UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyme Inc.,
Patent Owner.

PGR2025-00003 (11,952,600 B2)
PGR2025-00004 (12,018,298 B2)
PGR2025-00006 (12,152,262 B2)
PGR2025-00009 (12,123,035 B2)
PGR2025-00017 (12,110,520 B2)
PGR2025-00033 (12,049,652 B2)
PGR2025-00039 (12,104,185 B2)
PGR2025-00046 (12,091,692 B2)
PGR2025-00024 (12,060,590 B2)
PGR2025-00030 (12,054,758 B2)
PGR2025-00052 (12,264,345 B2)
PGR2025-00042 (12,037,618 B2)
PGR2025-00050 (12,077,791 B2)
PGR2025-00053 (12,195,773 B2)

PETITIONER’S OPPOSITION TO PATENT OWNER’S MOTION TO TERMINATE PROCEEDINGS

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I. Introduction

At the eleventh hour, Halozyme, unable to defend its patent portfolio on the merits, seeks to terminate these proceedings by alleging that Merck & Co., Inc. ("MCI")—the parent [redacted] of Petitioner Merck Sharp & Dohme LLC ("MSD LLC" or "Petitioner")—is an unnamed real party-in-interest ("RPI"). The record evidence conclusively refutes this allegation. [redacted]. EX1244, 2. [redacted]. It has not directed, controlled, or funded any aspect of these PGR proceedings. Nor could it have done so. Every material fact in the record confirms that Petitioner alone initiated, funded, and directed these proceedings, without any involvement by MCI.

Halozyme requested discovery, which, in December 2025, Petitioner voluntarily provided. Petitioner's production included answers to Halozyme's interrogatories and production of official employment records, corporate registrations, engagement letters, billing records, and confirmations of other pertinent facts about the corporate structure of Petitioner.[1] EX2401. This confirmed

[1] In view of the Board's Order (PGR2025-00003, Paper 81 at 2), Petitioner has not filed a declaration. Should the Board find a declaration helpful, or necessary, to addressing the operative facts, including the corporate structure of Petitioner and MCI, Petitioner respectfully requests the opportunity to file such a declaration.

MCI is not an RPI. *Id.*; EX2402-2406; 2426-2444.[2] Rather than grapple with this dispositive evidence, Halozyme ignores it, and relies instead on speculative (and incorrect) inferences from sources that are not definitive of the facts represented by Halozyme—such as SEC filings, LinkedIn pages, trade organization directories, and websites. Indeed, the Board has rejected the reliance of patent owners on documents such as consolidated SEC filings and LinkedIn listings to show a parent corporation is an RPI. And the Board already rejected Halozyme's attempt to supplement the record with additional discovery, finding that much of the same evidence Halozyme relies on in this motion was inconsistent with Halozyme's theory of MCI involvement in the PGR proceedings. *See* PGR2025-00003, Paper 80 at 3, Paper 63 at 8-9.

Halozyme cites *Yangtze Memory Techs., Ltd, v. Micron Tech., Inc.*, IPR2025-00098, Paper 38 (PTAB Jan. 15, 2026) (informative) to suggest that Petitioner has failed to provide clarity regarding the identity of an alleged RPI. Motion, 1, 4-5, 19. 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. *Id.* at 7-8. As a result, the Director did "not have a sufficient answer to whether all RPIs have been identified." *Id*. at 7.

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[2] Paper and exhibit numbers refer to the numbering in PGR2025-00003.

Petitioner leaves no such unanswered questions. It met its burden to show it is the only RPI. It has presented definitive evidence showing that MCI, the only alleged unnamed RPI, has no ability to control and/or fund the PGR proceedings, as well as evidence of corporate separateness between the entities. Halozyme's Motion to Terminate should be denied.

