) (pages as designated in document). Indeed, referring to itself as “the Company,” Merck & Co. told the SEC and the investing public that it “*began filing a series of post grant review (PGR) petitions* before the PTAB,” meaning that Merck & Co. attributed instigating these PGRs to itself. EX2400 at 25 (emphasis added).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

This and other evidence show the blurred lines between MSD and Merck &

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<sup>2</sup> Applications for registration to practice before the PTO include a field titled “Employer, corporation, law firm, U.S. Government Agency.” Information in that field represents part of the “address used for official correspondence.” EX2450 at 1. (PTO form 158) Statements to the OED are certified accurate under 18 U.S.C. § 1001. Applicants are “required to update the foregoing information promptly upon any change.” *Id.*

Co., as the corporations are such that one has difficulty telling one from the other. Indeed, there appears to be a complete overlap in the companies' Executive Leadership (including their CEO and General Counsel) and Board of Directors, and according to the websites for Merck & Co. and MSD they have an identical place of business, both of which are registered to Merck, Sharp, and Dohme LLC. EX2407; EX2408; EX2409; EX2410; EX2451; EX2411; EX2412; EX2452; EX2453; EX2469; EX2470. Merck & Co. also has made clear in its SEC filings that it has a significant interest in, desires, and greatly benefits from these PGR proceedings. *See, e.g.*, EX2400 at 8 (last ¶) (discussing Merck & Co.'s exclusive license to a key component of KEYTRUDA QLEX<sup>TM3</sup>), 25, 37-38, 47-49 (discussing Merck & Co.'s planned revenue and liabilities related to KEYTRUDA QLEX<sup>TM</sup>); EX2468 at 4. As the Board stated in *Corning*, Petitioner's actions "have blurred sufficiently the lines of corporate separation with its parent, [Merck & Co.], such that [Merck & Co.] could have controlled the filing and participation of the [PGRs]." *Corning* at 15 (quoting *Zoll Lifecor Corp. v. Philips Elec. N. Am. Corp.*, IPR2013-00606, Paper 13 at 10 (P.T.A.B. Mar. 20, 2014)). The evidence shows "an involved and controlling parent corporation representing the unified

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<sup>3</sup> KEYTRUDA QLEX<sup>TM</sup> is the accused product in the parallel district court litigation involving the patents challenged in these PGRs.

interests of itself and Petitioner.” *Galderma S.A. v. Allergan Industrie, SAS*, IPR2014-01422, Paper 14 at 12 (P.T.A.B. Mar. 5, 2015).

The Board designated *Corning* as precedential on October 28, 2025. Petitioner filed its petition in this proceeding on November 10, 2025, nearly two weeks later. Thus, Petitioner was well-aware when it filed the petition that failing to identify *all* RPI in its petition is fatal. As stated in 35 U.S.C. § 322(a)(2) and reiterated in *Corning*, an IPR or PGR petition “may be considered *only* if” it “identifies *all* real parties in interest.” 35 U.S.C. § 312(a)(2), § 322(a)(2) (emphasis added). MSD has still failed to do so. “Petitioner’s failure to provide clarity as to its actual identity is fatal to its petition[.]” *Yangtze Memory Techs., Ltd, v. Micron Tech., Inc.*, IPR2025-00098, Paper 38 at 6 (P.T.A.B. Jan. 15, 2026) (designated informative Jan. 16, 2026). MSD should not be allowed to try to circumvent estoppel rules on behalf of its parent company.

For these reasons, the petition should be denied.

## **II. BACKGROUND**

After MSD filed several of its PGR Petitions, Patent Owner filed a lawsuit alleging that MDS’s product, KEYTRUDA QLEX™ (a subcutaneous injectable version of KEYTRUDA®) infringes 12 of Patent Owner’s patents now involved in the Halozyme PGRs. EX2036. Since that time, the Board has instituted 14 out of the 15 Halozyme PGRs, with the most recent institution (PGR2025-00052) on

October 16, 2025. In the present proceeding, the Board issued a Notice of Filing date Accorded to MSD's petition on November 20, 2025. *See* Paper 5.

On October 28, 2025 (about two weeks before MSD filed its petition in this case), the Director designated *Corning* as precedential for its holding that petitions failing to identify all RPI "have not met the requirements" of 35 U.S.C. § 312(a)(2) (or § 322(a)(2)), "and, therefore, are incomplete and cannot be considered." *Corning* at 24-25. Such incomplete petitions "will not be accorded a filing date" and will be dismissed unless corrected before "the expiration of the statutory deadline in which to file a petition for post-grant review." 37 C.F.R. § 42.206; *Corning* at 24-25; 35 U.S.C. §§ 312, 322.

Soon after designating *Corning* as precedential, the Director also designated as informative *Yangtze*. As stated in *Yangtze*, "[o]nly precisely-identified real parties in interest are entitled to have their petitions considered, 35 U.S.C. 312(a)," and a "Petitioner's failure to provide clarity as to its actual identity is fatal to its petitions." *Id.* at 5.

