UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyme, Inc.,
Patent Owner.

IPR2026-00313
Patent No. 11,041,149

AUTHORIZED RESPONSE TO DIRECTOR REVIEW REQUEST

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I. Introduction

Halozyme's Request (Paper 26, "Br.") asks the Director to vacate his own decision instituting this and two related IPRs (Paper 23, "ID"). It fails to identify any abuse of discretion, misapprehension of fact or law, or any other basis for review.

IPR2026-00313 concerns U.S. Patent No. 11,041,149 (the '149 Patent). The challenged claims of the '149 Patent are substantively indistinguishable from those in ***eleven*** family members that have been either disclaimed by Halozyme or found unpatentable under 35 U.S.C. § 112 by the Board in final written decisions (FWDs).[1] Appeals of four of those FWDs are now pending before the Federal Circuit, and FWDs in three other proceedings will issue soon. Most notably, all but one challenged claim in the '149 Patent ***expressly*** requires modified PH20 polypeptides that are enzymatically active. In short, the merits here are exceptionally strong.

This Request repackages arguments that Halozyme presented in its discretionary denial brief and preliminary patent owner response (Papers 10 ("DD Br."), 14 ("POPR")) (as well as in its requests for Director Review in the related PGR FWDs). Merck thoroughly explained why those arguments are wrong (Paper 16, "DD Reply"). The Director then correctly denied Halozyme's request for

[1] Trials in IPR2026-00312 and -00314 based on patents with the same disclosure and highly similar claims were instituted on the same date as -00313.

discretionary denial (Paper 22), and instituted after finding a reasonable likelihood Merck would prevail on the merits and that "no other non-discretionary considerations warrant denial of institution" (ID, 2). Halozyme identifies nothing the Director failed to consider. It simply disagrees with the result.

First, Halozyme complains of delay, settled-expectations, "abuse" of the patent system, and the petitions being a "PGR in disguise." (Br., 1, 3-6). These are discretionary denial arguments the Director already considered. *See* DD Br., 2-4, 11-20; POPR, 4-9. Halozyme also has it backwards—***Halozyme*** is the party abusing the patent system through impossibly broad claims encompassing immense numbers of modified PH20 proteins it never made, did not describe and cannot enable. Halozyme also ignores well-established precedent finding it proper to raise anticipation grounds in an IPR proceeding when the disclosure of a priority application fails to describe and enable what is being claimed. The Board has found a lack of written description and enablement support for similar claims in in ***eleven*** FWDs to date, and the evidence demonstrates that is true for these challenged claims, too. Because the claims are not entitled to either the benefit of or priority to any earlier-filed application, they are anticipated by US-275's disclosure of increased activity single substitution mutants. *See, e.g.*, *Indivior UK Ltd. v. Dr. Reddy's Labs. S.A.*, 18 F.4th 1323, 1330 (Fed. Cir. 2021); Pet., 28-29 (compiling additional cases).

Halozyme's arguments also rest on false premises: (i) it has ***never*** licensed

modified PH20s under the '149 Patent (or any other patent being challenged in Merck's PGR and IPR proceedings); and (ii) the novel hyaluronidase in Merck's product is ***not*** a "copycat" of Halozyme's product. Contrary to its assertions, Halozyme has never commercialized a modified PH20 within the scope of any claim of the patents Merck is challenging, and it is undisputed that Halozyme's product (a truncated native human sequence PH20) is not claimed by those patents. DD Reply, 9-10. The hyaluronidase in Merck's product combines numerous amino acid substitutions and both N- and C-terminal truncations that Halozyme's patents never suggested. *Id.* at 10-11. Merck also did not "delay" in filing these petitions or change its positions. *Id.* at 14-20. Merck's § 112 arguments are the same ones advanced in the PGRs—Halozyme even labels them "recycled." Br., 5. And in the 16 months preceding the IPRs, Merck was preparing and litigating ***15*** PGR challenges, and filed these IPRs within the one-year statutory window. DD Reply, 14-16.

Second, Halozyme's RPI argument (Br., 6-10) is the same theory the Board ***thoroughly rejected*** in a detailed 24-page Order based on a wealth of evidence the Board thoroughly considered and weighed. PGR2025-00003, Paper 131 ("Order"). The Director declined to disturb that Order in four related PGRs (PGR2025-00003, -04, -06, -09). Halozyme's RPI arguments here are substantively indistinguishable from those in its discretionary denial ***and*** POPR briefs before institution of these IPRs. DD Br., 4-11; POPR, 12-19. As Halozyme concedes, "[t]he factual record here

is identical." Br., 2. There is also no difference in applicable law. *Viance* and *Sun* are the Director's own decisions. *Sun* was raised during discretionary denial briefing (DD Br., 10; DD Reply, 9), and both decisions are distinguishable on the evidence.

