

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyme Inc.,
Patent Owner.

PGR2025-00087 (12,371,685 B2)

PETITIONER'S PRELIMINARY REPLY

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I. Introduction

Citing an assortment of sentences in SEC filings, LinkedIn profiles, and other public documents, Halozyme contends in its Patent Owner Preliminary Response (“POPR”) that Merck & Co., Inc. (“MCI”), the corporate parent to Petitioner Merck Sharp & Dohme LLC (Petitioner or “MSD LLC”), is an unnamed real party-in-interest (“RPI”). It alleges, in particular, that MCI “not only directs and funds the Halozyme PGRs, but controls or has the opportunity to control them.” POPR, 2.

The evidence MSD LLC voluntarily produced in this proceeding conclusively establishes that Halozyme’s allegations are false: MCI, as [REDACTED], has not—and could not have—directed, controlled, or funded these proceedings. Petitioner’s evidence includes confidential corporate records (*e.g.*, tax filings, employment documents, accounting records, and engagement letters), interrogatory responses, and the confirmatory testimony of Kelly Grez, who holds dual roles as Assistant Vice President, Legal, and Secretary of MSD LLC and Corporate Secretary of MCI. Ms. Grez’s testimony comprises a detailed declaration and seven hours of cross-examination, taken over a long ten-hour plus day, that conclusively refutes every argument Halozyme makes. *See* EX1224 (“Grez Decl.”); EX1225. This evidence establishes that MCI and MSD LLC are separate entities with different purposes, and that MCI has played no role whatsoever in these PGR proceedings.

MCI is a [REDACTED] EX1244, 2; Grez Decl., ¶¶ 7-9. It did not, and could not have, directed, controlled, or funded any aspect of these PGR proceedings. EX2401, 9; Grez Decl., ¶ 17; EX2426-2428; EX2436-2444. MCI's role is *oversight*, not direction, of its subsidiaries. The oversight function is carried out through MCI's Board of Directors, which does not direct or control any aspect of the Halozyme patent dispute, including these PGRs. In fact, according to Ms. Grez, it's highly unlikely the [REDACTED] [REDACTED]. EX1225, 145:23-146:2, 146:22-24. Similarly, while MCI has officers, those officers also serve an oversight function and are not involved in the legal proceedings of MCI's subsidiaries in their MCI capacity. EX1225, 98:21-24, 108:18-109:8, 289:14-18, 114:14-116:7.

The evidence also shows that Petitioner MSD LLC alone initiated, funded, and directed these proceedings, without any involvement by MCI. Grez Decl., ¶¶ 17, 22, 24-25; EX2426-2428. While some MSD LLC employees also act as officers in MCI—including Ms. Grez and Jennifer Zachary, the General Counsel of MCI and the General Counsel of MSD LLC—they have wholly different responsibilities when serving MSD LLC versus MCI. Grez Decl. ¶¶ 22-25, 30. Ms. Zachary instructs or directs legal strategy solely in her role as General Counsel of Petitioner MSD LLC, and there is no evidence Ms. Zachary has been involved in the Halozyme PGR proceedings. *Id.*, ¶¶ 17, 22, 24-25; EX2401, 9; EX1225, 294:21-295:7, 295:16-21,

314:8-315:8, 346:18-347:5, 100:6-14, 98:5-24. Thus, only MSD LLC—who is responsible for commercialization of KEYTRUDA QLEX™ in the United States and employs a legal department with IP counsel—had the capability and reason to file these PGRs. Grez Decl., ¶¶ 17, 26-28.

Halozyme has long known about MCI's lack of involvement in these PGR proceedings. Halozyme raised the RPI issue for the first time in November 2025, shortly after this Petition was filed, and late in the fourteen earlier-filed PGR proceedings. EX2401, 16-18. In December 2025, Petitioner responded to all of Halozyme's discovery requests. *Id.*, 7-10; EX2402-2406; EX2426-2444. The Board acknowledged the completeness of Petitioner's production by denying Halozyme's Request for Additional Discovery. *See Merck Sharp & Dohme, LLC v. Halozyme, Inc.*, PGR2025-00003, Paper 80 at 3 (PTAB Feb. 12, 2026); *Merck Sharp & Dohme, LLC v. Halozyme, Inc.*, PGR2025-00003, Paper 63 at 8-9 (PTAB Jan. 6, 2026). When Halozyme disputed the accuracy of Petitioner's assertions regarding the corporate relationship between MCI and MSD LLC (*Merck Sharp & Dohme, LLC v. Halozyme, Inc.*, PGR2025-00003, Paper 114 at 30:22-31:8, 31:16-23 (PTAB Mar. 2 2026)), Petitioner provided the comprehensive 12-page declaration of Ms. Grez, and made her available for **seven hours** of deposition. EX1224.

Halozyme, apparently realizing the inadequacy of its evidence, then devoted much of Ms. Grez's seven-hour deposition to **seventeen previously uncited exhibits**

(EX1225, 9-10)—sixteen of which were publicly available before Halozyme filed this POPR. This was after the Board had expressly instructed the parties that Halozyme “may introduce documents outside the record during that deposition to aid its cross-examination, but Patent Owner is not authorized to file those documents as exhibits in these proceedings absent express authorization pursuant to a particularized showing of good cause.” EX1227; *see also* EX3102 (“No additional new evidence is permitted.”). Halozyme’s counsel badgered Ms. Grez by asking her approximately one hundred similar questions regarding who has the authority, oversight, and/or authorization to act on legal matters. *See, e.g.*, EX1225, 56:18-70:25; 104:14-116:7; 123:14-129:22; 135:18-137:25; 140:25-142:15; 216:11-17; 238:22-239:8; 246:19-252:1; 288:19-310:19; 314:24-315:8; 330:4-331:22. Ms. Grez consistently and candidly testified throughout this questioning that MCI is a [REDACTED] that oversees the “consolidated business,” [REDACTED] [REDACTED] and could not (and as a practical matter, would not even attempt to) control litigation involving subsidiaries like MSD LLC, such as these PGR proceedings. EX1225, 112:14-20, 106:5-20, 107:23-110:14.

