UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner

v.

HALOZYME INC.,
Patent Owner

Case IPR2026-00314
U.S. Patent No. 11,066,656

PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW OF THE INSTITUTION DECISION

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I. INTRODUCTION

Halozyme, Inc. requests Director Review of the September 9, 2026 Institution Decision ("Institution Decision"), which should be vacated for three reasons.

First, institution here is contrary to the purpose of IPRs and rewards Petitioner's strategic delay. Halozyme spent over a decade developing the claimed technology, and the '656 patent had been in force for nearly five years when Petitioner filed this IPR. Petitioner knew of the patent family—in fact pursued licensing discussions with Halozyme—and was developing subcutaneous KEYTRUDA, which includes a modified PH20 polypeptide, when the patent issued. Yet Petitioner let the PGR window close and waited until March 2026—after it had filed 15 PGRs over the course of 12 months—to challenge the '656 patent on what are effectively § 112 grounds. Petitioner does not raise any new art or identify any Examiner error—indeed, it does not even argue anyone other than Halozyme has ever innovated as to PH20. Its Petition is a PGR petition in disguise. Institution gives Petitioner a pass for years of inaction and rewards Petitioner's abuse of the Patent Office's review processes. Institution should be vacated.

Second, the Petition is defective because Petitioner did not identify Merck & Co., Inc. ("MCI") as a real party-in-interest and thus has not satisfied the statutory requirements of § 312(a)(2). Institution here appears to be in tension with the Director's denial of institution in PGR2025-00087. There, the only issue raised by

Halozyme was Petitioner's failure to name MCI as a real party in interest, and the Director denied institution. The factual record here is identical, and as in PGR2025-00087, Halozyme has raised the RPI issue since the start of the proceedings. There is no way to reconcile institution here with denial in PGR2025-00087. As it stands, it appears that MCI is being treated as an RPI and not-an-RPI on the same set of facts, completely occluding the clarity the Director has otherwise sought to bring to RPI issues, including in current jurisprudence. For example, the Director's recent *Sun* and *Viance* decisions conflict with any determination that MCI (which clearly has the ability to control this IPR, as evidence establishes) is not an RPI. Institution should have been denied based on the RPI issue alone.

Third, Petitioner grounds its priority attack on a claim construction that the PTAB has declined to adopt across 14 related proceedings for the same claim term, despite Petitioner repeatedly arguing that it should be adopted. Yet the Director inexplicably appears to accept Petitioner's arguments and evidence applying that rejected construction in its IPR Petition. Specifically, in 14 of the PGRs already filed and 9 of its FWDs, the PTAB has performed a full claim construction analysis and construed the phrase "modified PH20 polypeptide" to require only "***some hyaluronidase activity***." In each of those proceedings, and in this IPR petition, Petitioner argued at length that "modified PH20 polypeptide" also required "proper folding" of PH20. *See* Section IV. Petitioner adopted this position as a matter of

gamesmanship, apparently to hedge its bets should it need to invent a non-infringement position in the district court proceedings. But in each PGR proceeding, the PTAB declined to adopt the additional requirement imposed by that construction.

Instituting here looks right past the inconsistency between Petitioner's grounds and expert testimony—all of which were founded on arguments about "proper folding"—and the PTAB's own prior constructions. Treated properly, Petitioner's expert testimony based on a rejected construction has no relevance. As binding case law indicates, the authority granted to the PTO "is not so broad that it allows the PTO to raise, address, and decide unpatentability theories never presented by the petitioner and not supported by record evidence." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016).

II. INSTITUTION IS CONTRARY TO THE PURPOSE OF IPRS, DISREGARDS SETTLED EXPECTATIONS, AND REWARDS PETITIONER'S ABUSE OF POST-GRANT REVIEW PROCESSES

Halozyme is an American biotechnology company founded in 1998 that has devoted itself to developing innovative technologies. And Halozyme has done what all technology companies do—file patent applications that disclose its inventions to the public in exchange for the protection that a patent claim provides. Halozyme also has licensed its technology to numerous American companies who use that technology to make important American products. For example, Halozyme's US licensee Bristol Myers Squibb ("BMS") sells OPDIVO QVANTIG, which is

manufactured in the US. EX2023, 3.

