UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner

v.

HALOZYME, INC.,
Patent Owner

Case PGR2025-00004
U.S. Patent No. 12,018,298

PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW OF THE FINAL WRITTEN DECISION

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Halozyme, Inc. ("Patent Owner") requests Director review of the Board's Final Written Decision (Paper 136, "Final Written Decision") that issued on June 8, 2026. Director Review is warranted because the Final Written Decision should not have issued. Specifically, the Board instituted and maintained trial based on a Petition that failed to name all real parties in interest ("RPI"). Thus, the Final Written Decision is premised on a petition that fails to comply with statutory and regulatory requirements and should be vacated. The passages below are reproduced verbatim from Patent Owner's June 23, 2026 Request for Director Review (Paper 137) of the Order Denying Patent Owner's Motion to Terminate and are included here for the Director's convenience. Patent Owner notes that if the Director resolves Patent Owner's June 23 Request and terminates the proceeding, this request is moot and no further action by the Director on this request will be necessary. *Aylo v. DISH*, IPR2024-00940, Paper 75 at 1–3 (Director Feb. 3, 2026).

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I. ARGUMENT

A. The Director has already considered and addressed RPI.

As noted above, the Director—who is the ultimate decision-maker on institution and whether to de-institute in this case—has already fully considered and addressed the RPI issue as it relates to MCI. In the -087 PGR, the Director denied institution after considering full briefing from both parties and the complete

evidentiary record on the RPI issue. The post-petition briefing in that proceeding addressed only RPI—nothing else—and the parties advanced the same arguments and relied on the same evidence concerning the same RPI issue affecting the entire family of cases, including this one.

For example, in all instituted PGRs in this family, the parties submitted the same arguments and evidence in a series of papers filed after the Board authorized Petitioner to submit a witness declaration on the RPI issue. Paper 105 (Mar. 3, 2026). In every PGR involving the family, including the -087 PGR and this one, Patent Owner raised the same concerns regarding RPI, Petitioner filed the same single declaration by Ms. Kelly Grez, Patent Owner cross-examined Ms. Grez in a single deposition, and the parties provided the same arguments in briefing based on that testimony. *Id*. at 3.

In short, by denying institution based on the RPI briefing in the -087 PGR, the Director effectively resolved the RPI issue for the entire family of cases involving these parties. For this reason alone, the Director need go no further and, based on the same record and for the same reasons, should vacate the Board's Order, terminate this PGR as improperly instituted, and vacate Board decisions issued post-institution.

B. The Board's Order repeatedly failed to address or acknowledge arguments and evidence establishing that MCI is an RPI.

In its Order, the Board either misapprehended or entirely failed to address

significant arguments and evidence provided by Patent Owner on the issue of RPI, including those presented in: (1) Patent Owner's Motion to Terminate ("MTT") (Paper 81), (2) Patent Owner's Reply in Support of its Motion to Terminate ("MTT Reply") (Paper 95), and (3) Patent Owner's Brief on Testimony of Ms. Kelly Grez ("PO Grez Brief") (Paper 122).

In doing so, the Board incorrectly assumed the Patent Owner must prove MCI *actually controls* the PGRs (including this one), while erroneously overlooking evidence that MCI has the clear "*opportunity to control*" these PGRs. *See Corning* at 14-15 (an RPI consideration is whether a non-party "has the actual measure of control *or opportunity to control*") (citing Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012) ("[a] common consideration is whether the non-party exercised *or could have exercised control* over a party's participation in a proceeding.")) (emphases added).

1. The Board wrongly assumed MCI exerts only "general control" over MSD and overlooked evidence that MCI has the power to control these proceedings.

Patent Owner submitted evidence showing MCI has the specific authority to control the proceedings, including *inter alia* MCI corporate resolutions delegating specific authority over patent matters, including this one. The Board, however, confined its analysis to MCI's "general control" over MSD by virtue of its role as MSD's corporate parent, stating that "the exercise or availability of general

'control' that stock ownership vests in stockholders . . . will not make one company a real party in interest of the other," citing *U.S. v. Bestfoods*, 524 U.S. 51, 61-62, 69 (1998). Order, 17. The Board noted that "it is entirely appropriate for directors of a parent corporation to serve as directors of its subsidiary." *Id*. (citing *Bestfoods* at 69). While that general proposition may be correct, it misses the point. The "ordinary" parent-subsidiary relationship described in *BestFoods* is not what was at issue here, nor was it the basis of Patent Owner's arguments.