II. The Facts Demonstrate that MCI Is Not a Real Party-In-Interest

A parent-subsidiary relationship, without more, is not enough to make a parent company 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). Neither is an overlap in “certain managers and other personnel.” *First Quality Baby Prods., LLC v. Kimberly-Clark Worldwide, Inc.*, IPR2014-01024, Paper 41 at 9 (PTAB July 16, 2015). Rather, whether a non-party is a “real party in interest” is a “highly fact-dependent question” with no “bright line test.” *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1342 (Fed. Cir. 2018) (“*AIT*”).

Relevant considerations include whether a non-party exercised or could have exercised control over a party’s participation in the proceeding; whether a non-party “funds and directs and controls” an IPR petition or proceeding; the non-party’s relationship with the petitioner; the non-party’s relationship to the petition itself, including the nature and degree of involvement in the filing; and the nature

of the entity filing the petition. *Corning Optical Commc'ns RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 at 14–15 (PTAB Aug. 18, 2015) (Precedential). The question "lying 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* PTAB Trial Practice Guide,[3] § I.D.1.

The facts here establish that MCI is Petitioner's parent company that has no specific relationship to these proceedings. Evidence produced by Petitioner makes clear that MCI has not, and could not have, controlled, funded, or directed the preparation of the PGR petitions or Petitioner's involvement in the proceedings. There has been no blurring of the lines between MCI and Petitioner. The corporate form governing their relationship has been maintained. MCI will only receive the generalized benefit of its subsidiary prevailing in a patent dispute, which is true of all parent-subsidiary relationships.

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

MCI's position as Petitioner's parent cannot alone establish that MCI had any involvement with the PGR proceedings. The focus must be on whether MCI had any relationships to these particular proceedings. *See Aruze Gaming Macau,*

[3] available at https://www.uspto.gov/patents/ptab/trial-practice-guide.

Ltd. v. MGT Gaming, Inc., IPR2014-01288, Paper 13 at 11 (PTAB Feb. 20, 2015). The evidence shows that it did not.

1. [redacted]

Halozyme's reading of MCI's consolidated SEC filing to support its RPI theory misstates their meaning. Halozyme repeatedly ignores that the "Company" in MCI's SEC filings refers collectively to MCI and its subsidiaries, without distinguishing them. Motion, 1, 8-13. 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. MCI is a parent [redacted] (EX1244, 2 ("Common parent corporation")) to over 400 subsidiaries worldwide, of which MSD LLC is but one. EX1237. The consolidated records addressed in these filings, therefore, encompass all MCI subsidiaries without distinguishing which subsidiary accounts for each item described in the filings. EX2415, 75.

Halozyme appears willfully blind to this standard corporate structure. 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. Motion, 8-9 (citing EX2400, 25; EX2454, 22). *See also id.*, 1. But this is not an indication that MCI specifically took, or could have taken, any action relating to the PGR

proceedings. It means an entity that is part of the collective "Company" began the PGR proceedings. The evidence shows it was MSD LLC alone. EX2401, 8-10.

"[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). This is not evidence that parent and subsidiary can be treated as the same entity. *Id.*; *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 rejected arguments, like those repeated by Halozyme here, that SEC documents referring collectively to a parent and its subsidiary in the context of a PTAB petition prove that the parent is an RPI. *Par Pharm., Inc. v. Horizon Therapeutics, Inc.*, IPR2015-01117, Paper 13 at 10 (PTAB Nov. 4, 2015) ("*Horizon*") ("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.").

Halozyme's contention that SEC filing statements are evidence that MCI is controlling these PGRs is also readily disproved. Along with the discussion of the PGRs, the SEC filings discuss the district court litigation filed by Halozyme "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." EX2400, 25 (emphasis added). Notably, Halozyme filed that litigation naming MSD LLC as the sole defendant. EX2036; EX1166; EX1167. 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." Motion, 3, 15-16. Halozyme had no difficulty distinguishing MSD LLC from MCI in its infringement allegations.