A petitioner bears the burden of proof to establish that its petition complies with the statutory requirement to identify all RPI. *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1356 (Fed. Cir. 2018) ("*AIT*"); *RPX Corp. v. Applications in Internet Time, LLC*, IPR2025-01750, Paper 128 at 5 (P.T.A.B. Oct. 2, 2020) (designated precedential Dec. 4, 2020) ("*RPX*"). Whether an unnamed

party is an RPI “is a highly fact-dependent question,” which may be shown through “direct or circumstantial” evidence. *Corning* at 14-15. Determining whether a non-party is an RPI “demands a flexible approach that takes into account both equitable and practical considerations, with an eye toward determining whether the non-party is a clear beneficiary that has a preexisting, established relationship with the petitioner.” *AIT* at 1351; *RPX* at 7-8.

On February 3, 2026, the Director de-designated as precedential two decisions, *Adello* and *Proppant*. See *Adello Biologics LLC v. Amgen Inc.*, PGR2019-00001, Paper 11 (P.T.A.B. Feb. 14, 2019) (designated precedential Apr. 16, 2019; de-designated Feb. 3, 2026) (“*Adello*”); *Proppant Express Investments, LLC v. Oren Techs., LLC*, IPR2017-01917, Paper 86 (P.T.A.B. Feb. 13, 2019) (designated precedential Apr. 16, 2019; de-designated Feb. 3, 2026) (“*Proppant*”). Both *Adello* and *Proppant* stood for the proposition that a petitioner may amend its RPI identification and still maintain its petition’s original filing date under certain circumstances. These cases are no longer precedential and, as a result, do not reflect current USPTO case law or policy on this issue.

The significance of the designation of *Corning* and *Yangtze* and the de-designation of *Adello* and *Proppant* is made manifest in a recent Director Review decision: *Aylo Freesites*, IPR2024-00940, Paper 75 at 2-4 (*sua sponte* Director Review decision). In *Aylo*, the Director initiated *sua sponte* Director Review of a

Final Written Decision after a Board panel denied a Motion to Dismiss the petition for failing to name all RPI. *Id.* at 1-2. The panel applied *Proppant* when it accepted an updated mandatory notice to correct RPI while still maintaining the petition's original filing date. On Director Review, in view of his designation of *Corning* and de-designation of *Proppant* and *Adello*, the Director stated that "Petitioner's correction to disclose additional RPIs requires according the Petition a new filing date," which resulted in the petition being time-barred under § 315(b). *Id.* at 3. On that basis, the Director dismissed the petition and vacated the Board's Final Written Decision. *Id.* at 3-4. Thus, *Aylo* indicates that considerations presented in *Adello* and *Proppant*, as to whether a petition might maintain an original filing date after an RPI is corrected, no longer apply in view of *Corning*.

Here, Petitioner filed its petition without identifying *all* RPI, and has made no effort to update its mandatory notices to correct this issue, despite being aware of the consequences. In fact, rather than attempt to correct its RPI problem, Petitioner doubled down on its position that MSD is allegedly the only RPI. The facts here are strikingly similar to those in *Corning*, where petitioner Corning Optical Communications maintained its position that Corning NC and Corning, Inc. were not RPI. Here, even after *Corning* became precedential and Patent Owner squarely raised the issue, Petitioner continues to assert that its parent company, Merck & Co., is not a real party-in-interest. Because MSD *still* has not correctly

identified all of its RPI, the petition has not met the requirements of 35 U.S.C. § 322(a)(2), and, therefore, “is incomplete and cannot be considered.” *Corning* at 24. The Director should deny institution.

### **III. LEGAL STANDARDS RELATING TO RPI**

#### **A. A complete PGR petition must identify all RPI**

Under 35 U.S.C. § 322(a)(2), a PGR petition may be considered “only if . . . the petition identifies all real parties in interest.” As stated in *Corning*, relevant Board rules also require compliance with § 42.8, which states that mandatory notices “must be filed,” including identifying “each real party-in-interest for the party.” 37 C.F.R. § 42.8(b)(1); *Corning* at 24-25. Moreover, under § 42.206, a PGR petition “will not be accorded a filing date until the petition satisfies” that requirement, among others. *Id.* at 24-25 (discussing 37 C.F.R. §§ 42.106, 42.104 in IPR proceedings, with similar counterparts in §§ 42.206, 42.204 in PGR proceedings).

Also under § 42.206(b), if a petitioner files an incomplete PGR petition, such as one that fails to name all RPI, the Office will dismiss the petition “if the deficiency in the petition is not corrected within the *earlier* of either [i] one month from the notice of an incomplete petition, or [ii] the expiration of the statutory deadline in which to file a petition for post-grant review.” 37 C.F.R. § 42.206(b) (emphasis added); *see also Corning* at 24-25.