Finally, Halozyme's claim construction arguments mischaracterize the record. Br., 10-14. The Board did not "reject[]" Merck's construction; it ***expressly*** adopted it. *See, e.g.*, DD Reply, 18-20; PGR2025-00003, Paper 128 (FWD), 23 ("Thus, ***we agree with Petitioner*** that the term, interpreted in light of the Specification, requires at least some hyaluronidase activity.").[2] The testimony of Merck's expert, Dr. Naismith, fully supports that construction, as does that of Halozyme's own expert who testified that PH20s must be "properly folded" to have activity, as the claims require. DD Reply, 18-20. Halozyme's allegation that Merck is advancing inconsistent claim constructions here and in the district court, and that Merck is engaging in "gamesmanship" are without merit: Merck's claim construction positions have been consistent across all PGR and IPR proceedings, and the district court case has been effectively stayed since its filing.

Halozyme's request for Director review should be denied.

II. Halozyme's Discretionary Denial Arguments Were Considered and Rejected

Section II of the Request (Br., 3-6) restates, nearly point-for-point, the

[2] All emphasis added unless otherwise noted.

discretionary denial brief that Merck fully answered (DD Reply, 9-20). The Director considered Halozyme's arguments (Paper 22), declined to exercise discretion and instituted review. Halozyme identifies no fact or authority the Director overlooked.

A. There Are No "Settled Expectations" in the Challenged Patents

The Challenged Patents issued between December 2020 and July 2021 and had been in force roughly five years when the Petitions were filed. The Office has found no settled expectations based solely on the number of years in force for patents of this vintage. *See* DD Reply 12-13 & n.15 (citing *Cambridge Indus. USA Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00434, Paper 11 at 2-3 (Acting Dir. June 26, 2025) (2019 and 2020 patents), and *Advanced Micro Devices, Inc. v. XtreamEdge, Inc.*, IPR2025-00223, Paper 12 at 2 (Acting Dir. Aug. 14, 2025) (2021 patent)).

Halozyme knew these claims were vulnerable to an IPR challenge. It began its defense of patents in related proceedings by statutorily disclaiming ***seventeen*** comparable claims after Merck's § 112 challenges began in November of 2024. DD Reply, 11-14 & nn.13, 16-17; *see POSCO Co. v. ArcelorMittal*, IPR2025-00370, Paper 10 at 2-3 (Acting Dir. June 25, 2025) (related claims being unpatentable "tips the balance against discretionary denial"); *Nintendo Co. v. Resonant Sys.*, IPR2025-00680, Paper 18 at 3 (Acting Dir. Aug. 14, 2025) (similar); *Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00217, Paper 9 at 2 (Acting Dir. June 13, 2025) (similar). When this IPR was filed, ***fourteen*** related PGRs had been instituted, and the Board

has issued FWDs finding all claims in ***eleven*** of those patents unpatentable, while the three others remain pending FWDs. Instituting here promotes "consistency and predictability to the public." *POSCO* at 3.

B. Merck Did Not Improperly Delay or Engage in "Road-Mapping"

Halozyme invokes *Multi-Color* for the Office's preference for PGRs. Br., 5. Merck prioritized its PGRs, filing fifteen petitions against related patents within their nine-month windows. It then promptly turned to IPRs for the Challenged Patents, which remained within the 12-month litigation deadline for IPRs defined by Halozyme's civil action. Pet. 6; DD Reply, 14 & n.18. The timing of Merck's challenges to Halozyme's portfolio reflected the development of its Keytruda QLEX® product that is the subject of Halozyme's infringement actions. Most directly, the patents Merck is challenging via IPR issued (and PGR windows for those closed) years before Merck filed its BLA in January 2025 (approved in September 2025). DD Reply, 14-16. A PGR filed before 2025 would likely have left Merck without Article III standing to appeal an adverse FWD, given the safe harbor of 35 U.S.C. § 271(e)(1). *Id.* at 15 & n.19 (citing *ironSource Ltd. v. Digital Turbine, Inc.*, 171 F.4th 1317, 1320-21 (Fed. Cir. 2026), and *Allgenesis Biotherapeutics Inc. v. Cloudbreak Therapeutics, LLC*, 85 F.4th 1377 (Fed. Cir. 2023)). And Halozyme's 2009 and 2015 discussions with Merck (Br., 4), occurred ***before any patent in the MDASE portfolio had issued*** (DD Reply, 15). Halozyme ignores these points.

Merck was not sitting on its hands. In the period before the IPRs were filed, Merck was preparing, filing, and litigating ***15*** PGRs, which resulted in near-constant activity and briefing for more than two years. DD Reply, 14-15. Halozyme's own conduct justified filing the IPRs after the PGRs: while Merck was filing PGRs, Halozyme was repeatedly statutorily disclaiming "increased activity" claims that are nearly-identical to the claims challenged here. *Id.* at 16.