Despite MCI not being a party to the Halozyme litigation, its SEC filings still address that litigation. It is a risk that impacts its subsidiary, MSD LLC. The PGRs, which challenge twelve of the patents asserted in that litigation, are related to the litigation involving Petitioner, and therefore are part of that disclosure. Such disclosures, however, are not evidence that MCI is specifically involved in the district court litigation or the PGR proceedings. It is not involved in either.

2. The PGR Proceedings Have Been Directed and Overseen Exclusively by Petitioner's In-House Counsel

Petitioner's interrogatory responses confirm that [redacted] all MSD LLC employees, oversee the PGR proceedings. EX2401, 8-10. Contrary to Halozyme's contention (Motion, 14-15), none are employed by MCI, which has no employees. EX2401,15. Petitioner MSD LLC is the only entity that employs Mark Stewart, Vice President, Global Intellectual Property Litigation, [redacted] *Id.*, 8-10. Records [redacted] show that each of these attorneys are employed by Petitioner, and no other Merck-related entity. *Id.*, 9; EX2430-2435.

Though they had this evidence, Halozyme instead points to documents that allegedly "indicated publicly that [MSD LLC's in-house counsel] work for Merck & Co., even if they also work for MSD." Motion, 15. Public documents, including LinkedIn listings, non-profit directories, and the USPTO's OED directory cannot usurp official employment records provided by Petitioner showing that MSD LLC alone employs every individual involved in these proceedings. *See Amneal Pharms., LLC v. Jazz Pharms., Inc.*, Case IPR2015-00545, Paper 25 at 10-14 (PTAB July 29, 2015) (finding parent corporation was not an RPI where patent owner relied on LinkedIn and website evidence).

Mr. Stewart's USPTO OED listing inadvertently included "Merck and Co." after listing MSD LLC. For the avoidance of doubt, he has since corrected his OED entry, which Halozyme acknowledges. Motion, 15 n.4. Halozyme does not explain how the now-corrected OED listing outweighs Mr. Stewart's employment agreement, HR records, and payroll information, all confirming that MSD LLC is Mr. Stewart's sole employer. EX2404; EX2430; EX2434. In its motion for additional discovery, Halozyme cited Mr. Stewart's OED listing to support its argument that "unredacted versions of documents Petitioner has produced," including Mr. Stewart's employment letter "will confirm Merck & Co. is an unnamed RPI." PGR2025-00003, Paper 63 at 8. The Board found the redacted information "does not 'reveal blurred corporate lines between MSD and [MCI]' or 'the ability of [MCI] to control and fund' these PGR proceedings." PGR2025-00003, Paper 77 at 3-4; Paper 80 at 3.

Halozyme also makes several allegations regarding General Counsel, Jennifer Zachary. Motion, 9-10, 15-16. Ms. Zachary is an employee of MSD LLC, not MCI. EX2431; EX2451; EX1236; EX1242. Although Ms. Zachary also serves as General Counsel to MCI as an officer, she is not an MCI employee. In her capacity as MCI's General Counsel, Ms. Zachary signed multiple SEC filings on behalf of MCI. Motion, 2, 9. [redacted]

[redacted] *Id.*, 9-10; EX2402, 8;

EX2403, 8. [redacted]

[redacted] EX2402; EX2403. [redacted]

The Board has rejected arguments, like those Halozyme makes here, suggesting Ms. Zachary "calls the shots" in her capacity as General Counsel to MCI versus General Counsel to Petitioner. Motion, 10. *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[].") The mere fact Ms. Zachary serves as General Counsel to MSD LLC and MCI fails to show that MCI exerts, or could exert, any control over this proceeding. *Horizon*, IPR2015-01117, Paper 13 at 10 ("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.").

Even considering the fiduciary duty imputed to Ms. Zachary's role as General Counsel to MCI (Motion, 10), nothing in the record indicates that Ms. Zachary took any action to give MCI the opportunity to control the PGR proceedings. *RODE Microphones, LLC v. Zaxcom, Inc.*, IPR2025-00230, Paper 61

at 13 (PTAB Jan. 21, 2026). Nor is there any basis to conclude Ms. Zachary has a "fiduciary duty to control the [PTAB proceedings] on behalf of both entities." *Id.* "Directors 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) (finding a parent corporation of petitioner did not have effective control over proceeding where same general counsel served parent and subsidiary). MCI conducts substantially all of its operations through its subsidiaries. EX1234, 9. Therefore, Ms. Zachary could not "call the shots" regarding the PGR proceedings on behalf of MCI.