In fact, Petitioner engaged Halozyme in licensing discussions in 2009 and again in 2015 regarding Halozyme's portfolio. EX2019, 21. But instead of licensing from the U.S. company Halozyme, Petitioner elected to source foreign hyaluronidase for its subcutaneous KEYTRUDA product ("QLEX"). As early as June 2020, Petitioner entered a license with Alteogen (a Korean company) to use Alteogen's "ALT-B4" PH20. EX2020, 2; EX2021, 2. Not only did Petitioner elect to shop abroad for its copycat modified PH20, Petitioner also chose to manufacture QLEX in Italy. Petitioner's product made with imported modified PH20 thus competes with BMS's American-made product.

Halozyme invested a decade in developing the claimed technology, and the '656 patent was in force for nearly five years when Petitioner filed this IPR. Petitioner knew of the patent family since at least 2020 and had pursued licensing discussions with Halozyme. Yet Petitioner let the PGR window close and waited until March 2026—nearly a year-and-a-half after filing its first PGR—to challenge the patent.

Institution here rewards that delay and invites repeated attacks on patent owners' collective rights, undermining the settled expectations the Office has pledged to protect. This type of behavior is "unfair to patent owners and is an inefficient use" of AIA trials. *General Plastic Indus. Co., Ltd. v. Canon Kabushiki*

Kaisha, IPR2016-01357, Paper 19 at 17-18 (PTAB, Sept. 6, 2017) (precedential). It also allows Petitioner to engage in "road mapping" by taking advantage of the developed record during prior proceedings. *See id.* at 17-18 (explaining that "strategically stag[ing] their prior art and arguments in multiple petitions, using our decisions as a roadmap" is unfair to Patent Owner and an inefficient use of IPRs).

Moreover, the Office favors PGRs precisely "because they must be filed no later than nine months from the grant of the patent … are close in time to examination, and occur before expectations in the patent rights are strongly settled." *Multi-Color Corp. v. Brook & Whittle Ltd.*, PGR2025-00025, Paper 10 at 2-3 (Acting Dir., July 16, 2025) (precedential). Petitioner knew or should have known about the '656 patent when it issued in July 2021. Petitioner could have asserted § 112 challenges during the '656 patent's 2021-2022 PGR window but chose not to—opting instead to file an IPR petition years later to upend settled expectations.

Petitioner's decision to wait to file its challenge is made more egregious by the fact that this IPR is really a PGR in disguise. Petitioner did not discover new prior art requiring review, and it does not assert that ***anyone*** other than Halozyme innovated as to PH20. Instead, the Petition repackages recycled § 112 assertions that should have been brought in a PGR as an "anticipation" ground via a priority challenge to the PGR-ineligible '656 patent. Petitioner cites no new prior art, relying instead on the '656 patent's own intervening published specification. The Petition is

a thinly veiled § 112 challenge that does not identify or seek to correct any real Examiner error. It is thus far outside the core purpose of IPRs.

III. INSTITUTION CONTRADICTS PRIOR DIRECTOR DECISIONS

MCI is a real party in interest, and the decision to institute here cannot be reconciled with other recent RPI decisions. Nor can it be reconciled with the decision to deny institution in PGR2025-00087, involving the same parties and the same underlying facts. Institution here effectively results in MCI being treated as a RPI in PGR2025-00087, but not in this proceeding. Moreover, as discussed below, treating MCI as an RPI is the only result consistent with the Director's recent decisions in *Viance, LLC v. Koppers Performance Chemicals, Inc.*, PGR2026-00023, Paper 32, 3–4 (Director Aug. 19, 2026), and *Sun Pharmaceutical Industries, Inc. v. Biofrontera Inc.*, PGR2026-00021, Paper 12, 2–3 (Director May 26, 2026). The Director should address MCI's RPI status and de-institute.