**B. It is Petitioner’s burden to prove all RPI were properly named**

A petitioner in an AIA proceeding bears the burden of proof to establish that its petition complies with the statutory requirement to identify all RPI. *See, e.g., Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1356 (Fed. Cir. 2018) (“AIT”); *see also RPX Corp. v. Applications in Internet Time, LLC*, IPR2025-01750, Paper 128 at 5 (P.T.A.B. Oct. 2, 2020) (designated precedential Dec. 4, 2020) (“RPX”). As the Board stated, “a petitioner is far more likely to be in possession of, or to have access to, evidence relevant to the issue than is a patent owner.” *Atlanta Gas Light Co. v. Bennett Regulator Giards, Inc.*, IPR2013-00453, Paper 88 at 8 (P.T.A.B. Jan. 6, 2015) (“Atlanta Gas”).

As discussed below, the petition fails to name all RPI, i.e., Petitioner’s parent company, Merck & Co. MSD has not, and cannot, establish otherwise.

**C. Multiple factors are considered when determining whether an unnamed party is an RPI**

As stated in *Corning*, whether an unnamed party is a RPI “is a highly fact-dependent question,” which may be shown through “direct or circumstantial” evidence. *Corning* at 14-15 (citing Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (citing *Taylor v. Sturgell*, 533 U.S. 880 (2008))). Determining whether a non-party is a RPI “demands a flexible approach that takes into account both equitable and practical considerations, with an eye toward determining

whether the non-party is a clear beneficiary that has a preexisting, established relationship with the petitioner.” *AIT* at 1351; *RPX* at 7-8.

Determining whether an unnamed party is an RPI involves consideration of various factors. *Corning* at 14-16; *RPX* at 10-11. The factors as to whether Merck & Co. is an RPI in these PGR proceedings fall into four general categories.: (1) whether Merck & Co. directed the filing of the PGR petition and exerts control over this proceeding; (2) whether Merck & Co. funds this PGR proceeding; (3) whether the lines of corporate separation between MSD and Merck & Co. are so blurred to indicate that Merck & Co. effectively controls or has the opportunity to control this PGR proceeding; and (4) whether Merck & Co. has a large interest in, desires, and greatly benefits from this PGR proceeding, and MSD is representing that interest. *See RPX* at 10; *Corning* at 14-16.

The first and second categories relate to whether Merck & Co. actually or effectively did, does, and/or could have directed, controlled, and funded these proceedings. *Corning* at 14. These two categories consider Merck & Co.’s relationship to the Petitions themselves, including the nature and/or degree Merck & Co.’s involvement in the filings. *See RPX* at 10; *Corning* at 14-16.

The third category is whether the lines of corporate separation between MSD and Merck & Co. are so blurred, such that Merck & Co. has actually or effectively controlled the filing and participation in these PGR proceedings. This category

takes into account factors such as the nature and business model of Petitioner MSD, its relationship with Merck & Co, whether MSD can be said to be representing Merck & Co.’s interest in these proceedings, whether, and under what circumstances, MSD has taken Merck & Co.’s interests into account when determining whether to file the PGR petitions, and the relevance of the fact that MSD and Merck & Co. had (and continue to have) identical executives and Board members. *See RPX* at 10 (citing *AIT*, 897 F.3d at 1353-55); *Corning* at 14, 16.

The fourth category considers whether Merck & Co. is a clear beneficiary from this PGR proceeding. This considers Merck & Co.’s “interest in” and “benefit from” the PGR proceeding and whether Merck & Co. “actually ‘desire[d] review of the patent.’” *See RPX* at 10 (citing *AIT*, 897 F.3d at 1353-55).

As discussed below, all four categories of considerations make it clear that Merck & Co. is an RPI in this PGR and should have been named. Because MSD has failed to list all RPI in its Mandatory Notices, the PGR petition cannot be considered under 35 U.S.C. § 322(a)(2) and must be denied.

#### **IV. MERCK & CO. IS AN RPI TO THIS PROCEEDING**

There can be no dispute that Merck & Co., as MSD’s parent company, has an unmistakable and preexisting established relationship with MSD. Evidence confirms that Merck & Co. likewise is a clear beneficiary of this PGR proceeding.

**A. Merck & Co. directed the filing of the PGR petition and controls this proceeding**

Merck & Co.’s own SEC filings indicate it has directed the filings of all the Halozyme PGR Petitions (including this one), and continues to direct and control the Halozyme PGRs, or at least has an unequivocal opportunity to do so. For example, Merck & Co.’s SEC Form 10-Qs, filed by its General Counsel, Jennifer Zachary, defines Merck & Co. as “the Company” or “Merck.” *See* EX2400 at 6, 53; EX2454 at 6, 47. As such, statements to the SEC and the investing public in these documents are statements by Merck & Co., about Merck & Co., and attributable to Merck & Co.