In sum, Halozyme fails to show that the attorneys who have overseen the PGRs, and the outside counsel who they instruct, have acted at the behest of any party other than Petitioner. There is nothing in the record to suggest that MCI has had any involvement with these PGR proceedings or any opportunity to control Petitioner's involvement in them.

3. Naming MSD LLC as the Sole RPI Is Consistent with Prior Proceedings

The evidence shows MCI is definitively not an RPI here. The fact that MCI was listed as an RPI in other proceedings (Motion, 11) does not mean MCI must always be an RPI to petitions filed by Petitioner, or establish that, in those prior cases, MCI was not simply named an RPI out of an abundance of caution, even though it was not actually an RPI. The RPI analysis applies on a petition-specific basis.

Other evidence is consistent with MSD LLC being listed as the only RPI. In its April 2025 patent infringement suit, Halozyme named only MSD Corp. (later corrected to MSD LLC) as defendant. EX2036. Halozyme's position is also irreconcilable 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™. *Id.*; EX1164. Quinn Emanuel correctly named Petitioner Merck Sharp & Dohme Corp. (now MSD LLC) as the only RPI. EX1165. In this PGR, which also relates to a Keytruda® (pembrolizumab) product, Quinn Emanuel takes the opposite position regarding whether MCI is an RPI. Motion, 3; EX1164; EX2036. Quinn Emanuel's prior representation that MCI was not an RPI in PGRs involving the same entities further undermines Halozyme's current position.

B. MCI Has Not Funded the PGR Proceedings

MSD LLC has funded these proceedings. All evidence supports this fact. Outside counsel Sidley and Dechert have been engaged by MSD LLC only. EX2402-2403. Documents produced by MSD LLC demonstrate that payments to Sidley and Dechert come directly from MSD LLC. EX2436-2444. Payments to outside counsel are reviewed and authorized by Mr. Stewart, who is employed by MSD LLC. EX2401, 8-9. Testifying expert witnesses were engaged solely on behalf of MSD LLC. EX2405; 2406. MSD LLC has therefore funded the entirety of these proceedings. *Contra 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. Instead, it places significant weight on misinterpretations of MCI's consolidated SEC filings that cover MCI and all of its subsidiaries to allege that MCI is involved in funding the PGR proceedings. Motion, 10-12. Halozyme points to MCI's discussion of the "Legal Defense Reserves" sub-section, which states that factors considered include "actual costs incurred by the Company," "development of the Company's legal defense strategy and structure," and "costs and outcomes of completed trials." *Id.*, 11-12 (citing EX2400, 26). Halozyme argues these statements indicate MCI expects to pay costs and is involved in litigation strategy for the PGR proceedings. This is not true.

Halozyme's reliance on the legal defense reserve disclosure in the SEC filings is misguided. First, as discussed above (*supra* § II.A.1), statements regarding "the Company" in SEC filings refer to "Merck & Co., Inc. ***and its subsidiaries***," not any particular entity. EX2415, 131. Second, these reserves are kept in order to protect against legal losses to ensure MCI and its subsidiaries are adequately capitalized. They are, however, not evidence of funding by MCI. The evidence of funding relevant to these proceedings is shown by the engagement letters and outside counsel billing records. These show payment by MSD LLC only, not MCI. EX2402-2403; 2436-2444. Nothing in the record refutes this.

