

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyne Inc.,
Patent Owner.

PGR2025-00009
Patent No. 12,123,035

AUTHORIZED RESPONSE TO DIRECTOR REVIEW REQUEST

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I. Introduction

Halozyme’s request for Director Review (Paper 136, “Request”) fails to identify any abuse of discretion, erroneous findings of fact or conclusions of law, or other valid basis for review of either the Board’s Final Written Decision (Paper 135, “FWD”) or denial of Halozyme’s motion to terminate (Paper 123, “Order”).

Notably, Halozyme raises **no arguments** justifying review of the FWD, merely asserting that it “intends to appeal.” Paper 136, 14. And its assertion that Merck & Co., Inc. (“MCI”) has the “*actual* ability to control” the PGR proceedings (see *e.g.*, *id.*, 5-6) is ***uniformly refuted by*** the voluminous evidence in this proceeding, as the Board found in its 24-page Order. Paper 123. The Board thus correctly denied Halozyme’s motion to terminate by finding Petitioner Merck Sharp & Dohme LLC (“MSD”) to be the ***sole*** Real-Party-in-Interest (“RPI”) of this proceeding.

Halozyme’s Request instead simply repackages the same RPI theories that, after ***four*** rounds of briefing, the Board fully considered and rejected as contrary to the evidence and relevant precedents. It thus does nothing more than ask the Director to improperly disregard the extensive (and largely uncontested) evidence along with the Board’s careful weighing of it and witness credibility.

First, while Halozyme claims MCI has the capacity to exert control over these proceedings, the Board cited uncontested evidence that demonstrates the contrary.

That evidence included corporate records and testimony from MCI's Corporate Secretary, Ms. Kelly Grez, [REDACTED]

[REDACTED] Thus, MCI does not, and cannot, intervene in legal proceedings of its subsidiaries (e.g., MSD).

Second, the Board identified uncontested evidence that refutes Halozyme's theory of "blurred corporate lines" between MCI and MSD. Payroll and employment records identified MSD as the sole employer of all individuals Halozyme incorrectly portrayed as acting for both entities. And detailed testimony from Ms. Grez, who herself holds dual roles, explained how corporate distinctions are always maintained.

Third, instead of crediting Halozyme's conjecture based on SEC filings and websites, the Board cited extensive evidence demonstrating that the only entity involved—and with any interest in being involved—in these PGRs is MSD. That evidence included interrogatory responses, business records, and testimony

[REDACTED] Indeed, Halozyme's own conduct in suing only MSD, and not MCI, in district court reinforces what this evidence proves—MSD is the **only** party relevant to these proceedings, and it was properly named the sole RPI.

Finally, the Director's Discretionary Denial of institution in PGR2025-00087 does not, as Halozyme speculates, indicate that the Director reviewed the same RPI

evidence as the Board and reached the opposite conclusion. The institution decision is silent as to the basis of the Director’s decision—it references unidentified “discretionary and other non-merits” reasons. Those may include that the patent at issue in that proceeding was not asserted by Halozyme in litigation or other considerations unrelated to the RPI issue. Another distinction is that the Board and the parties have invested a tremendous amount of resources in this and thirteen other instituted PGR proceedings, four of which so far have resulted in a Final Written Decision (“FWD”) finding all claims unpatentable. Halozyme’s last-ditch effort to avoid cancelation of its remaining patent claims should be denied.

II. Halozyme Fails to Justify Director Review of the Board’s RPI Decision

Halozyme argues this proceeding must be terminated because MCI is an unnamed RPI. Paper 136, 2. The Board’s Order, and extensive underlying evidence, demonstrate that is false. The Board addressed every factor relevant to RPI and provided an exhaustive review of the *entire* evidentiary record submitted by both parties. This included four rounds of briefing, Ms. Grez’s detailed declaration and protracted deposition testimony, and numerous corroborating internal records MSD voluntarily produced. The Board even considered and cited testimony not cited in the parties’ briefs. *See, e.g.*, Order, 23 (“Considering the totality of the arguments and evidence...”); *id.*, 16 (citing EX1225, 73:12-15) (testimony not cited by the parties that Ms. Grez is only an employee of MSD LLC)); *id.* (citing EX1225,

190:4-20) (testimony not cited by the parties that “[r]evocation proceedings in other countries on similar patents” were brought by subsidiaries, not MCI)). The evidence conclusively and uniformly disproves Halozyme’s RPI theory.