Merck & Co.’s recent 10-Q SEC filing expressly states that the “Company,” i.e., Merck & Co., has filed a series of PGRs against Halozyme. EX2400 at 25; EX2454 at 22. Specifically, as it relates to “Subcutaneous Pembrolizumab,” i.e., KEYTRUDA QLEX™, Merck & Co. states: “In November 2024, *the Company began filing a series of post grant review (PGR) petitions* before the PTAB alleging that certain patents in [Halozyme’s hyaluronidase] MDASE portfolio are invalid.”<sup>4</sup> EX2400 at 25 (emphasis added); EX2454 at 22. These public filings

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<sup>4</sup> The patents involved in the Halozyme PGRs—including the ’685 patent challenged here—are the only Halozyme patents any Merck entity has challenged.

also discuss institution of the PGRs “filed by the Company” and three related Halozyme patents involved in the parallel district court litigation but not challenged in PGR petitions. *Id.*

Notably, Jennifer Zachary signed these SEC filings as Merck & Co.’s “Executive Vice President and General Counsel.” EX2400 at 53; EX2454 at 47. When Ms. Zachary signed the SEC documents, she expressly did so on behalf of Merck & Co., in her capacity as an executive leader for Merck & Co., as indicated in the documents themselves. EX2400 at 53 (indicating Ms. Zachary signed on behalf of “MERCK & CO., INC.”); EX2454 at 47 (same); *see also* EX2415 at 142 (same), EX2456 (same); EX2462 at 12-13 (same). Moreover, corporate filings to the SEC are required to be accurate and there are severe penalties for inaccuracies. EX2457 at 35 (Sarbanes-Oxley Act of 2002, discussing corporate responsibility of officers signing SEC financial disclosures).

Petitioner may argue that Merck & Co.’s SEC filing does not relate to *this PGR proceeding* because Merck & Co.’s 10-Q statement was purportedly submitted to the SEC a mere five days before Petitioner filed its petition in this case. But there can be no dispute that the ’685 patent challenged here is related to the challenged patents in the other 14 Halozyme PGRs. EX1001, face. Nor is there

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Merck & Co. was certainly referring to the Halozyme PGRs.

any dispute that this PGR proceeding is related to the other 14 Halozyme PGRs. *See* Pet. at 7 (Petitioner’s mandatory notices listing the other 14 Halozyme PGRs as related proceedings). Indeed, in a December 15, 2025 email discussing the use of witness deposition transcripts in the Halozyme PGRs, Counsel for Petitioner stated that Petitioner “propose[s] including the 15th PGR [i.e., PGR2025-00087], if it is instituted, *given the overlap in the issues with the instituted PGR proceedings.*” EX2471 at 2 (emphasis added); *see also, id.* (including PGR2025-00087 in “PGRs 5-15.”); Paper 9 at 4 (Petitioner including PGR2025-00087 when discussing “*these PGRs*”) (emphasis added). Moreover, as shown in this Preliminary Response, Merck & Co. unquestionably has *the opportunity* to control this PGR proceeding, and that is sufficient to make Merck & Co. an RPI here. *Corning* at 15, 22; *Zoll* at 9.

Also significant, Ms. Zachary [REDACTED]

[REDACTED]

[REDACTED] That

Ms. Zachary [REDACTED] cannot wipe away the fact that she at all times has had the opportunity to “call the shots” in these PGRs on behalf of Merck and Co. and has represented to the general public and the SEC that, in fact, it was Merck & Co. that filed and controls the Halozyme PGRs.

Additionally, as General Counsel of Merck & Co. and a Member of the New

Jersey bar association (EX2458), Ms. Zachary at all times has a fiduciary duty to Merck & Co., regardless of whether she is also an employee of Petitioner. EX2459 at 17-19 (RPC 1.13). Ms. Zachary also “leads the company’s [i.e., Merck & Co.’s] office of general counsel and sets the company’s global legal strategy.” EX2458. She performs the identical functions for MSD. EX2460. Accordingly, she supervises, directly or indirectly, all in-house practitioners who worked on these PGRs. In short, she calls the shots.

**B. Merck & Co. funds the Halozyme PGRs**

Merck & Co.’s SEC filings leave no doubt that it (as the parent company) funds the litigation matters involving Patent Owner, including the Halozyme PGRs. For example, in its November 2025 10-Q statement, under Section 8 entitled “Contingencies,” Merck & Co. states: “The Company [i.e., Merck & Co.] is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, *intellectual property*, commercial litigation, and securities litigation, as well as certain additional matters including governmental and environmental matters.” EX2400 at 21 (emphasis added).