Halozyme’s fishing expedition has returned evidence that refutes its assertions. MSD LLC is the sole and proper RPI. Institution of this PGR is warranted.

II. MCI Is Not a Real Party-In-Interest to the PGR Proceedings

A. MCI Has Not Controlled and Could Not Control the Preparation of the PGR or Conduct of the PGR Proceedings

MCI has had no involvement with this PGR, so it cannot be an RPI. *See Aruze Gaming Macau, Ltd. v. MGT Gaming, Inc.*, IPR2014-01288, Paper 13 at 11 (PTAB Feb. 20, 2015) (“RPI is the relationship between a party and a *proceeding*; RPI does not describe the relationship between *parties*.”). Employment records (EX1236; EX1242; EX2402-EX2404; EX2426-EX2427; EX2430-EX2434; EX2435; EX2451; EX2458; EX2462; Grez. Decl., ¶¶ 17-25), tax records (EX1244), and litigation records (EX2012; EX1166; EX1167; EX2454; Grez. Decl., ¶¶ 33-35), combined with Ms. Grez’s confirmatory declaration and deposition testimony (EX1224; EX1225), show that MSD LLC is the only entity that has and can control the PGR.

Halozyme instead places undue emphasis on MCI’s position as a parent company, mischaracterizing statements (including in SEC filings) regarding the consolidated global enterprise of all MCI-owned entities, which includes hundreds of subsidiaries that are responsible for business operations. POPR, 2, 4-5, 16-18. These documents are not intended to disseminate information regarding specifics events and actions of specific subsidiaries, nor do they establish that MCI calls the shots. Grez Decl., ¶¶ 31-32. The evidence establishes the opposite.

A parent corporation of a petitioner is not automatically an RPI. *Syngenta*

Crop Prot. AG v. FMC Corp., PGR2020-00028, Paper 8 at 15 (PTAB Sept. 15, 2020); *Sony Comput. Ent. Am. LLC v. Game Controller Tech. LLC*, IPR2013-00634, Paper 31 at 7-8 (PTAB Apr. 2, 2015). Whether a party is an RPI is a “highly fact-dependent question,” for which there is no “bright line test.” *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1342 (Fed. Cir. 2018) (“*AIT*”). The RPI determination depends on several factors, including whether the parent exercised or could have exercised control over a petitioner’s participation in the proceeding; whether the parent “funds and directs and controls” the proceeding; the relationship between parent and petitioner; and the parent’s relationship to the proceeding, including the nature and degree of involvement in the proceeding. *Corning Optical Commc’ns RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 at 14-15 (PTAB Aug. 18, 2015) (Precedential). “[L]ying at [the] heart” of “[d]etermining whether a non-party is a ‘real party in interest’” is “whether a petition has been filed at a nonparty’s ‘behest.’” *AIT* at 1351; *see also* Consolidated Trial Practice Guide, § I.D.1.

Petitioner’s ample evidence unequivocally proves that MCI is not an RPI.

1. The PGR Proceedings Have Been Directed and Managed Exclusively by MSD LLC’s In-House Counsel

MCI is a [REDACTED] Grez Decl., ¶ 8; EX1244, 2 (stating it is a [REDACTED]); EX1225, 126:16-20. MCI has [REDACTED] Grez Decl., ¶ 8; EX1225,

58:4-17, 78:11-15, 98:21-24, 224:10-21, 198:7-17. MCI also has [REDACTED] Grez Decl., ¶ 8. Business operations, including legal operations and product commercialization, [REDACTED] Grez Decl., ¶ 9; EX1225, 114:8-24, 106:5-16, 100:24-101:10, 115:7-22, 115:24-116:7. MSD LLC is the main U.S. operating entity for the human health business. *Id.* The MCI board *oversees* the global consolidated business; its authority “is not to make operational decisions,” which “are conducted through subsidiaries.” *Id.*, 108:18-109:8, 105:22-106:20, 136:13-137:4.

Legal proceedings concerning intellectual property, like this PGR, are controlled exclusively by MSD LLC. Grez Decl., ¶¶ 17-25. MCI “is not involved ... in the litigation [or] the PGR proceedings.” EX1225, 311:5-9. In fact, MCI “[REDACTED] *Id.* at 98:21-24. MCI does not control subsidiaries’ legal affairs (*id.*, 114:14-24), direct subsidiaries on legal matters (*id.*, 115:24-116:7), or provide instructions on legal matters (*id.*, 114:25-115:22). Indeed, Ms. Grez, who has attended at least a portion of all MCI board meetings in the past two years (*id.*, 144:18-19, 145:6-11), [REDACTED]

[REDACTED] In fact, it would be [REDACTED] *Id.*, 145:23-146:2, 146:22-24. Ms. Grez also clarified that KEYTRUDA QLEX™, the product that is the subject of Petitioner’s dispute with

Halozyme, accounted for only \$40 million in worldwide sales. *Id.*, 185:7-186:1. This is compared to \$31 billion for Keytruda[®] I.V., a product that has nothing to do with the Halozyme dispute. *Id.*; EX2467, 1.