First*,** in response to Petitioner's recent petition (PGR2025-00087), Halozyme raised ***only the RPI issue in its Preliminary Response, and the Director denied institution following briefing from both parties and a complete evidentiary record on that single issue. *Id.*, Paper 22 (May 15, 2026) ("the -087 PGR"). The relevant facts concerning Petitioner's relationship with MCI here are ***identical*** to those presented in the -087 PGR, and the parties here advanced the same arguments concerning the same RPI issue as in the -087 PGR. Yet the Director instituted here.

For example, in this IPR (and its companions) and in the -087 PGR, the parties submitted the same arguments and evidence after the PTAB authorized Petitioner to submit a witness declaration on the RPI issue. Papers 10, 16; -087 PGR, EX3101-02, Papers 13, 16. In both the -087 PGR and this IPR, Halozyme raised the same concerns regarding RPI, Petitioner filed the same single declaration by Ms. Kelly Grez, Halozyme cross-examined Ms. Grez in a single deposition, and the parties provided the same arguments in briefing based on that testimony. *Id*. And, like the -087 PGR, Halozyme raised the RPI issue from the outset of proceedings here.

In short, by denying institution after receiving the RPI briefing in the -087 PGR, the Director effectively resolved the RPI issue on a materially identical record. Accordingly, as in the -087 PGR, institution should have been denied because the facts are identical and the Petition fails to name all RPI. *See Corning Optical Comms. RF, LLC v. PPC Broadband, Inc*., IPR2014-00440, Paper 68 at 24-25 (P.T.A.B. Aug. 18, 2015); 35 U.S.C. § 312(a)(2). MCI has been, for all intents and purposes, treated as both an RPI and not as an RPI on the same facts. The Director should not let that inconsistency stand.

***Second*,** treating MCI as an RPI is the only consistent result in view of the Director's recent decisions in *Viance* and *Sun Pharmaceutical*. In *Viance*, the Director concluded that "Petitioner's corporate owner Venator is an unnamed RPI" where "(1) Venator is Petitioner's majority owner, (2) Venator is the 'clear

beneficiary' of this proceeding, and (3) Venator could exercise control over the proceeding." *Viance* at 2. Petitioner argued that "its two owners do not have unilateral control of Petitioner," but the Director rejected that argument as "not the standard" and further clarified that "as I previously explained, RPIs are not limited to entities that are actually funding and controlling the proceeding ***but include entities that have the ability to control the proceeding***." *Id.* at 3 (emphasis added).

Similarly, in *Sun*, the Director agreed with patent owner that petitioner's parent company, which owned "100%" of petitioner, was an unnamed RPI. *Sun* at 3. In that case, in addition to 100% ownership, the Director noted that the parent company "consolidates its financial statements with [Petitioner] and other related subsidiaries, issues press releases in the name of [Petitioner] and otherwise shares common interests." *Id.* at 2. In response, petitioner provided evidence that it was "solely funding and controlling the instant proceeding." *Id.* But the Director rejected petitioner's evidence, explaining that "RPIs are not limited to entities that are actually funding and controlling the proceeding, ***but include entities that have the ability to control the proceeding***." *Id.* The Director concluded "[o]n this record, Petitioner fails to carry its burden to establish that it has identified all RPIs." *Id.*, 3.

Here, the facts show MCI is in the same position as the RPIs in *Viance* and *Sun* (and in the -087 PGR), and clearly has the ability to control these proceedings. Specifically, MCI is a "global pharmaceutical company with more than $200 billion

in market cap" that operates through its subsidiaries. EX2027, 57:16-19, 126:16-20, 129:6-15. MCI itself is a holding company that "is responsible for the global enterprise … [and] the business of that enterprise is conducted through subsidiaries." *Id*., 106:21-107:6; EX2014-15. Petitioner MSD is the "main U.S. operating entity for [MCI's] human health business," (EX2027, 58:10-13), and MCI operates through MSD.