That 10-Q SEC filing goes on to explain how *Merck & Co. itself funds litigations and related proceedings*, such as the Halozyme PGRs. Within the “Contingencies” section is a sub-section entitled “Patent Litigation,” which lists and describes different patent infringement lawsuits involving the “Company,” i.e.,

Merck & Co. *Id.* at 24-26. This sub-section discusses, among others, litigation involving KEYTRUDA<sup>®</sup> (same active ingredient as KEYTRUDA QLEX<sup>™</sup>) and Johns Hopkins, as well as IPRs related to that litigation. *Id.* at 25. Notably, Merck & Co. was listed as an RPI in each of those IPRs related to KEYTRUDA<sup>®</sup>. *See* EX2417–EX2425.

The 10-Q SEC filing also discusses litigation involving “the Company’s subcutaneous pembrolizumab product” (i.e., KEYTRUDA QLEX<sup>™</sup>), as well as the Halozyme PGR Petitions. EX2400 at 25 (under “*Subcutaneous Pembrolizumab*” stating “[o]n April 24, 2025, Halozyme, Inc. filed a complaint . . . alleging that the Company’s activities [infringe] patents . . . which are the subject of the Company’s already filed PGR petitions.”). In this context, as noted above, Merck & Co. expressly states to the SEC that it (the “Company”) filed the Halozyme PGR Petitions. *Id.*

Thereafter, also in the “Contingencies” section, is another sub-section entitled “Legal Defense Reserves,” placed immediately after the descriptions of the different litigations. *Id.* at 26. Here, Merck & Co. refers to “[l]egal defense costs expected to be incurred with a loss contingency.” *Id.* The introduction in “8. Contingencies” clarifies that “contingencies” in this context refers to “possible loss” and “liability” as it relates to the litigations discussed in Section 8. *Id.* at 21. Thus, statements in the “Legal Defense Reserves” sub-section (in Section 8)

indicate that Merck & Co. expects that it will pay for the previously described litigations, including the PGR proceedings at issue here.

Merck & Co. further states in the same “Legal Defense Reserves” sub-section:

Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company’s legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials; and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation.

*Id.* at 26. In other words, as it relates to all litigation listed in the “Patent Litigation” sub-section, Merck & Co.’s expected legal defense costs include “actual costs incurred,” the development of “legal defense strategy and structure,” and “the outcome of completed trials.” *Id.* Thus, Merck & Co.’s admissions to the SEC show that the “Company” (i.e., Merck & Co.) expects to pay litigation costs, including in the Halozyme PGRs.

Moreover, this sub-section goes on to state that the “amount of legal defense reserves as of September 30, 2025 and December 31, 2024 of approximately \$220 million and \$225 million, respectively, represents the Company’s best estimate of

the minimum amount of defense costs to be incurred in connection with its outstanding litigation.” *Id.* Thus, this statement similarly indicates that Merck & Co. has reserves in place to pay for all litigations described in the “Patent Litigation” sub-section, including the Halozyme PGRs. *See also id.* (stating that “[t]he Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.”). In sum, Merck & Co. told the SEC that it pays for, and is involved in, strategy in relation to all litigation listed in its SEC documents, including all of the Halozyme PGRs.

**C. Blurred lines of corporate separation between Merck & Co. and Petitioner indicate Merck & Co. effectively controls the Halozyme PGRs**

MSD and its parent company, Merck & Co., 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.*, IPR2013-00453, Paper 88 at 2-6; *see also id.* at 11 (noting that “[a]lthough parent-subsidiary relationships are not among those expressly identified by the Supreme Court in the second *Taylor* factor, this factor weighs heavily in favor of finding [the parent company] to be a real party in interest in this proceeding”) (citing *Taylor*, 553 U.S. at 894)). As such, consistent with evidence discussed above, Merck & Co. controls, or at least has ample

opportunity to control, all of the Halozyme PGRs, including this one.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] And Back-up

Counsel Mark Stewart previously submitted information to the USPTO Office of Enrollment and Discipline (OED) indicating that his “Firm Name” is “Merck

Sharp & Dohme, LLC *and Merck and Co.*” EX2416.<sup>5</sup> Additionally, [REDACTED]

[REDACTED]

[REDACTED] Thus,

[REDACTED]

[REDACTED]

As discussed above, Merck & Co. funds, directs, and controls (or, at a minimum, has the opportunity to control) the Halozyme PGRs. *See* Sections IV.A–B. The legal standard for determining real-party-in-interest status does **not** require evidence of actual control; the opportunity to control is sufficient. *Corning* at 15, 22; *Zoll* at 9–10. Here, the Merck & Co. individuals identified in the record undoubtedly had and still have the opportunity to control the Halozyme PGRs.

Additional evidence of the blurred lines of corporate separation between Merck & Co. and its subsidiary Petitioner MSD is presented in the table below.