Four in-house legal counsel at MSD LLC direct and manage the PGR proceedings: Mark Stewart, Vice President, Global Intellectual Property Litigation, Eric Majchrzak, Director, Legal, Laura Ginkel, Senior Vice President, Assistant General Counsel, and Li Su, Director, Legal. EX2401, 8-10; Grez Decl., ¶ 17; EX1225, 100:24-101:10. None are employed by or holds any position in MCI. EX2401, 15; Grez Decl., ¶ 17; *contra* POPR, 20. MSD LLC’s employee records, including those used for federal tax reporting, show that all are employed solely by Petitioner. EX2401, 9; EX2430-2435; Grez Decl., ¶ 17. The PGRs are managed day-to-day by Mark Stewart. EX1225, 306:4-9. Mr. Stewart [REDACTED] [REDACTED] *Id.*, 193:12-20. He [REDACTED] [REDACTED] [REDACTED] *Id.*, 194:1-5; Grez Decl., ¶¶ 22, 24-25.

Halozyme’s argument that some of these in-house counsel may also work for MCI (POPR, 20) is wrong. Halozyme’s supporting “evidence”—LinkedIn pages, non-profit directories, and the USPTO’s OED directory—does not usurp Petitioner’s official employment records. *See Amneal Pharms., LLC v. Jazz Pharms., Inc.*, Case IPR2015-00545, Paper 25 at 10-14, 18 (PTAB July 29, 2015) (finding parent

corporation was not an RPI where patent owner relied on LinkedIn and website evidence). That Mr. Stewart took action to correct his OED profile does not refute formal employment agreements, HR records, payroll information, and Ms. Grez's testimony confirming that MSD LLC is the sole employer of Mr. Stewart, Mr. Majchrzak, Ms. Ginkel, and Ms. Li—it confirms the evidence. EX2404; EX2430-2435; Grez Decl., ¶17.

2. Jennifer Zachary's Separate Roles Do Not Allow Her to Control the PGRs on MCI's Behalf

Ms. Zachary is employed by MSD LLC, not MCI. Grez Decl., ¶ 18; EX1225, 91:19-21, 92:11-94:25; EX1236; EX2451; EX1242. Her salary is [REDACTED] Grez Decl., ¶ 18; EX1242. When Ms. Zachary directs any legal operations, such as patent litigation, she can only do so through her role as Executive Vice President and General Counsel of MSD LLC. Grez Decl., ¶¶ 22-25; EX2402, 8; EX2403, 8; EX1225, 294:17-295:7, 295:16-21, 98:5-19, 100:6-14. For example, Ms. Zachary [REDACTED]

[REDACTED] Grez Decl., ¶ 25; EX2402, 8; EX2403, 8. And Ms. Zachary has the authority [REDACTED]

[REDACTED] EX1225, 307:18-308:22. While there is no evidence Ms. Zachary has had any actual involvement in these PGR proceedings, any involvement she *could* have would thus solely be through her role at MSD LLC. *Contra* POPR, 14-

16, 22-23.

MCI has [REDACTED] Grez Decl., ¶ 23. Ms. Zachary's role as an officer with MCI is separate and distinct from her work at MSD LLC. *Id.*, ¶ 21. When Ms. Grez advises MCI's Board on governance matters and fiduciary duties or signs SEC filings for MCI she does so as an officer of MCI. *Id.*, ¶¶ 23, 30; EX1225, 97:13-19. There is no scenario in which Ms. Zachary could "call[] the shots" (POPR, 16) in a PGR proceeding through her role at MCI. EX1225, 314:8-315:8.

Halozyme's incorrectly alleges that Ms. Zachary "has a fiduciary duty to act on behalf of Merck & Co." to control the PGRs. PGR2025-00003, Paper 114 at 13:20-24; *see also* POPR, 15-16. Halozyme misunderstands—or misrepresents—how Ms. Zachary's fiduciary duties differ between her roles at MCI and MSD LLC. MCI's directors have "fiduciary duties to the public shareholders," but these duties do not include control over particular legal proceedings, because "the role [MCI] plays ... is not in operations." EX1225, 114:14-24. Consistent with her responsibility to advise the board on legal issues (Grez Decl., ¶ 30), Ms. Zachary's fiduciary duties to MCI would include informing the MCI board of legal issues that may require that board's attention. EX1225, 232:3-12. But because MCI does not control legal proceedings, Ms. Zachary has no fiduciary duty to control this PGR on behalf of MCI.

The fact that Ms. Zachary holds these dual (but separate) roles is not evidence that MCI could exert any control over this proceeding. The Board has rejected the type of argument Halozyme makes here. POPR, 16. *Par Pharm., Inc., v. Jazz Pharms., Inc.*, IPR2015-00546, Paper 25 at 19 (PTAB July 28, 2015) (“[T]he fact that . . . corporate officers in this case may hold themselves out in some instances as employees of [parent entity] rather than [subsidiary], does not persuade us to find RPI status for the [] parent[.]”); *Par Pharm., Inc. v. Horizon Therapeutics, Inc.*, IPR2015-01117, Paper 13 at 10 (PTAB Nov. 4, 2015) (“*Horizon*”) (“the evidence [fails to] show that Par Co. exerts control over this proceeding merely because Par Co. and Petitioner are in a similar business and the same person has roles in both Par Co. and Par Inc.”).