A. The Board Correctly Found that MCI Lacks the Ability to Control and Fund the PGRs

In response to Halozyme’s repeated assertions that MCI “effectively did, does, or could have directed, controlled, and funded these proceedings,” (Paper 81, 6; *see also id.*, 8, 13, 17; Paper 91, 2, 4; Paper 136, 3, 10), the Board considered both actual control and funding **and** whether MCI had any opportunity to control or fund these proceedings: as the Board stated, it considered whether MCI “exercised **or could have exercised control**” over MSD’s PTAB proceedings. Order, 4-5. The Board found from the evidence that MCI did not and could not do so, explaining that “control through ownership ... alone does not eviscerate corporate distinctions between a parent and its subsidiaries, particularly where the evidence shows—**as it does here**—those distinctions have **at all times** been maintained with respect to the activity at issue.” *Id.*, 4-5, 9, 16-18, 21 (citing, *inter alia*, EX2402, 1, 8; EX2405-2406; EX2440-2444; EX2430; EX2451; EX1236; EX1242, EX1224, ¶¶ 6, 10, 17-18) (finding MCI lacks actual control and “abundant evidence that MSD personnel, funds, and assets were directly involved in these PGR proceedings, which Petitioner has shown it alone controls”). The Board’s findings regarding MCI’s lack of ability

to control and fund these PGRs were fully consistent with the evidentiary record.

1. The Evidence Confirms Only MSD Has the Ability to Control These Proceedings

The Board correctly found that MCI [REDACTED] [REDACTED] that MSD has a separate governance structure and separate set of officers and directors—facts Halozyme’s Request omits. *Id.*, 13. MSD alone employs all in-house individuals that participate in or direct these proceedings, engaged outside counsel and experts in these proceedings, and provides all funding. *Id.*, 11-13, 18-20 (citing EX1236, EX1238, EX1240, EX1244, EX2401-2406, EX2426-2444). Thus, MSD “alone controls” these proceedings. *Id.*, 21.

The Board thoroughly considered the credibility of Ms. Grez’s testimony. The Board found it was “not conclusory,” contained “considerable explanation ... with citations to supporting exhibits,” and had been “subject to extensive cross-examination by Patent Owner” over a “more than 350-page deposition transcript.” *Id.*, 19. As Ms. Grez explained, MCI has no practical way or reason to control MSD’s PTAB proceedings [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] EX1224, ¶¶ 21-25; EX1225, 80:9-83:15,

84:8-85:5, 92:5-10, 97:8-98:24, 100:6-14, 294:17-295:21, 307:18-308:22, 311:23-312:16, 313:13-20, 314:8-315:8, 330:18-331:22, 346:18-347:5.

The Board thoroughly considered and rejected Halozyme’s arguments that MCI’s “corporate documents” and legal leadership and authority structure give it the actual ability to direct the strategy and conduct of these PGRs” (Paper 136, 4-5). Order, 6 (citing PO Suppl. Br. (Paper 120), 1) (considering Halozyme’s argument that “MCI’s corporate documents delegate control, including over patent matters, to dual-role personnel”); *see also id.*, 7-8 (citing Paper 120, 4-5) (considering “resolutions authorizing dual role MCI officers/MSD employees—including Mr. Davis and Ms. Zachary (both of whom have dual roles)—to ‘execute and to revoke’ documents related to any patent matters, including with respect to litigation, on behalf of both MCI and its affiliates, including MSD”).

As the Board recognized, the fact that Ms. Zachary wears two hats, with distinct responsibilities for MCI (e.g., signing SEC disclosures) versus MSD (e.g.,

outside counsel engagements), is the **converse** of an employee of the parent engaged actively in its subsidiary's proceedings. *Id.*, 11-12, 20. The Board was "not persuaded by Patent Owner's arguments regarding the role of Ms. Zachary or other employees as both officers of MCI and as employees of MSD," instead finding the evidence confirmed corporate "distinctions" had been maintained "at all times," including with respect to the PGRs. *Id.*, 18, 20.