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<sup>5</sup> Mr. Stewart apparently modified his employer information with the USPTO OED after Halozyme raised the issue. *Compare* EX2416 (search conducted on Oct. 30, 2025) and EX2461 (search conducted on Feb. 13, 2025).

| <b>Blurred lines</b>                                                                                                                                                                                                                                                                             | <b>Evidence</b>                                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Based on a websites registered to Merck, Sharp, and Dohme LLC, the Executive Leadership (11 members), appears to overlap between MSD and Merck & Co., including Robert M. Davis as “Chairman and Chief Executive Officer” and Jennifer Zachary as “Executive Vice President and General Counsel” | EX2407; EX 2408; EX2400 at 53; EX2462 at 12-13 (indicating Ms. Zachary works for Merck & Co.); EX2463 at 66 (indicating Ms. Zachary is compensated by Merck & Co.); EX2469; EX2470 |
| Based on a websites registered to Merck, Sharp, and Dohme LLC, the Boards of Directors (BOD) appear to overlap between MSD and Merck & Co., (13 members)                                                                                                                                         | EX2409; EX2410; EX2469; EX2470                                                                                                                                                     |
| MSD and Merck & Co. have an identical physical location, business hours, and phone number                                                                                                                                                                                                        | EX2411; EX2412; EX2452; EX2453                                                                                                                                                     |

| Blurred lines                                                                                                                                                                                                                                                                                                                                                                                                           | Evidence                                                                                                                                                                                                                                                                                                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Merck & Co. invests in, makes financial and investment decisions, and reports to the SEC all investment holdings, on behalf of MSD                                                                                                                                                                                                                                                                                      | EX2452; EX2453; <i>see also</i> EX2464                                                                                                                                                                                                                                                                                                                                                                  |
| <div style="background-color: black; width: 200px; height: 1.2em; margin-bottom: 0.5em;"></div> these PGR proceedings on behalf of Petitioner, i.e., <div style="background-color: black; width: 150px; height: 1.2em; display: inline-block;"></div> <div style="background-color: black; width: 100px; height: 1.2em; display: inline-block;"></div> and back-up counsel Mark Stewart, serve both MSD and Merck & Co. | <div style="background-color: black; width: 150px; height: 1.2em; margin-bottom: 0.5em;"></div> <div style="background-color: black; width: 200px; height: 1.2em; margin-bottom: 0.5em;"></div> <div style="background-color: black; width: 220px; height: 1.2em; margin-bottom: 0.5em;"></div> <div style="background-color: black; width: 190px; height: 1.2em; margin-bottom: 0.5em;"></div> EX2416. |
| Back-up counsel Mark Stewart's <div style="background-color: black; width: 220px; height: 1.2em; margin-bottom: 0.5em;"></div> <div style="background-color: black; width: 240px; height: 1.2em; margin-bottom: 0.5em;"></div> <div style="background-color: black; width: 150px; height: 1.2em; margin-bottom: 0.5em;"></div>                                                                                          | <div style="background-color: black; width: 220px; height: 1.2em; margin-bottom: 0.5em;"></div> <div style="background-color: black; width: 180px; height: 1.2em; margin-bottom: 0.5em;"></div>                                                                                                                                                                                                         |
| MSD's and Merck & Co.'s websites are nearly identical.                                                                                                                                                                                                                                                                                                                                                                  | EX2411; EX2412; EX2413; EX2414                                                                                                                                                                                                                                                                                                                                                                          |
| MSD is listed as the Registrant and Domain Administrator for both MSD's                                                                                                                                                                                                                                                                                                                                                 | EX2469 at 1-2 (listing MSD as registrant for domain                                                                                                                                                                                                                                                                                                                                                     |

| Blurred lines                                                                                                                         | Evidence                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| and Merck and Co.’ websites.                                                                                                          | “MSD.COM.”); EX2470 at 1-2<br><br>(listing MSD as registrant for<br><br>domain “MERCK.COM.”)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| MSD listed Merck & Co. as an RPI in<br><br>other IPRs involving patents relevant to<br><br>a related product, KEYTRUDA <sup>®</sup> . | <ul style="list-style-type: none"><li data-bbox="837 579 1372 1136">• EX2417 at 67 (“Merck<br/><br/>identifies Merck Sharp &amp;<br/><br/>Dohme LLC and Merck &amp; Co.,<br/><br/>Inc. as the real parties-in-<br/><br/>interest.”); <i>see also</i>, EX2418-<br/><br/>EX2425 (same) (<i>MSD v. Johns<br/>Hopkins University</i> IPRs);</li><li data-bbox="837 1178 1372 1734">• <i>See e.g.</i>, IPR2016-01217, -<br/><br/>01218, -01219, -01221, Papers 1<br/><br/>at i-ii (“Merck Sharp &amp; Dohme<br/><br/>Corp. and Merck &amp; Co., Inc<br/><br/>(Merck) are the real parties of<br/><br/>interest of this petition.”) (<i>MSD<br/>v. Ono Pharm.</i> IPRs);</li><li data-bbox="837 1776 1372 1818">• EX2472 at 1 (discussing the</li></ul> |

| Blurred lines | Evidence                                                           |
|---------------|--------------------------------------------------------------------|
|               | <i>MSD v. Ono Pharm.</i><br><br>KEYTRUDA <sup>®</sup> litigation). |