Mere overlap in “certain managers and other personnel” does not make a parent an RPI to its subsidiary’s proceedings. *First Quality Baby Prods., LLC v. Kimberly-Clark Worldwide, Inc.*, IPR2014-01024, Paper 41 at 9 (PTAB July 16, 2015). Prior Board decisions acknowledge that “[d]irectors and officers holding positions with a parent and its subsidiary can and do ‘change hats’ to represent the two corporations separately, despite their common ownership [T]he evidence as a whole must establish that the nonparty possessed effective control over a party’s conduct ... as measured from a practical, as opposed to a purely theoretical, standpoint.” *Daifuku Co. Ltd. v. Murata Machinery, Ltd.*, IPR2015-01538, Paper 11

at 9-11 (PTAB Jan. 19, 2016) (quotation omitted). *Daifuku* found that a petitioner's parent corporation did not have effective control over an IPR where the same general counsel had roles with both parent and subsidiary. *Id.*

Because MCI conducts its operations through its subsidiaries, like MSD LLC, there is no practical way for MCI (including through its General Counsel Ms. Zachary) to be involved in this PGR. Grez Decl., ¶¶ 7-8.

3. MCI's Consolidated SEC Filings Are Not Evidence that MCI Is Involved with the PGR or any Legal Proceeding

Halozyme's reading of MCI's consolidated SEC filings to support its RPI theory misinterprets their meaning. Halozyme ignores that the "Company" in MCI's SEC filings refers *collectively* to MCI *and all of its subsidiaries*, without distinguishing among them. POPR, 2, 13-19; Grez Decl., ¶¶ 31-35. "This is standard practice in Merck & Co., Inc.'s consolidated SEC filings, which explain that they are consolidated reports that gather and report information from Merck & Co., Inc. and its subsidiaries taken together." Grez Decl., ¶ 31; EX1225, 129:23-130:5, 187:4-11, 287:2-22, 329:18-22.

MCI is the only publicly traded Merck entity. When SEC filings refer to the "Company," they are referring to "Merck & Co., Inc. *and its subsidiaries*." EX2415, 131; EX1225, 129:23-130:5, 187:4-11, 287:2-22, 329:18-22; Grez Decl., ¶ 31. MCI is a parent and [REDACTED] (EX1244, 2) to hundreds of subsidiaries worldwide, of which MSD LLC is but one. EX1237; Grez Decl., ¶ 7; EX1244, 2. MCI must

present information “in a way that is clear and accessible to investors and the investing public.” EX1225, 49:11-19, 120:16-121:19; Grez Decl., ¶¶ 31-32. Investors in MCI stock are investing in the *consolidated* global enterprise, not in any one subsidiary. The SEC filings serve an “investor-focused purpose” of identifying information in an accessible way that is not intended to indicate that MCI itself is involved in any particular operation or legal proceeding. Grez Decl., ¶ 32; EX1225, 49:11-19, 121:10-19. The consolidated records addressed in these filings, therefore, encompass all MCI subsidiaries without necessarily distinguishing or identifying which subsidiary accounts for each item described in the filings. EX2415, 75.

Courts have long recognized that SEC filings, because of their nature and purpose, are not definitive proof of whether a parent or a subsidiary was responsible for a disclosed event. “[I]t is a standard business practice in many industries for a parent company to prepare consolidated financial statements on behalf of its subsidiaries.” *Tahaya Misr Inv., Inc. v. Helwan Cement S.A.E.*, 2016 WL 9024808, at *5 (C.D. Cal. May 23, 2016). Consolidated statements, therefore, are not evidence that a parent and subsidiary should be treated as the same entity. *Id.*; *see also Bellomo v. Pa. Life Co.*, 488 F. Supp. 744, 745 (S.D.N.Y. 1980) (holding that “annual reports [that] describe the business of the parent, subsidiaries and sub-subsidiaries as if they were all part of a common enterprise” did not permit parent and subsidiary to be treated as the same entity); *Darrick Enters. v. Mitsubishi Motors Corp.*, 2007 WL

6813810, at *6 (D.N.J. Jan. 19, 2007) (quotation omitted) (“It is questionable whether these annual reports qualify as ‘competent evidence’” for establishing jurisdiction over a parent corporation).

The Board has likewise rejected arguments that SEC filings referring collectively to a parent and its subsidiary in the context of a PTAB petition prove that the parent is an RPI. *Horizon*, IPR2015-01117, Paper 13 at 10 (“Specifically, the use of the term ‘we’ in an SEC filing, even if used deliberately when referring to what could be the current Petition, does not establish adequately that [parent] has control over this proceeding.”); *D-Link Sys. Inc. v. Chrimar Sys., Inc.*, IPR2016-01425, Paper 15 at 8 (PTAB Jan. 17, 2017) (“statements of [parent corporation] in its Annual Reports about other litigation involving the Petitioner” do not “prove that [parent corporation] is able to control the actions of Petitioner in this proceeding”).

Ms. Grez’s testimony confirms that “[s]tatements made about ‘the Company’ in these filings”—including those related to legal proceedings—are not intended to be attributed specifically or exclusively to MCI itself. Grez Decl., ¶¶ 31, 33-35. But Halozyme willfully blinds itself to the standard corporate relationship that exists between MCI and MSD LLC. For example, Halozyme alleges that a statement in SEC filings that “[i]n 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” is evidence that MCI

controls PGR filings. POPR, 13-14 (citing EX2400, 25; EX2454, 22). This statement does not indicate that MCI specifically took, or could have taken, any action relating to the PGR proceedings. It merely indicates that an MCI subsidiary that is part of the “Company”—in this case MSD LLC—began the PGR proceedings. Grez Decl., ¶¶ 33-35.

Other litigation-related SEC statements—including those concerning Halozyne—are treated in the same, standard way. For example, an MCI 10-Q states that the “Company filed revocation actions (the ’622 patent) against EP Patent No. 2 797 622 owned by Halozyne, Inc. in the UK, France, Germany and The Netherlands.” EX2400, 25; Grez Decl., ¶ 34. Those actions were brought by particular subsidiaries—Merck Sharp & Dohme (UK) Limited, MSD France, MSD Sharp & Dohme GmbH, and Merck Sharp & Dohme B.V.—not MCI itself. Grez Decl., ¶ 34.