The Board has rejected SEC filings as evidence that a parent is an RPI to a subsidiary petitioner. *Horizon*, IPR2015-01117, Paper 13 at 10; *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"). Indeed, courts generally have rejected such collective SEC filings as "competent evidence" of a parent company's activities. *Darrick Enters.*, 2007 WL 6813810, at *6; *see also Tahaya*, 2016 WL 9024808, at *5; *Bellomo*, 488 F. Supp. at 745. The Board has also rejected arguments that an unnamed party should have been named an RPI, when the evidence indicates, like here, that the petitioner "independently made the decision

to file" and where the unnamed party "does not direct, control, or fund" the proceeding. *Aruze*, IPR2014-01288, Paper 13, at 18.

MSD LLC alone decided to file the PGR petitions and has remained the only party to oversee the PGR proceedings. EX2401, 8-9, 15. Thus, there is no basis for the Board to conclude that MCI directs, controls, or funds MSD LLC's participation in the PGR proceedings.

In summary, the record evidence establishes that MCI had no input, influence, direction, or control over any of the PGRs. *Id.* This includes no funding, preparation, drafting, strategy, prior art selection, or argument selection. MSD LLC, not MCI, made the decision to file the petitions, oversees the proceedings, and pays the fees and costs for these PGRs. EX2402-2403; 2436-2444. MSD LLC has been, and continues to be, the only entity involved with the PGR proceedings.

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.”).

1. MCI and Petitioner MSD LLC Are Separate Entities

Both MCI and MSD LLC are incorporated in New Jersey (EX1238; EX1240), where corporate law indicates that corporate “veil piercing” can overcome the presumption of legal corporate separateness only in special circumstances. “[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 has also said that a court can’t pierce the corporate veil under New Jersey law unless 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 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)).

Nothing in the record evidence suggests "significant control" exercised by MCI over Petitioner's operations, much less over its involvement in the PGR proceedings. The evidence makes clear that the input, influence, direction, and control over the PGRs came solely from Petitioner. *Supra* § II.A-B.

2. MSD LLC and MCI Have Different Boards

Halozyme's arguments concerning a lack of corporate separateness rely heavily on alleged identity between the Boards of MSD LLC and MCI. Motion, 15-16. Halozyme argues that "there is a complete overlap in the companies' Executive Leadership (including their CEO and General Counsel) and Board of Directors." *Id.*, 3. This is wrong. The exhibits that Halozyme represents show that the Executive teams and Boards of "Merck & Co., Inc." (EX2408; 2410) and "MSD" (EX2407; 2409), are from two websites, www.merck.com and wwww.msd.com, identifying the MCI board members. Neither website identifies MSD LLC's board members.

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. This stems from an agreement with the German entity Merck KGaA, which is a different company than Merck & Co., Inc., that prohibits Merck & Co., Inc. entities from being referred to as "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 and Executive team is just an "MSD"-branded website representing Merck & Co., Inc., and identifying the same Board and Executive team make-up as listed on the "Merck"-branded website.

The naming issue, which is public knowledge (*id.*), exposes a glaring error in Halozyme's motion and its reasoning. Halozyme misled the Board because it sought evidence that supported its arguments, without considering its accuracy.

The Boards of MCI and MSD LLC are, in fact, different. 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.").

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

Halozyme's evidence does no more than establish a parent-subsidiary relationship among 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-subsidiary relationship is ***not*** enough to demonstrate that a parent of a petitioner is an RPI, Halozyme 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. Motion, 17. Halozyme's motion 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." Motion, 17-18. Halozyme 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). The facts here are readily distinguished from *Galderma*.

Halozyme's arguments concerning MCI's ability to control these proceedings are pure theory. They are also clouded by Halozyme's misconception of the facts. MSD and MCI have different Boards. *Supra* § II.C.2; *contra* Motion, 15-16. Official documentation demonstrates that all in-house counsel who have directed and overseen the PGR proceedings are employed exclusively by MSD

LLC (*supra* § II.A.2), 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 any degree of effective control over the PGR proceedings, or that it could wield control over them.