MCI not only has the ability to, but in fact does, control MSD. MCI is the "sole owner" of MSD and appoints (and can remove) the Board of managers that controls MSD. EX2027, 63:17-25, 65:8-67:12. In fact, two of the three MSD managers also serve as MCI officers. *Id.*, 347:10-23, 348:18-23. For instance, MSD's president and manager, Dalton Smart, is MCI's global controller. *Id.*, 347:10-16. And seven of the officers that control MSD's "day-to-day operations" are MCI personnel. *Id.*, 54:10-54:17, 348:3-365:15.

MCI's oversight and control over MSD extend to this IPR. Specifically, MCI passed resolutions authorizing MCI's CEO Robert Davis and general counsel Jennifer Zachary to "execute and to revoke" documents related to *any* patent matters on behalf of both MCI and MSD, which cover this IPR. *Id.*, 241:20–248:4. Ms. Zachary in particular has "responsibility" for litigation, including authority to settle this IPR. *Id*., 295:3-21, 305:12-15. It would be error to ignore the evidence that MCI authorized ***its CEO and general counsel*** to control this IPR proceeding.

MCI thus has the ability to control MSD and these proceedings, whether it is actually controlling them or not. Consistent with *Sun* and *Viance*, MCI should be found an RPI, and the Director should not let the Institution Decision stand for this additional reason. To let it stand would only confuse an issue the Director's recent decisions have otherwise set straight.

IV. PETITIONER'S GROUNDS ARE FOUNDED ON A CONSTRUCTION REJECTED BY THE PTAB IN 10 FWDS

In 14 of the related PGRs and 9 FWDs (i.e. a total of 23 times), the PTAB has performed a full claim construction analysis and consistently construed the phrase "modified PH20 polypeptide" to require "polypeptides with ***some hyaluronidase activity***." PGR2025-00017, Paper 106, 11, 24-27.

In providing that construction, the PTAB rejected the position set forth by Petitioner and its expert: that that term also requires "modified PH20 polypeptides" to be "properly" or "stably" "folded." -17 PGR, Paper 106, 14–15, 42-45, 24-27. Petitioner spent significant time arguing this particular issue at the oral hearing in the PGRs (-17 PGR, EX1278, 19-22, 66-69, Paper 107, 14:4–7, 14:13–17, 16:6-13; EX2035, ¶¶ 101, 104), but the PTAB did not accept that position in any FWD. That is because Petitioner's position has no basis whatsoever in the claims or intrinsic evidence: the words "folded," "properly folded" and "proper folding" do not appear in the specification, and Petitioner itself has previously argued that the specification provides "no evidence of proteins in supernatants or their folded state." EX2034, 33.

Yet, Petitioner founded its priority attack in this IPR on the "properly folded"/"stably folded" claim construction, not on the PTAB's construction. This creates significant issues warranting vacatur of the Institution Decision. There is no way to square the PTAB's rejection of Petitioner's claim construction position on "proper folding" in its FWDs with the acceptance of Petitioner's grounds here based on similar claim language, and the PTAB cannot and should not make up grounds or arguments that are not supplied by the Petitioner. Furthermore, Petitioner should not be allowed to engage in gamesmanship regarding claim construction.

Despite the PTAB's construction of "modified PH20 polypeptide," Petitioner and its expert founded their priority attack on a different construction—the one Petitioner advocated for in the prior hearings but was not adopted by the PTAB—that the "modified PH20 polypeptide" must "properly" or "stably" "fold."

Petitioner's expert states in his declaration that he is "reading 'modified PH20 polypeptide' to mean a stably folded protein." (EX1003, ¶ 206; *see also id*. at ¶¶ 203-207) ("Stable folding is what differentiates a 'PH20 polypeptide' from being just a '(poly)peptide.'"). He previously testified that "stable" or "proper" folding requires activity after 8-12 hours. -17 PGR, EX2038, 180:3–19, 252:6–10. Petitioner relies on that claim construction in its petition to argue that the specification does not provide § 112 support because of a POSA's alleged inability to know "what portion of the claims' sequence space **will properly fold** and exhibit increased

activity" and because the specification "does not otherwise guide a POSA to select combinations of changes (substitutions, deletions and additions) **that will yield properly folded**, enzymatically active PH20s." Pet., 3-4 (emphasis added).