Similarly, patent litigation reported as filed by “the Company” relating to BRIDION[®] were filed by MCI subsidiaries, not MCI. *Id.*, ¶ 35.

Finally, MCI’s SEC reporting on the district court litigation filed by Halozyne “in the U.S. District Court for the District of New Jersey alleging that the *Company’s* activities related to subcutaneous pembrolizumab infringe or will infringe 15 patents belonging to the MDASE portfolio, 12 of which are the subject of the *Company’s* already filed PGR petitions” named MSD LLC as the sole

defendant. EX2400, 25; EX2012; EX1166; EX1167; Grez Decl., ¶ 33. Indeed, Halozyme has made no attempt to name MCI as a party in the New Jersey litigation. By naming **MSD LLC** as the *only* defendant, Halozyme belies its assertion of “blurred lines” between MCI and MSD LLC such that “one has difficulty telling one from the other.” POPR, 3-4, 19-21. Halozyme had no difficulty distinguishing MSD LLC from MCI in its infringement allegations.

Members of the MSD LLC legal department are responsible for gathering and summarizing the information for legal proceedings that appear in SEC filings. EX1225, 268:10-271:1. When preparing those disclosures, employees of the relevant operating subsidiary are contacted for information and updates. *Id.*, 200:20-201:14; Grez Decl., ¶ 36. For instance, MSD LLC employees, including Mark Stewart, provide the information that is included in MCI’s SEC disclosures. Grez Decl., ¶ 36. This process of collecting information from the operating subsidiaries involved in each disclosed litigation illustrates the consolidated nature of the SEC disclosures, and confirms that MCI is not involved in these proceedings.

4. Other Evidence Confirms MSD LLC as the Sole RPI

As explained (*supra* § II.A.3), in its April 2025 patent infringement suit, Halozyme named only MSD Corp. (later corrected to MSD LLC) as defendant. EX2012; EX1167. Halozyme’s position cannot be reconciled with the RPI position its PGR counsel, Quinn Emanuel, took when representing Petitioner in prior PGR

proceedings related to Petitioner's Keytruda[®] (pembrolizumab) product, which contains the same active ingredient as KEYTRUDA QLEX[™]. EX1164 at 1,4. Quinn Emanuel correctly named Petitioner Merck Sharp & Dohme Corp. (now MSD LLC) as the only RPI. EX1165, 1. In this PGR, which also relates to a Keytruda[®] (pembrolizumab) product, Quinn Emanuel takes the opposite position regarding whether MCI is an RPI. EX1164; EX2012. Quinn Emanuel's prior representation that MCI was not an RPI in PGRs involving the same entities further undermines Halozyme's current position.

Halozyme contends MCI has demonstrated its "power to control MSD's patent activities involving KEYTRUDA QLEX[™]" based on MCI's "General Corporate Resolution #5 – Patent Matters." POPR, 25-26 (citing EX2473). But that resolution is actually consistent with MSD LLC being the sole RPI in these proceedings. The Resolution authorizes named individuals to "execute and to revoke on behalf of Merck & Co., Inc. and its affiliates (including subsidiaries)," certain patent-related documents. The resolution is invoked to the extent MCI owns a patent. EX2473, 22; EX1225, 251:15-252:1, 250:1-8. But MCI does not own the patent in this proceeding, and there is therefore no need for action on behalf of MCI. EX1225, 247:7-15. Moreover, the Power of Attorney for the patent application in EX2473 identified the assignee as "Merck Sharp & Dohme, LLC" and Cynthia Francisco signed a Power of Attorney stating she was "authorized to act on behalf of the

assignee,” MSD LLC. EX2473, 20. This is consistent with the authorization in Corporate Resolution #5 to act “on behalf of [MCI’s] affiliates (including subsidiaries),” and confirms that the authority is used to act on behalf of the entity that owns the patent.

Importantly, there is no evidence that the Resolution was ever invoked to control *these* PGR proceedings. *See* Consolidated Trial Practice Guide § I.D.1; *Gonzalez v. Banco Cent. Corp.*, 27 F.3d 751, 759 (1st Cir. 1994) (requiring control “from a practical, as opposed to a purely theoretical, standpoint”). The Resolution does not empower MCI to control or direct MSD LLC or these PGR proceedings. EX2473, 22.

B. MCI Has Not Funded the PGR Proceedings

Direct and irrefutable evidence shows that MSD LLC alone has funded these proceedings. Outside counsel Sidley and Dechert have been engaged by MSD LLC only. EX2402, 8; EX2403, 8; Grez Decl., ¶ 25. All payments to Sidley and Dechert come directly from MSD LLC. EX2436-2444. Mr. Stewart reviewed and authorized these payments. EX2401, 8-9. Expert witnesses were also engaged solely on behalf of MSD LLC. EX2405; EX2406. This proceeding thus is readily distinguished from proceedings where the Board has found a parent company to be an RPI because it funded the proceedings. *See, e.g., Corning*, IPR2014-00440, Paper 68 at 4-5, 7-11, 19-23 (RPI parent company engaged and paid outside counsel, and employed in-

house counsel that directed PTAB proceedings).