In fact, the Board ignored evidence that MCI has direct control over patent matters like this one. For example, MCI passed corporate resolutions authorizing dual-role MCI officers/MSD employees, including MCI's CEO Robert Davis (who does not have a title at MSD) and MCI's and MSD's "Executive Vice President and General Counsel" Jennifer Zachary, to "execute and to revoke" documents related to *any* patent matters, including with respect to litigation, on behalf of MCI and its affiliates, including MSD. PO Grez Brief, 4-5 (citing Ms. Grez's testimony (EX1225, 241:20–246:18, 252:6-257:11, 258:18-259:4)). The Board did not address this evidence, which demonstrates MCI's direct control over legal matters (including this one) handled by MSD employees. Beyond that, as discussed in detail below, MCI has publicly represented to investors in SEC disclosures that "the Company [MCI] *began filing*" these PGRs. EX2400, 25; EX2454, 22 (emphasis added). In fact, Ms. Zachary signed those SEC disclosures [redacted]

[redacted]. MTT, 1-2, 8-10; MTT Reply, 2; PO Grez Brief, 1. This is not a situation where a director of a parent corporation merely served as a director of its subsidiary (Order, 17). Rather, an officer at the parent engaged in active operations (this PGR) for its subsidiary.

The Board also ignored that MCI/MSD's legal leadership and authority structure gives it the actual ability to direct the strategy and conduct of these PGRs. Two of three MSD managers (appointed by MCI) are *also* MCI officers. PO Grez Brief, 2 (citing EX1225, 347:10-23, 348:18-23). For instance, MCI's global controller, Dalton Smart, is MSD's President and manager. *Id*. Similarly, "MSD's 'day-to-day operations are managed by [MSD] officers,' but—like the managers—seven of these [MSD] officers are MCI personnel." *Id*., 2-3 (citing EX1225, 54:10-54:17, 348:3-365:15). This authority structure does not indicate "theoretical" control but shows actual control over MSD operations by MCI officers.

2. The Board applied the wrong legal standard by requiring evidence of actual control rather than recognizing that the power to control is sufficient to establish RPI status.

The Board cited *Daifuku Co. v. Murata Mach., Ltd*., IPR2015-01538, Paper 11 at 11 (P.T.A.B. Jan. 19, 2016) to suggest that mere "theoretical power" by MCI to control MSD "eviscerate[s] the RPI test." Order, 18. But it is not the case that Patent Owner provided merely "theoretical, hypothetical, or speculative assertions about effective control, unsupported by evidence," as discussed in *Daifuku. Id.* For

example, as discussed above, ***MCI's*** corporate resolution documents demonstrate an *actual* ability to control. These MCI resolutions granted specific MCI officers and MSD employees, including MCI's CEO Robert Davis and MCI's General Counsel Ms. Zachary, the power to "execute and to revoke" documents related to *any* patent matters, including with respect to litigation (such as settlement agreements in these proceeding), on behalf of MCI and its affiliates such as MSD. PO Grez Brief, 1, 4-5 (citing EX1225, 241:20–246:18, 252:6-257:11, 258:18-259:4). In other words, these individuals were unquestionably vested with power to control patent proceedings by action in MCI's own corporate resolutions.[1]

3. The Board overlooked or misapprehended statements by MCI in numerous SEC filings indicating that MCI is an RPI.

In its briefing, Patent Owner discussed SEC documents filed by MCI (Form 10-Qs and Form 10Ks), including those filed on MCI's behalf by Ms. Zachary.

These SEC filings expressly state that the "Company"—meaning MCI—"*began filing a series of*" of PGRs (i.e., this family). *See* MTT, 8 (citing EX2400, 25; EX2454, 22) (emphasis added). The filings further describe how the

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[1] The Board also failed to acknowledge that neither Petitioner nor Ms. Grez provided MSD's governing LLC agreement or intercompany agreements [redacted] despite having the burden on this issue. PO Grez Brief, 1 n.1, 4.