Finally, the corporate history of MSD LLC, which has included mergers and name changes,[4] may explain why some MSD LLC employees inadvertently refer to themselves publicly as Merck & Co. employees (Motion, 17), even though they are employed only by MSD LLC. 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. Motion, 16. That line could not be clearer; MSD LLC is an operating subsidiary and MCI [REDACTED] (EX1244, 2)

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[4] In a 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. Schering-Plough was renamed Merck & Co., Inc. and continued as the surviving publicly traded corporation and parent company of MSD Corp. *Id*. On May 1, 2022, MSD Corp. changed from a Corporation to a Limited Liability Company. EX1166-1167. MSD LLC remains as the entity responsible for the U.S. human health business operations of what was formerly known as Merck & Co., Inc.

[REDACTED] and thus no ability to oversee PGR proceedings. EX2401, 15.

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" (Motion, 19), 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*, IPR2019-00379, 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 (citing *AIT*, 897 F.3d at 1348) ("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"). That logic applies here.

E. Halozyme's Allegation of Estoppel Circumvention Is Unfounded

Halozyme's argument that Petitioner "appears to be trying to circumvent estoppel rules on behalf of its parent company" is baseless and should have no bearing on the Board's consideration of Halozyme's motion. Halozyme fails to articulate 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 Board need not consider Halozyme's allegations of estoppel circumvention because the evidence makes clear that MCI is not an RPI.

III. Halozyme Waived the RPI Issue By Delaying and Failing to Raise this Issue Here and in Other Proceedings

Halozyme has known about MCI's relationship as corporate parent to MSD LLC since *at least* July 2025, and likely years prior. In April 2025, Halozyme filed suit naming MSD Corp. (later corrected to MSD LLC) as the lone defendant. EX2036. In July 2025, Petitioner also served a corporate disclosure identifying

MCI as its parent. EX1168. Halozyme never sued MCI. Quinn Emanuel also knew of Petitioner's corporate structure based on its prior, and temporally overlapping, Keytruda® (pembrolizumab) work for its client MSD LLC, and Halozyme relies heavily on public documents to allege MCI is an RPI. These facts render Halozyme's delay in raising the RPI issue until mid-November 2025, after nearly all challenged patents were past their nine-month PGR window, inexcusable.

Halozyme claims it was spurred to action when the Director designated *Corning* precedential. Motion, 3-4. But the designation of *Corning* has not altered the statute requiring that a petition name all RPIs. 35 U.S.C. § 312(a); 37 C.F.R. § 42.8(b)(1). Neither did it alter the definition of an RPI or the standard governing who qualifies. PTO *practice* may have changed on October 28, but without legislation, a judicial decision, or notice-and-comment rulemaking, the *law* did not. And only "a sufficiently sharp *change of law*" justifies "permitting a party to advance a position that it did not advance earlier in the proceeding." *See In re Micron Tech., Inc.*, 875 F.3d 1091, 1097 (Fed. Cir. 2017) (emphasis added). The Director, in fact, recently declined to reopen the RPI issue in response to a late-raised RPI argument. *See Recor Med. Inc. v. Medtronic Ireland Mfg. Unlimited Co.*, IPR2022-00431, Paper 53 (Director Feb. 10, 2026).

The Board's recent decision declining to find waiver because of "the change in legal precedent, occurring after the date for the Patent Owner Responses" also

does not excuse Halozyme here. *RODE*, IPR2025-00230, Paper 61 at 4. Halozyme continued to not raise the RPI issue in ***all*** of its PORs, including those filed in January 2026, months after the Director designated *Corning* precedential. The Board has made clear in every scheduling order that Halozyme's failure should result in waiver. *E.g.* PGR2025-00003, Paper 26 at 9; *Interactive Commc'ns Int'l, Inc. v. Blackhawk Network Inc.*, IPR2024-00465, Paper 36 at 5 (PTAB July 14, 2025) (previously-raised RPI issue waived for failure to raise in POR). To uphold the integrity of the PGR process, the Board should not consider Halozyme's untimely request to upend these common proceedings.

Dated: February 24, 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 24th day of February 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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