Halozyme ignores this evidence and instead points to MCI's discussion of the "Legal Defense Reserves" in its SEC filings, which discusses "actual costs incurred by the Company," "development of the Company's legal defense strategy and structure," and "costs and outcomes of completed trials." POPR, 18 (citing EX2400, 26). Halozyme again argues the use of "the Company" in these SEC filings indicates that it is MCI that expects to pay the costs of the PGR proceedings. This (again) misreads the language used in these filings (as explained in § II.A.3) because "the Company" in these filings includes "Merck & Co., Inc. *and its subsidiaries*." EX2415, 131; Grez Decl. ¶¶ 31-35. Indeed, the evidence shows the legal defense reserves that were referenced are not held by MCI but by **MSD LLC**. Grez Decl. ¶ 37. MCI does not have its own legal defense reserves. *Id.*, ¶ 37. The evidence thus unequivocally demonstrates that MSD LLC alone has funded this PGR.

C. MCI and MSD LLC Have Maintained Their Corporate Separateness

MCI's "mere status as a corporate parent" to MSD LLC "is insufficient to render an entity an RPI (or even a privy)." *Syngenta*, PGR2020-00028, Paper 8 at 15; *TRW Auto. US LLC v. Magna Elecs. Inc.*, IPR2014-01497, Paper 7 at 10 (PTAB Mar. 19, 2015) ("generic references to the existence of a parent/subsidiary business relationship in SEC documents" do not establish RPI); *see also Gillig v. Nike, Inc.*, 602 F.3d 1354, 1362 (Fed. Cir. 2010) (emphasis added) ("[C]ontrol of a *party* to the

litigation through stock ownership or corporate officership is not enough to create *privity*, absent a showing that the corporate form has been ignored”).

MCI and MSD LLC are separate and distinct entities with separate purposes. MCI is a publicly traded [REDACTED] that is the parent to hundreds of subsidiaries throughout the world. *See* Grez Decl., ¶ 7; EX1237. Consistent with its [REDACTED], MCI’s subsidiaries, including MSD LLC, are responsible for conducting [REDACTED] Grez Decl., ¶ 9. MCI has [REDACTED] *Id.*, ¶¶ 8, 23, 31.

MSD LLC is the main operating entity in the U.S. for the human health business, including for the U.S. commercialization of KEYTRUDA QLEX™. *Id.* ¶¶ 9, 26-28. MSD LLC has employees, operations, and a legal department, which is the sole employer of all of the attorneys who can direct and manage this PGR. *Id.*, ¶ 17, 22, 24-27; EX2401, 8-9. This means that MSD LLC is the only entity that can exercise input, influence, direction, and control over the PGRs. *Supra* § II.A-B.

Even though it is wholly owned by MCI, MSD LLC “is structured so that there’s a separate board of managers consisting of three individuals who are charged with managing the LLC.” EX1225, 54:22-55:9; Grez Decl., ¶ 10. Both MCI and MSD LLC are incorporated in New Jersey (EX1238; EX1240), where corporate “veil piercing” is permitted only in special circumstances where the presumption of

legal corporate separateness is overcome. “[T]he New Jersey Supreme Court and the Third Circuit have made clear that even a parent’s ‘significant control’ of its subsidiary is insufficient to pierce the corporate veil of the subsidiary; ‘complete domination’ [sic] of the subsidiary is the key.” *Las Vegas Sands Corp. v. Ace Gaming, LLC*, 713 F. Supp. 2d 427, 445 (D.N.J. May 2010) (quoting *Craig v. Lake Asbestos of Quebec, Ltd.*, 843 F.2d 145, 150 (3d Cir. 1988)).

The Third Circuit, interpreting New Jersey law, has also said that a court can only pierce the corporate veil if it finds that the “subsidiary was a mere instrumentality of the parent corporation.” *Marzano v. Comput. Sci. Corp. Inc.*, 91 F.3d 497, 513 (3d Cir. 1996) (quotation omitted) (parent corporation cannot be liable for employment discrimination by its subsidiary). “In determining corporate dominance, courts engage in a fact-specific inquiry considering whether the subsidiary was grossly undercapitalized, the day-to-day involvement of the parent’s directors, officers and personnel, and whether the subsidiary fails to observe corporate formalities, pays no dividends, is insolvent, lacks corporate records, or is merely a facade.” *Las Vegas*, 713 F. Supp. at 445 (quoting *Verni ex rel. Burstein v. Harry M. Stevens, Inc. of N.J.*, 903 A.2d 475, 498 (N.J. Sup. Ct. App. Div. 2006)). Halozyme has established no such facts.

1. MSD LLC and MCI Have Different Boards

Halozyme’s arguments concerning a lack of corporate separateness rely

heavily on an incorrect and misleading allegation of identity between the boards of MSD LLC and MCI. POPR, 22. Halozyme argues that “there is a complete overlap in the companies’ Executive Leadership (including their CEO and General Counsel) and Board of Directors.” *Id.*, 4. This is wrong. The exhibits that Halozyme claims show the executives and board of “Merck & Co., Inc.” (EX2408; EX2410) and “MSD” (EX2407; EX2409), are from two websites, www.merck.com and www.msd.com, which *both* identify the *MCI* board members. Neither website identifies MSD LLC’s board members. Grez Decl. ¶ 16.

The reason there are two nearly identical websites is that the “Merck” branded website, www.merck.com, is directed to the U.S. and Canada, and the “MSD” branded website, www.msd.com, is used for the rest of the world. EX1241; Grez Decl., ¶ 15. Due to a dispute with the German entity Merck KGaA—unrelated to Merck & Co., Inc.—Merck & Co., Inc. entities do not use the name “Merck” alone outside the U.S. and Canada. *Id.* Thus, the brand “MSD” represents Merck & Co., Inc. and all its subsidiaries outside the U.S. and Canada. *Id.* The website that Halozyme cites as identifying the MSD LLC Board of Directors and Executive team is just an “MSD”-branded website representing MCI, and identifying the same MCI Board of Directors and Executive team listed on the U.S.-facing “Merck”-branded website. Grez Decl., ¶ 16.