Petitioner’s KEYTRUDA QLEX<sup>™</sup> patent portfolio further evinces the blurred corporate lines between MSD and Merck. & Co. For example, MSD is the applicant for U.S. Application No. 19/346,638 (the “’638 application”), which is a grandchild continuation application of KETRUDA QLEX<sup>™</sup> “Product patent,” U.S. Patent No. 11,633,476. EX2473 at 37-38; EX2374 at 3.<sup>6</sup> When filing the ’638 application, MSD included with its Power of Attorney a copy of Merck & Co.’s “General Corporate Resolution #5 – Patent Matters,” which is certified by Kelly E. W. Grez, “Corporate Secretary of Merck & Co., Inc.,” as being a true and correct copy and in “full force.” EX2473 at 20-22. Merck & Co.’s Corporate Resolution states that (among others), **Robert M. Davis, Jennifer Zachary, Laura M. Ginkel, and Mark Stewart** are each “authorized to execute and to revoke *on behalf of Merck & Co., Inc.* and its affiliates (including subsidiaries) ... powers of attorney relating to the prosecution or defense of patent rights before the courts of

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<sup>6</sup> Notably, the KEYTRUDA QLEX<sup>™</sup> patent listings occur on a webpage for which Merck & Co., Inc. owns the copyright. EX2474 at 3, 7.

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.” EX2473 at 22. Thus, Merck & Co. is not merely an uninvolved parent company of MSD. To the contrary, Merck & Co. has the power to control MSD’s patent activities involving KEYTRUDA QLEX™, including litigation.

Patent practitioners from the Merck organizations also seem to have difficulty understanding the lines between the two entities. [REDACTED]

[REDACTED]

[REDACTED] But a search of the OED’s “register of active patent practitioners” page indicates otherwise. Searching simply “Merck” in the “business/firm” field yields five results for Merck, Sharp, & Dohme and 12 results for Merck & Co.

EX2465. Thirty-one practitioners just generically list “Merck.” [REDACTED]

[REDACTED] the lines between the entities are so blurred that even many patent practitioners inside the Merck organizations have trouble understanding which entity they work for.

Indeed, the corporate lines are so blurred between MSD and Merck & Co. that Merck & Co. has the opportunity to, and in fact does, control the Halozyne PGRs. *See Corning* at 15 (citing *Zoll*, IPR2013-00606, Paper 13 at 10; *Galderma S.A.*, IPR2014-01422, Paper 14 at 12 (finding the same person serving as both

President and CEO of both Petitioner and the parent company “implies ‘an involved and controlling parent corporation representing the unified interests of itself and Petitioner.’”).

As stated in *Galderma*, relevant to the overlap in executive leadership at MSD and Merck & Co., including their CEO, “[w]e need not consider whether [the President and CEO of both the parent and subsidiary] did or did not, directly or indirectly, exercise this control. It is sufficient that he had, in the words of *Gonzales*, ‘the power— . . . to call the shots’”). *Id.* at 12 (citing *Gonzalez v. Banco Cent. Corp.*, 27 F.3d 751, 758 (1st Cir. 1994)); 8 (noting *Gonzalez* refers to “the power—*whether exercised or not*—to call the shots”).

**D. Merck & Co. has a large interest in, desires, and greatly benefits from the Halozyme PGRs, and MSD is representing that interest**

When considering whether Merck & Co. benefits from the Halozyme PGRs, the relevant question “is not to probe [MSD]’s interest (it does not need any); rather, it is to probe the extent to which [Merck & Co.]—as [MSD’s parent]—has an interest in and will benefit from [MSD]’s actions, and inquire whether [MSD] can be said to be representing that interest after examining its relationship with [Merck & Co.]” *AIT*, 897 F.3d at 1353.

Merck & Co. benefits directly from the sale of KEYTRUDA QLEX™ and reports its sales and revenue KEYTRUDA QLEX (EX2400 at 8 (last ¶), 37-38, 47-

49; EX2466 at 3 (referring to press release (Exhibit 99.1) issued by Merck & Co.); EX2467 at 1, 5 (Exhibit 99.1 referring to KEYTRUDA QLEX™ “Sales of \$40 Million”); EX2468 at 4. Not only that, Merck & Co.’s recent SEC 10-Q filing indicates it pays royalties and carries the liability regarding milestone payments under an exclusive license relating to a key component of KEYTRUDA QLEX™ (i.e., berahyaluronidase). EX2400 at 8 (last ¶). Operating under that license, Merck & Co. sells, and generates revenue from, the KEYTRUDA QLEX™ product accused in the parallel district court litigation. An earlier SEC filing in 2025 by Merck & Co. also states that “Other Assets” include millions of dollars “of inventories produced in preparation for product launches (primarily MK-3475A, subcutaneous pembrolizumab),” i.e., KEYTRUDA QLEX™. EX2454 at 18.