"Company" (MCI) funds patent litigation and maintains "Legal Defense Reserves" to cover litigation liability. *See, e.g.,* MTT, 10-13 (citing EX2400, MCI's 10-Q SEC filing, "Contingencies" section and "Patent Litigation" and "Legal Defense Reserves" sub-sections); Reply, 4-5 (citing Opp., 14). Thus, SEC documents show that MCI controls and funds this PGR, or at minimum, has the clear actual ability to do so.

Patent Owner also showed that those SEC documents define MCI (not any of its subsidiaries, such as MSD) as "the Company." *See, e.g.*, MTT, 8 (citing EX2400, 6, 53; EX2454, 6, 47). For example, Patent Owner identified that "the first page of FY 2024 Form 10-K refers to 'Merck & Co., Inc. (Merck or the Company),' consistent with definitions in other filings. EX2415, 1; EX2400, 6; EX2454, 6." MTT Reply, 2. Patent Owner also showed when Merck & Co. intended the term "Company" in SEC documents to encompass subsidiaries (such as MSD), it knew how to do so. *See, e.g.*, MTT Reply, 2 (citing EX2415, 75; EX1234, 4; EX2415, 104-05 (distinguishing between "the Company" and "its subsidiary Merck Sharp & Dohme LLC. (MSD)").

The Board overlooked this evidence entirely. Rather than rely on what the SEC documents themselves actually say, the Board referred to a page in an auditor's report provided by PricewaterhouseCoopers LLP ("PWC") that is a *separate document* attached to the end of one SEC Form 10-K from FY 2024

(EX2415). Order, 13-14, 22-23 (citing EX1224, ¶¶31-32 (discussing EX2415, 183 (also called page 131))); *see* MTT Reply, 2.

In fact, that Form 10-K and the attached PWC report define "Company" very differently. Specifically, MCI's Form 10-K refers to "Merck & Co., Inc. (Merck or the Company)," while the attached PWC report refers to "Merck & Co., Inc. and its subsidiaries (the 'Company')" (*Compare* EX2415, 1 (PDF pg. 4) to *id*. at 131 (PDF pg. 183)). How PWC defines "Company" in a separate independent report does not provide evidence as to how MCI defines "Company" in its own SEC filings, especially when MCI's definitions are clear and so obviously different. Notably, the Board ignored evidence and argument on this point. The Board also failed to mention that MCI "does not include a similar audit report nor make any such statements in its Nov 2025 filing." MTT Reply, 2 (citing EX2400). In other words, there are other SEC filings that have the same definition of "Company" upfront, with no attached report providing a different definition. Thus, when MCI itself defines "Company" in its SEC documents, it clearly means MCI.

These errors by the Board led it to disregard wholesale, without further explanation, the importance of many statements made by MCI itself in multiple SEC documents discussing MCI's involvement in these PGRs. *See, e.g.*, EX2400, 6, 25; EX2454, 6, 22. These errors are significant because the SEC documents clearly state MCI filed and controls and funds (or at minimum has vehicles in place

to control and fund) this family of PGRs. It is not correct, as the Board suggested, that "no evidence" exists that "MCI personnel, funds, or other assets were involved" in these PGRs. Order, 21.

4. The Board overlooked or misapprehended Ms. Zachary's job description and what she actually does, which show control by MCI and blurred lines between MCI and MSD.

In its analysis of what Ms. Zachary actually does for MCI and MSD, the Board failed to acknowledge evidence establishing blurred lines in her roles and blurred corporate lines between MCI and MSD generally.[2]

For instance, the Board misapprehended or overlooked evidence indicating Ms. Zachary is responsible for "advis[ing] the board of directors of Merck & Co., Inc. on the global enterprise impact" "in her capacity as general counsel of Merck & Co., Inc.," using legal advice from MSD's attorneys. PO Grez Brief, 5 (citing and quoting Ms. Grez's testimony). Thus, contrary to the Board's assumption, Ms. Zachary functions in her dual role in a blurred capacity and certainly does not maintain corporate distinctions "at all times" or otherwise make a line of demarcation "clear." Order, 18, 20.

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[2] The Board also ignored the fact that Petitioner has not provided any testimony from Ms. Zachary about her roles or any firsthand knowledge she may have.