Halozyme further points to ICANN domain registration records, purportedly

showing that both www.msd.com and www.merck.com are registered to MSD LLC. POPR, 23-24 (citing EX2469; EX2470). That is unsurprising because MCI [REDACTED] [REDACTED] Grez Decl., ¶ 8. It therefore 1 [REDACTED] [REDACTED] Nor does a domain name registration have any bearing on RPI status. It merely reflects which entity handles the technical and administrative function of maintaining a website.

The boards of MCI and MSD LLC are, in fact, different. Grez Decl., ¶ 10; EX1243; EX1238; EX1240; EX2408. MCI has a thirteen-member Board of Directors. MSD LLC has a three-member Board of Managers, and there is no overlap between the two. There is some overlap between the MCI and MSD LLC officers. But this does not support Halozyme's argument that MCI is an unnamed RPI. Indeed, the Board has held that "mere overlap of personnel between [parent and subsidiary] does not indicate a sufficient blurring of corporate separation such that the parent corporations could have controlled the filing and participation of the Petition." *Syngenta*, PGR2020-00028, Paper 8 at 15-16; *see also Nuseed Ams. Inc. v. BASF Plant Sci. GMBH*, IPR2017-02176, Paper 16 at 10 (PTAB Apr. 11, 2018) ("Although overlap exists in the leadership of Nuseed Pty and Nuseed Americas, it does not mean that Nuseed Pty has the ability to control Nuseed Americas in this *inter partes* review, as Patent Owner argues.").

2. No Record Evidence Suggests Blurring of the Corporate Lines Between MSD LLC and MCI

Halozyne's evidence does no more than establish a parent-subsidary relationship between MCI and MSD LLC. *Daifuku*, IPR2015-01538, Paper 11 at 10. "Moreover, evidence of a common address and telephone number, substantial overlap of officers, and the other evidence on which Patent Owner relies, establishes a relationship between *parties*; it does not establish a relationship between [the parent corporation] and this *proceeding*." *Id.*, 10-11.

To circumvent the law that a parent-subsidary relationship is **not** enough to demonstrate that a parent of a petitioner is an RPI, Halozyne resorts to arguing that "the corporate lines are so blurred between MSD and Merck & Co. that Merck & Co. has the opportunity to, and in fact does, control these PGR proceedings. POPR, 26. Halozyne relies on *Galderma S.A. v. Allergan Indus., SAS*, IPR2014-01422, Paper 14 at 12 (PTAB Mar. 5, 2015) (quoting *Gonzalez v. Banco Cent. Corp.*, 27 F.3d 751, 758 (1st Cir. 1994)) for the general proposition that a non-party may be an RPI where it has "the power—whether exercised or not—to call the shots." POPR, 26-27. Halozyne is not the first party to take this quote out of context, and misconstrue its meaning.

As stated in *Gonzalez*, the evidence as a whole must establish that "the nonparty possessed effective control over a party's conduct . . . as measured from a practical, as opposed to a purely theoretical, standpoint." 27 F.3d 759 (emphasis added). Theoretical, hypothetical,

or speculative assertions about effective control, unsupported by evidence, are neither probative nor persuasive. Every corporate parent has the theoretical power to control its subsidiaries. If theoretical power, whether exercised or not, were the controlling test for determining a real party in interest, the test would be eviscerated of substance.

Daifuku, IPR2015-01538, Paper 11 at 11 (citing *U.S. v. Bestfoods*, 524 U.S. 51, 61–62 (1998)). In *Galderma*, the same individual was President and CEO of both parent and subsidiary, and it was determined that he “wields a significant degree of effective control *over the present matter*.” *Galderma*, Paper 14 at 12 (emphasis added). Halozyme has failed to establish that MCI has *any* control over this proceeding, much less a significant degree of effective control.

Halozyme’s unsupported attorney argument regarding MCI’s purported ability to control this proceeding is clouded by Halozyme’s misconception and misrepresentation of the facts. POPR, 22. MSD and MCI have different boards. *Supra* § II.C.1. As Ms. Grez explained, MCI could have structured MSD LLC to operate under MCI’s direction as MCI is a “member” of the LLC. EX1225, 54:22–55:9, 65:5–23. It did not do so—instead, MSD LLC was structured to be governed by its own Board of Managers. Official documentation demonstrates that all in-house counsel who have directed and managed the PGR proceedings are employed exclusively by MSD LLC (*supra* § II.A.1), and the evidence that Halozyme relies

on to speculate otherwise is of no probative value. There is nothing in the record to suggest that MCI wields, or could wield, control over the PGRs .

Ms. Grez confirmed this in her deposition. She testified that MCI does not provide [REDACTED]

[REDACTED] This is the practical reality of how MCI operates. Notably, as MCI's Corporate Secretary, Ms. Grez has attended most MCI board meetings, and parts of all MCI board meetings in the past two years, but has no recollection of t [REDACTED]

[REDACTED] *Id.*, 144:11-25. Indeed, Ms. Grez considered it [REDACTED]

[REDACTED] *Id.*, 145:23-147:13. Managing legal proceedings is not what MCI does. *Id.*, 311:5-9.

Finally, the corporate history of MSD LLC, which has included mergers and name changes,¹ may explain why some MSD LLC employees inadvertently refer to

¹ In 2009, Merck & Co., Inc. merged with a subsidiary of Schering-Plough and the operating entity formerly known as Merck & Co., Inc. changed its name to Merck Sharp & Dohme Corp. ("MSD Corp."). EX1235, 2; Grez Decl., ¶¶ 11-12.