That finding was fully consistent with the evidentiary record explaining the relationship between these entities. As the Board observed, the evidence shows

“the two companies have separate governance structures, and their own sets of officers and directors,” which “differ significantly.” *Id.*, 13-15, 17-18 (citing, *inter alia*, Paper 120, 2; EX1224, ¶¶ 6, 8; and *Daifuku Co. v. Murata Mach., Ltd.*, IPR2015-01538, Paper 11 at 11 (PTAB Jan. 19, 2016)).

The Board also credited evidence confirming that “the parent-subsidary relationship[] among MCI and MSD” did not extend beyond MCI’s “legal status of stockholder[]” in MSD. Order, 17-18. That status, if sufficient to confer RPI status, would “eviscerate corporate distinctions between a parent and its subsidiaries.” *Id.* (citing *U.S. v. Bestfoods*, 524 U.S. 51, 61 (1998)). As the Board explained, “the

exercise or availability of general ‘control’ that stock ownership vests in stockholders, such as in the parent-subsidary relationships among MCI and MSD, which includes the election of directors, the making of by-laws, and other acts incident to the legal status of stockholders, will not make one company a real party in interest of the other.” *Id.*, 17 (citing *Bestfoods*, 524 U.S. at 61-62).

Halozyne’s attempt to paint routine corporate governance documents between a parent and subsidiary as evidence of “an officer at the parent engaged in active operations (this PGR) for its subsidiary” is fiction. Paper 136, 5. The 2009 restructuring that created MCI and MSD as distinct entities (Paper 88, 21 n.4) may have given MCI power over appointment of MSD’s managers, but it did not make MCI “liab[le] for its subsidiary’s acts.” Order, 17 (citing *Bestfoods*, 524 U.S. at 69). And since the initial separation of MCI and MSD into distinct corporate entities,

[REDACTED]

[REDACTED]

[REDACTED] *Id.*, 13, 20-21; EX1224, ¶¶ 6-10, 23, 26-28. MSD is solely responsible for human health business operations in the United States—including Keytruda QLEX™, the product relevant to this dispute, including conduct of legal proceedings. EX1224, ¶¶ 26-28. Thus, MCI has neither the ability nor any reason to control MSD’s actions, including in these PGRs.

2. The Board Did Not Overlook or Misapprehend Halozyme's Arguments Regarding MCI's Consolidated SEC Filings

The Board thoroughly considered and rejected Halozyme's contentions (Paper 81, 1-3, 8-13, 15, 17-18; Paper 91, 1-4) regarding MCI's consolidated SEC filings, thus disproving Halozyme's assertion that the "Board overlooked this evidence entirely." Order, 5-7, 13-14, 22-23; Paper 136, 6-8. Most directly, the Board found credible Ms. Grez's testimony that the use of "Merck" or "the Company" in SEC statements refers to *all* subsidiaries of MCI collectively. Order, 13-14, 22-23 (citing EX1224, ¶¶ 31-32) ("[W]e find that in view of the totality of the circumstances here, the collective language in SEC filings does not demonstrate that the activities described therein are attributable to MCI specifically, much less that MCI directs, controls, or funds these PGRs."). Citing precedent from the Office and federal courts, the Board found Ms. Grez's testimony to be consistent with "common business practice" that was allowed *and recommended* by the IRS, SEC, and generally accepted accounting principles. *Id.*, 23 (citations omitted).