In addition, the Board acknowledged that Ms. Grez testified that Ms. Zachary and Ms. Grez, in the context of appointing MSD managers, "may sign on behalf of MCI." *See* Order, 15 ("When discussing appointment of Managers to MSD by MCI, Ms. Grez testified authorized officers, including herself as the secretary and Ms. Zachary, may sign on behalf of MCI."); EX1225, 56:14-57:7, 62:10-21. The Board inexplicably assumed, however, this clear evidence of blurred lines was only relevant to "theoretical power" of MCI to act. Order, 18. This ignored entirely the blurred lines aspect of Ms. Zachary's and Ms. Grez's roles, and that the proper RPI consideration is "whether the non-party exercised *or could have exercised control* over a party's participation in a proceeding." *Corning* at 14 (quoting Trial Practice Guide, 77 Fed. Reg. at 48,761) (emphasis added). The Board instead relied only on Ms. Zachary's job offer and Ms. Grez's testimony—inconsistent with the record—that corporate "distinctions have at all times been maintained." Order, 11, 18, 20

Moreover, the Board failed to acknowledge that Ms. Zachary's offer letter states: "In the Position, you will report to me [Chairman and CEO of MCI], will be a member of my Executive Committee and will be an Officer of Merck (as defined in Section 16 of the Securities Exchange Act of 1934)." EX2451, 1; Order, 10-11,

18. The Board also glossed over the fact that her offer letter referred to "Merck Sharp & Dohme Corp., a wholly-owned subsidiary of *Merck & Co., Inc.*

('Merck' or the 'Company')," and that the letter offered her a position of "Executive Vice President & General Counsel" with "Merck." EX2451, 1 (emphasis added); Order 10-11, 18. In other words, Ms. Zachary's offer letter indicates she reports to directly to MCI's Chairman and CEO, and she was hired by MCI's CEO to work as both MCI's and MSD's Executive Vice President and General Counsel in what appears to be the same "Position." EX2451, 1.

Additionally, as discussed above, Ms. Zachary signed corporate SEC filings on MCI's behalf that say MCI filed these PGRs. MTT, 9; MTT Reply, 1 (citing Opp., 9; EX2400, 25, 53; EX2454, 22, 47). The Board failed to recognize that Ms. Zachary's involvement in those SEC filings means she understood what those documents said, and how they defined "Company" to mean MCI.

5. The Board overlooked other evidence indicating extremely blurred lines of corporate separation between MCI and MSD

i. More than "a few" MSD employees have "misidentified" themselves as working for MCI

When addressing blurred corporate lines, the Board relied on its finding that only a "few" employees have "misidentified themselves in LinkedIn or been misidentified by hosting organizations such as IPO." Order, 18-19. That finding, however, ignored evidence establishing that *four of five* MSD individuals (Mr. Stewart, Ms. Zachary, Ms. Ginkel, Ms. Su) who are *actively involved* in these PGRs have represented publicly at some point they work for MCI, including Mr.

Stewart in an initial legal disclosure to the USPTO OED. MTT, 2, 14-16. The Board also failed to acknowledge that many other Merck individuals have held themselves out as working for MCI, including before OED. MTT, 17 (citing EX2465). The Board overlooked the significance of such sworn statements to OED.

ii. MCI job postings indicate confusion at MCI itself

MCI's own job postings state MCI is "also known" as MSD. PO Grez Brief, 2 n.2; (citing EX1225, 334:17-339:16). Thus, even MCI publicly blurs itself with MSD and/or is confused about whether it hires employees to work at MCI or MSD. The Board did not address this evidence showing blurred lines.

iii. Significant overlap in corporate leadership and duties

The significant overlap in corporate leadership between MCI and MSD also indicates corporate blurring. *See, e.g., Radware, Inc. v. F5 Networks, Inc.*, IPR2017-01249, Paper 10 at 12-13 (P.T.A.B. Oct. 23, 2017) (stating that "significant overlap in corporate leadership between Petitioner and Radware, Ltd. also is indicative of corporate blurring."); *see also* PO Grez Brief, i (listing individuals and their titles at MSD and/or MCI). The Board misapprehended or overlooked evidence in this regard, as discussed above in relation to Ms. Zachary and below regarding other MCI officers or MSD managers acting on MCI's behalf.