Schering-Plough was renamed Merck & Co., Inc. and continued as the surviving

themselves publicly as Merck & Co. employees (POPR, 20). Regardless of the reason, this fact does not indicate a “difficulty understanding the lines between the two entities” in terms of their corporate structure and operations. POPR, 26. That line could not be clearer: MSD LLC is an operating subsidiary and MCI is [REDACTED] [REDACTED] (EX1244, 2) with [REDACTED] and thus no ability to control PGR proceedings. EX2401, 15; Grez Decl., ¶ 8.

D. A General Benefit to MCI Should Petitioner Prevail in the PGR Proceedings Does Not Render MCI an RPI

Although there is no dispute that both Petitioner and MCI “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” (POPR, 28), this does not render MCI an RPI here. If such a generalized benefit were enough for a corporate parent to be an RPI, then all corporate parents would be RPIs. But “mere benefit is not the standard for determining whether a party is an RPI.” *Bowtech, Inc., v. MCP IP, LLC*, IPR2019-

publicly traded corporation and parent company of MSD Corp. EX1235, 2; Grez Decl., ¶ 14. On May 1, 2022, MSD Corp. changed from a Corporation to a Limited Liability Company. EX1166-1167; Grez Decl., ¶ 13. MSD LLC remains as the entity responsible for the U.S. human health business operations of what was formerly known as Merck & Co., Inc.

00379, Paper 14 at 23 (PTAB July 3, 2019).

Because a parent of a subsidiary petitioner “always ‘has a preexisting, established relationship with the petitioner’ and is likely to benefit when and to the degree that its subsidiary benefits, the preservation of the common-law meaning of RPI in [*AIT*] suggests that the mere establishment of parent-company status is insufficient to render a non-party an RPI.” *Puzhen Life USA, LLC v. ESIP Series 2, LLC*, IPR2017-02197, Paper 24 at 9 (PTAB Feb. 27, 2019); *see also Bowtech*, IPR2019-00379, Paper 14 at 25 (“Therefore, to be an RPI, a party must be more than merely one ‘who will benefit’ from a favorable result in an *inter partes* review”) (citing *AIT*, 897 F.3d at 1348). That logic applies here.

Halozyme’s contention that MCI bears license obligations for the berahyaluronidase component of KEYTRUDA QLEX™ has been refuted. POPR, 4, 28. Halozyme again relied on the term “the Company” in MCI’s SEC filings to mean just MCI. POPR, 28. In fact, the SEC filings describe activities of the *consolidated* enterprise, Grez Decl., ¶ 31, and MCI is [REDACTED]

[REDACTED] *id.* ¶ 28. Nor

[REDACTED]

[REDACTED] *Id.* Such obligations [REDACTED]

Id. [REDACTED]

[REDACTED] *Id.*, ¶ 26.

E. Halozyme’s Allegation of Estoppel Circumvention Is Unfounded

Halozyme’s argument that MSD is “circumvent[ing] estoppel rules on behalf of its parent company” is baseless and should have no bearing on the Director’s consideration of the RPI issue. POPR, 30. Halozyme failed to show that MCI “has a vested interest in securing freedom to operate within the scope of [the challenged claims]” separate from that of Petitioner, because no such interest exists. *Nuseed*, IPR2017-02176, Paper 16 at 11.

Even if Halozyme prevails in these PGR proceedings, MCI would be unlikely to avoid estoppel under 35 U.S.C. § 325(e)(1) or the statutory bar under 35 U.S.C. § 315(b). These statutes apply to not only a petitioner and its RPIs but also to any “privy of the petitioner.” 35 U.S.C. §§ 315(b), 325(e)(1). In contrast to RPIs, a petitioner is not required to list privies. Indeed, Halozyme has failed to articulate a credible reason why, if MCI was in fact an RPI, Petitioner declined to list MCI. The Director need not consider Halozyme’s allegations of estoppel circumvention because the evidence makes clear that MCI is not an RPI.

III. Petitioner’s Evidence Distinguishes the PGRs from Recent RPI Decisions

The circumstances here are distinctly different from those in recent designated decisions in which an unnamed party was found to be an RPI. *Tianma Microelectronics Co., Ltd. v. LG Display Co., Ltd.*, IPR2025-01579, Paper 12 (Director Mar. 18, 2026) (precedential) (“*Tianma*”); *Yangtze Memory Techs., Ltd. v.*

Micron Tech., Inc., IPR2025-00098, Paper 38 (Director Jan. 15, 2026) (informative) (*Yangtze*). In *Tianma*, the Director denied institution because the petitioner responded to an RPI challenge with nothing more than a conclusory, uncorroborated declaration. *Tianma*, Paper 12 at 9-10 (“This type of declaration alone, unsupported by relevant documents, is insufficient to rebut Patent Owner’s credible arguments that Petitioner failed to name all RPIs.”). In contrast, Petitioner here marshaled a comprehensive and document-supported evidentiary record, which includes a seven-hour deposition that forecloses any reasonable conclusion other than that MCI is not an RPI.

In *Yangtze*, patent owner presented evidence that an unnamed party exercised control over the petitioner, and petitioner failed to provide evidence to rebut this allegation. *Yangtze*, Paper 38 at 7-8. Thus, the Director did “not have a sufficient answer to whether all RPIs have been identified.” *Id.* at 7. Petitioner here leaves no such unanswered questions. MCI is not an RPI. The Director should institute this PGR.

IV. Conclusion

Because the petition correctly names all RPI, the Director should grant institution.

Dated: April 2, 2026

Respectfully Submitted,
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 2nd day of April 2026, I caused to be served a true and correct copy of the foregoing and any accompanying exhibits by email on the following counsel:

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