In its recent SEC 10-Q filing, Merck & Co. discusses how litigations and AIA cases relevant to both KEYTRUDA® and KEYTRUDA QLEX™ may impact the “Company,” and discusses Merck & Co.’s expectations in winning relevant cases. EX2400 at 25, 21 (“Contingencies”). Merck & Co. discusses such cases as potential risks and benefits to Merck & Co. itself. *Id.* at 25, 21 (“Contingencies”).

Both MSD and Merck & Co. benefit from the sales of both KEYTRUDA® and KEYTRUDA QLEX™, as well as any positive outcome in litigation (in district court or at PTAB) related to the sale of either KEYTRUDA® product. Merck & Co. has a large interest in, desires, and greatly benefits from all PGR

proceedings. Its subsidiary, Petitioner MSD represents that interest. Accordingly, Merck and Co. is an RPI to these proceedings.

**V. IF PETITIONER TRIES TO CORRECT ITS RPI, IT CANNOT MAINTAIN ITS ORIGINAL PETITION FILING DATE**

Under *Corning* and *Yangtze*, “[o]nly precisely-identified” RPI “are entitled to have their petitions considered” and “Petitioner’s failure to provide clarity as to its actual identity is fatal to its petitions.” *Yangtze* at 5; *Corning* at 24-26. Because Petitioner has not even attempted to correct its RPI here, the petition cannot be considered under 35 U.S.C. § 322(a)(2). Petitioner stated in its Opposition to Patent Owner’s Motion for Additional Discovery that, “[i]f [Merck & Co.] is found to be an RPI, Petitioner is willing to amend its notices to identify [Merck & Co.] provided the petitions’ filing dates are maintained.” Paper 9 at 10. Petitioner’s proposition is foreclosed by *Corning*, *Yangtze*, and the Office’s February 3, 2026 de-designation of *Proppant Express Investments, LLC v. Oren Technologies, LLC*, IPR2017-01917, Paper 86 (P.T.A.B. Feb. 13, 2019) and *Adello Biologics LLC v. Amgen Inc.*, PGR2019-00001, Paper 11 (P.T.A.B. Feb. 14, 2019), from precedential status. This is further evident from the *sua sponte* Director Review decision in *Aylo*, IPR2024-00940, Paper 75 at 2-4. Petitioner cannot amend its identification of RPI while maintaining the Petition’s filing date in this proceeding or in any of the other 14 Halozyme PGRs.

While the present petition is not currently time-barred under 35 U.S.C. §§ 315(b) or 321(c), the proper identification of all RPI is required by law for the petition to be considered under § 322(a)(2). Moreover, proper identification of all RPI assists “in identifying potential conflicts, and to assure proper application of the statutory estoppel provisions.” PTAB Trial Practice Guide at 12-13. MSD should not be allowed to circumvent estoppel rules on behalf of its parent company.

Because Petitioner has failed to update its Mandatory Notices and name Merck & Co. as an RPI, the Director should dismiss the petition as incomplete under § 322(a)(2) and deny institution.

## **VI. HALOZYME TIMELY RAISED THE ISSUE OF RPI**

Prior to *Corning*’s designation as precedential, consistent with *SharkNinja*,<sup>7</sup> the Board did not engage in an RPI analysis in AIA cases absent an allegation that the petition would be time-barred or a petitioner would be estopped based on an unnamed RPI as of the petition’s original filing date. Since October, however, RPI is an issue the Board can, and must, address if a Patent Owner brings the matter

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<sup>7</sup> *SharkNinja Operating LLC v. iRobot Corp.*, IPR2020-00734, Paper 11 (P.T.A.B. Oct. 6, 2020) (designated precedential Dec. 4, 2020) (de-designated on Sept. 26, 2025) (“*SharkNinja*”).

into dispute, even if no bar or estoppel existed when a petition was filed.

After *Corning* was designated, Patent Owner immediately began a review of publicly available documents to investigate whether MSD had identified all RPI in its Petitions. Based on public information uncovered, Patent Owner requested tailored additional discovery from Petitioner relating to RPI on November 11, 2025. Patent Owner was also diligent in pursuing that discovery through motion practice. Paper 7; Paper 8. Thus, Patent Owner has been as timely as possible in raising the RPI issue after the change in PTAB policy and binding case law.

## **VII. CONCLUSION**

Because the petition fails to correctly name all RPI, the Director should deny institution.

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 18,700 words, comprising 6,752 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.

Respectfully submitted,

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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. § 42.207(a)**, Exhibits 2446-2454 and 2456-2474, and the public, redacted version of Exhibit 2401, were served in their entirety on February 20, 2026, upon the following parties via electronic mail:

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