The Board also correctly found that Ms. Grez's testimony disproves Halozyme's speculation that legal defense reserves described in SEC filings demonstrate that MCI funds these proceedings. Paper 136, 7; Paper 81, 11-13; Order, 6-7. [REDACTED]

[REDACTED]

3. The Board Thoroughly Considered Halozyme’s Allegations of “Blurred Lines”

The evidence also refutes Halozyme’s repeated “blurred lines” assertions. Paper 136, 9-10; Paper 81, 3, 13-16; Paper 91, 4-5; Paper 120, 1-2 n.2; Order, 6-7, 11-12, 15-16, 18-21. For example, the Board thoroughly considered evidence regarding Ms. Zachary’s employment. Order, 11 (citing EX1236; EX1242); *see also id.*, 10 (citing EX2431; EX2451; EX1236; EX1242). The Board correctly found that she “wears multiple hats serving as general counsel for both MSD and MCI” and that the “line of demarcation was made clear” as to when Ms. Zachary is representing each entity. *Id.*, 11, 20. This finding was fully consistent with the testimony of Ms. Grez (who also holds dual roles at MSD and MCI), who explained how “employee” and “officer” roles are separate and distinct. EX1224, ¶¶ 18-23; EX1225, 80:9-83:15, 84:8-85:5, 92:5-10, 97:8-98:24. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The MSD in-house employees charged with direction of these PGRs report to Ms. Zachary only within her MSD role. EX1224, ¶ 22; Order, 12-13, 20.

The fact that, as officers of MCI and employees of MSD, Ms. Zachary and Ms. Grez “may sign on behalf of MCI” when conducting duties for MCI, such as when signing SEC filings (Paper 136, 10; Paper 81, 2, 9-10; Paper 91, 1; Paper 120, 4-5), **confirms** the clear demarcation of duties between their roles at MCI and MSD. Order, 15, 20. Indeed, when conducting duties on behalf of MSD, such as retaining outside patent counsel, Ms. Zachary **clearly** identified that she was doing so **in her capacity at MSD**. *Id.* 12, 20 (citing EX2400, 86; EX2402, 8). Ms. Zachary is “careful to note which ‘hat’ she is wearing in the relevant documentation.” *Id.*, 20.

The Board also thoroughly considered Halozyme’s other “blurred lines” allegations, including its cherrypicked examples of public statements or LinkedIn pages where MSD LLC employees inadvertently misidentified their employer. *See* Paper 136, 11; Paper 81, 2, 14-15; Paper 91, 3-4; Paper 120; Order, 11-13, 15-16, 18-19. Ms. Grez unequivocally confirmed that any such postings listing MCI as a person’s employer were “incorrect,” [REDACTED] EX1225, 338:25-339:16. The Board credited that testimony, and it further explained that inadvertent misidentification by select employees “does not rise to the level of legal significance as employment agreements, paystubs, and signed legal agreements with outside counsel,” all of which MSD voluntarily produced for the employees involved in these PGRs. Order, 19; EX1224, ¶ 17 (compiling internal documents). The Board also found credible Ms. Grez’s explanations why employees may have mistakenly

stated their corporate affiliations. *Id.*, 17 n.5, 19 n.6; EX1224, ¶¶ 11-16.

The Board's rejection of Halozyme's arguments regarding MSD's VP of Global IP Litigation, Mark Stewart (Paper 120, 5; Paper 136, 13-14), is also fully supported by the evidence. Order, 16, 20-21. For example, the Board recognized that Mr. Stewart had attended foreign patent revocation proceedings that were brought by other MCI subsidiaries ("not MCI itself"), but found his mere participation did not establish that Mr. Stewart was "require[d]... to act directly on behalf of MCI." *Id.*, 20-21 (citing EX1225, 190:4-20; EX1224, ¶ 34). This finding was fully consistent with Ms. Grez's testimony that Mr. Stewart does not report to anyone in their capacity as an officer of MCI [REDACTED] *Id.*, 20 (citing EX1225, 194:1-5); EX1224, ¶¶ 8-9. As Ms. Grez testified, Mr. Stewart's appearance on behalf of "Merck" in a German court also is not evidence of him representing MCI. *Id.*, 8 (citing EX1225, 205:18-210:17).

Finally, that MCI may have been named as an RPI in unrelated proceedings (Paper 136, 14), such as where MCI was named a defendant in a related litigation out of an abundance of caution, does not make MCI an RPI to these PGRs. Paper 81, 16; Paper 88, 12. Indeed, Halozyme's current position here is irreconcilable with positions taken by its own counsel, who named MSD as the only RPI in other Keytruda®-related PGR proceedings where it represented MSD. Paper 88, 12 (citing EX1164, EX1165, EX2058). The Board also found Halozyme's arguments

inconsistent with its conduct in the parallel New Jersey litigation, where Halozyme named only MSD as defendant despite having access to the SEC filings it now relies upon to allege confusion. As the Board observed, “even Patent Owner has treated MCI and MSD as distinct entities.” Order, 21 (citing EX2058, 1).