For instance, the Board did not mention that MSD's president and manager,

Dalton Smart, is MCI's global controller. EX1225, 347:10-16. Or that Ms. Grez performs both her dual roles (as Assistant Vice President, Legal, and Secretary at MSD and Corporate Secretary at MCI) using the same office, desk, computer, email, and phone, without notifying colleagues when she allegedly "switches" roles. PO Grez Brief, 3 (citing EX1225, 87:5-90:13); EX1224, ¶2. Or Ms. Grez has a single performance evaluation for both roles. PO Grez Brief, 3. (citing EX1225, 77:14-78:6).

[redacted] This coordination is consistent with MCI's delegation of authority concerning patents. *Id*.

The Board found, without basis, that Mark Stewart, who is actively involved in these PGRs, does not act on behalf of MCI. Order, 12, 20-21. In doing so, the Board ignored Ms. Grez's testimony that international proceedings are centrally "run" through Mark Stewart, who MCI has authorized to act on its behalf. PO Grez Brief, 5 (citing EX1225, 191:7-193:3, 241:20-248:4, 250:22-251:21). The Board also ignored that Mr. Stewart's title is "VP of Global IP Litigation," and Ms. Grez admitted he "has global responsibilities." *Id*. (citing EX1225, 191:3-192:24). In this capacity, for example, Mr. Stewart attended a German proceeding between

MCI (not MSD) and Halozyme, on behalf of "Merck," not MSD. *Id*., (citing EX1225, 205:18-210:17). At minimum, this evidence establishes Mr. Stewart, who allegedly has an official role solely at MSD, acts on behalf of MCI, as is the case with many others in corporate leadership at both companies.

iv. MSD has listed MCI as an RPI in other IPRs

Lastly, the Board failed to address that MSD has listed MCI as an RPI in other IPRs involving patents relevant to KEYTRUDA®. *See* MTT, 16 (citing EX2417-EX2425 (*MSD v. Johns Hopkins University* IPRs); IPR2016-01217, -1218, -01219, -01221 (Papers 1 at i-ii) (*MSD v. Ono Pharm.* IPRs). This shows that MSD itself understands that MCI is an RPI.

Although the Board did not discuss those IPRs filed by MSD listing MCI as an RPI, the Board mentioned that Patent Owner filed a complaint against MSD that does not name MCI as a defendant. Order, 16, 21. That litigation is in its infancy, and Halozyme is well within time to amend pleadings to name additional defendants and may do so. Oral Hearing Tr., 9:7-15, 10:3-24.

* * *

Separate from the issue of RPI, Patent Owner intends to appeal the panel's findings in its Final Written Decision should that decision be permitted to stand. It is Patent Owner's understanding, under applicable rules, that its previous June 23 Director Review Request on the panel's interlocutory decision on Patent Owner's

Motion to Terminate resets the time for appeal. In particular, 37 C.F.R. § 42.75(d)(1) provides that a timely request for rehearing or Director Review of a final agency decision prevents that decision from becoming final. Under that reading, in view of Patent Owner's pending June 23 Request on the RPI issue, the Final Written Decision does not constitute a final agency decision for purposes of triggering the notice of appeal period. Indeed, once a Notice of Appeal is filed, jurisdiction over the proceeding transfers to the Court of Appeals for the Federal Circuit and the Office is divested of authority over matters on appeal. *See Loshbough v. Allen*, 359 F.2d 910, 912 (C.C.P.A. 1966). Notwithstanding Patent Owner's understanding that the timing for filing any notice of appeal is already tolled, out of an abundance of caution, Patent Owner submits this Request for Director Review of the Final Written Decision to ensure that the notice of appeal deadline is unambiguously reset under 37 C.F.R. § 42.75(e)(3).

For the foregoing reasons, including in view of the Director's recent decision denying institution in the -087 PGR (with same RPI briefing and underlying evidence as here) (PGR2025-00087, Paper 22 (May 15, 2026)) and for the reasons stated in Patent Owner's June 23 Director Review Request (Paper 137) reproduced above, Patent Owner respectfully requests that the Director grant this request for Director Review, vacate the Board's Final Written Decision, terminate this PGR, and vacate all post-institution decisions.

Respectfully submitted,

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

I certify that the above-captioned **PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW OF THE FINAL WRITTEN DECISION** was served in its entirety on July 8, 2026, upon the following parties via electronic mail:

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