Petitioner's § 112 challenge is based on a claim construction the PTAB has repeatedly declined to adopt. As a result, Petitioner has supplied no evidence that the challenged claims as construed by the PTAB are not entitled to the benefit of priority of the earlier-filed applications. Specifically, to perform a priority analysis, Petitioner had to properly construe the claims. *Uniloc USA, Inc. v. Sega of America, Inc.*, 711 Fed.Appx. 986, 990 (Fed. Cir. 2017) ("When determining priority, the Board must first construe the relevant claim terms.") Yet Petitioner did not do so. Petitioner willfully refused to adopt or address the PTAB's prior construction (requiring only "some hyaluronidase activity") and added its own requirement—that of "proper folding." But whether the earlier-filed applications support claims requiring "some hyaluronidase activity" is a significantly different question than whether they support claims that require both increased hyaluronidase activity ***and*** proper folding. Petitioner supplied no evidence on the first question under the PTAB's construction, and its Petition fails for that simple reason alone.

To institute IPR proceedings, the Director must conclude that Petitioner establishes a reasonable likelihood of success as it pertains to its priority date underpinning the anticipation ground. But that is impossible because Petitioner's

priority date evidence is based on the "properly folded" construction that the PTAB declined to adopt and Petitioner failed to address. Thus, the Director could not have concluded that Petitioner can establish the claims lack priority under the "at least some hyaluronidase activity" claim construction. To do so would have been error because Petitioner presented no such evidence as it relates to that claim construction. *Magnum Oil Tools* 829 F.3d at 1381 ("[W]hile the PTO has broad authority to establish procedures for revisiting earlier-granted patents in IPRs, that authority is not so broad that it allows the PTO to raise, address, and decide unpatentability theories never presented by the petitioner and not supported by record evidence.")

Petitioner's use of a different claim construction than the one adopted raises a second issue as well: gamesmanship. Petitioner and Halozyme are involved in a related district court case, and Petitioner's shifting claim constructions suggest it is trying to preserve a non-infringement position for that case.

The timing here is telling. The PTAB issued 14 prior Institution Decisions putting Petitioner on notice of the PTAB's preliminary construction of "modified PH20 polypeptide" requiring "some" hyaluronidase activity (*e.g.,* -17 PGR, Paper 31, 17) before Petitioner ever filed its Petition here. But the PTAB had not yet issued any FWDs on patentability before Petitioner filed its IPRs (or else face a statutory bar). So Petitioner hedged, because it was not sure it would win in the PGRs on its construction. Rather than adopt the PTAB's construction, Petitioner pressed a

different construction with an additional "proper folding" requirement that it apparently believes would support a non-infringement position. That way, if Petitioner lost its PGRs and the related IPRs, it could still claim (1) the PTAB's construction was not binding on the district court and, (2) it had never acceded to the PTAB's preliminary construction. Presumably, it wants to argue that the copycat modified PH20 it uses is not "properly folded."

This kind of gamesmanship should not be tolerated. The PTAB requires petitioners to "choose a single claim construction that best captures the true meaning of the patent claim." *Revvo Technologies, Inc. v. Cerebrum Sensor Technologies, Inc.,* IPR2025-00632, Paper 20, at 3 (Director, November 3, 2025). Petitioner refuses to do so, instead preserving its ability to pursue a different claim construction in district court. As the Director has explained, "you can't have it both ways and certainly not without a sufficient explanation." *Id.*

Petitioner's construction here is simply "an assertion that a petitioner should be permitted to raise different claim constructions in the two forums when there is a chance that the district court will reject that petitioner's preferred construction … The appropriate course of action under these circumstances is to deny institution." *Revvo*, at 4.; *Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00340, Paper 18 at 3 (Director Nov. 5, 2025).

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 INSTITUTION DECISION** was served in its entirety on October 9, 2026, upon the following parties via electronic mail:

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