B. The Board’s Order Is Consistent with All Relevant RPI Authority

Without a legitimate response to the robust evidence confirming the Board’s RPI analysis, Halozyme presumes the Director’s non-institution decision in a related proceeding is proof that the Director has already found in its favor. Paper 136, 1-2, 15. Halozyme ignores that the institution decision in the -087 proceeding says *nothing* about RPI issues. The Director has significant discretion to deny institution for many reasons unrelated to RPI, including allocation of Office resources. That the -087 proceeding was denied institution for “discretionary and non-merits considerations” does not compel the conclusion that the Director reached an inconsistent conclusion with the Board regarding RPI. PGR2025-00087, Paper 22 (Director, May 15, 2026). The circumstances in these 14 *instituted* proceedings are simply different than in the -087 proceeding.

Importantly, “the facts here are [also] quite different” from those in *Corning*, as the Board observed. Order, 18-19 (citing *Corning Optical Commc’ns RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 at 17-22 (PTAB Aug. 18, 2015) (precedential)). Petitioner and its parent in *Corning* were structured to give the

parent the opportunity to control the proceeding. As the Board observed, “[i]n *Corning*, there was evidence that employees managed the same product line at both the parent and subsidiary, that engagement letters with outside counsel referred to both entities, that the corporate parent funded the litigation, and that counsel for the corporate parent provided direction to outside counsel.” *Id.*, 18. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Halozyme’s RPI theory would effectively make any corporate parent an RPI. As the Board correctly reasoned, this cannot possibly be correct given *Corning*’s holding that mere status as “the ultimate parent of Petitioner is **not** sufficient evidence” to show that the parent “exerts control over these proceedings.” *Id.*, 16 (quoting *Corning*, 22 (emphasis added)); see also *Tianma Microelectronics Co. v. LG Display Co.*, IPR2025-01579, Paper 12 at 8 n.6 (Director Mar. 18, 2026) (precedential) (“*Tianma*”) (“percentage ownership (whether greater or lesser than 10%) is not necessarily dispositive of the RPI inquiry.”); *Gillig v. Nike, Inc.*, 602 F.3d 1354, 1362 (Fed. Cir. 2010) (“[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.”).

The facts here create a stark distinction from those in *Sun*, where petitioner’s

declarant focused only on whether its parent company was “*actually* funding or controlling the proceeding” and ignored whether it had the “*ability* to control” those proceedings. *Sun Pharm. Indus., Inc. v. Biofrontera Inc.*, PGR2026-00021, Paper 12 at 2-3 (Director May 26, 2026). As discussed above, Ms. Grez’s testimony takes that issue head on and shows that MCI does ***not have the ability*** to control these proceedings. See Paper 117, 1-2; EX1224, ¶¶ 8-9, 22-23. Unlike *Tianma*, Ms. Grez’s testimony “provided significant documentary evidence,” “[wa]s not conclusory,” “provide[d] considerable explanation ... with citations to supporting exhibits,” and was “subject to extensive cross-examination.” Order, 19 (citing *Tianma*, 10).¹

III. Conclusion

Halozyme identifies ***no decisions*** terminating proceedings where a petitioner filed such robust evidence to support its representation that it is the sole RPI because there are none. Halozyme’s Request for review of the Board’s decisions should be denied.

¹ *Aylo Freesites Ltd. v. DISH Techs. LLC*, IPR2024-00940, Paper 75 at 1-3

(Director, Feb. 3, 2026), cited by Halozyme (Paper 136, 1), is also inapposite.

Unlike here, the *Aylo* Board found that the unnamed party ***was*** an RPI, and the petitioner’s attempt to rectify that error resulted in a time bar. *Id.*

Dated: July 17, 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 17 day of July 2026, I caused to be served a true and correct copy of the foregoing by email on the following counsel:

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