Halozyme's road-mapping theory (Br., 4-5) is irreconcilable with its description of the Petitions as "recycled" PGR arguments (*id.* at 5). Road-mapping concerns are minimal where, as here, a later petition raises grounds substantially overlapping those previously filed and is not refined by lessons learned. DD Reply, 17-20 & n.20 (citing *Code200, UAB v. Bright Data Ltd.*, IPR2022-00861, Paper 18 (Dir. Aug. 23, 2022) (precedential)). Merck fully refuted Halozyme's discretionary denial assertions that Merck "changed" its positions and experts (DD Br., 17-19; DD Reply, 18-20), and Halozyme does not renew them here. *General Plastic*, where petitioner relied on entirely new grounds in follow-on petitions, is clearly distinguishable. DD Reply, 20.

C. Merck's Petitions Are Proper IPR Challenges

Halozyme calls the Petitions a "PGR in disguise" that identifies no "Examiner error." Br., 5-6. But the Petitions assert that the claims are not entitled to their claimed priority dates and are therefore anticipated by the increased-activity PH20

mutants disclosed in US-275, a printed publication. Pet., 23-25; DD Reply, 2-3, 11-12. That is a ground "that could be raised under section 102 or 103" on the basis of "patents or printed publications." 35 U.S.C. § 311(b). There is no dispute that these grounds were never considered during examination. DD Reply, 11 (citing Pet., 18-19). The Office and the Federal Circuit have repeatedly confirmed that IPRs are appropriate for priority-based unpatentability challenges. *Id.* at 11-12 & n.14 (citing *Motorola Mobility LLC v. Largan Precision Co.*, IPR2022-01170, Paper 11 at 10-11 (PTAB Jan. 26, 2023); *Ajinomoto Co. v. AbTis Co.*, IPR2025-00283, Paper 16 at 12-16 (PTAB Aug. 8, 2025)); *Indivior*, 18 F.4th at 1330; *Arthrex, Inc. v. Smith & Nephew, Inc.*, 35 F.4th 1328, 1342-44 (Fed. Cir. 2022); *Zenon Envtl., Inc. v. United States Filter Corp.*, 506 F.3d 1370, 1381-82 (Fed. Cir. 2007); Trial Practice Guide, II.D.2 ("a dispute about priority date" can support parallel IPRs.).

D. Halozyme's Equitable Arguments Mischaracterize the Record

Halozyme casts itself as an innovator whose technology is licensed to U.S. companies, such as BMS, but which Merck bypassed in favor of a "copycat" product. Br. 3-4. Merck has repeatedly explained that this narrative is false. *See, e.g.*, DD Reply, 9-11; PGR2025-00017, Paper 109, 11-14. Halozyme does not make, sell, or license any product that practices the challenged claims. Its only hyaluronidase product is rHuPH20 (Hylenex®), the basis of its ENHANZE® platform, which, in Halozyme's own words, is "totally separate" from the MDASE patents challenged

in Merck's petitions. DD Reply, 9-10 & n.9 (quoting EX1101, 9 ("Importantly, MDASE is totally separate from ENHANZE. So think about MDASE's and this Merck litigation has been all upside. There was zero risk, zero risk to it, because ENHANZE was separate.")). BMS licensed ENHANZE® in 2017, before any MDASE patent issued. DD Reply, 10 & n.10 (citing EX1247; EX1229, 10-19).

Halozyme's "copycat" label of Merck's product is equally unfounded. The hyaluronidase in Keytruda QLEX® (ALT-B4/"BHA") was developed by Alteogen, and is unlike any of the 6,000+ single-substitution PH20 mutants disclosed in Halozyme's patents. DD Reply, 10-11. In fact, it contains two substitutions (positions 319 and 321) that Halozyme's patent disclosure identifies as ***inactivating*** and instructs should ***not*** be made in active mutants. DD Reply, 11 & n.11 (comparing EX1245 with EX1001 at 271, Table 10); PGR2025-00017, Paper 109, 11-13.

Excerpt of Halozyme Complaint, Exhibit T (Annotated)

Needleman-Wunsch Global Sequence Alignment Between SEQ ID NO: 3 (Query) and BHA (Sbjct)

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Query  301  IVIWGTLSIMRSMKSCLLLDNYMETILNPYIINVTLAAKMCSQVLCQEQGVCIRKNWNSS  360
Sbjct  299  .....SWENT.TKE..QAIKE..D.T.................................  358
                                    L319I  N321E
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Excerpt of EX1001 (Annotated)

TABLE 10-continued

Inactive Mutants							
F040G	Y099G	R176C	A223G	F266T	N321E	S360L	D413H
F038L	D095Y	K173S	E220R	V265N	L319I	S359A	C408R

It is also entirely different from rHuPH20, which is a truncated form of the

unmodified native human PH20 sequence having ***none*** of the amino acid substitutions in ALT-B4. EX1001, 72:38-62.

Halozyme is the aggressor here, seeking to force Merck—a U.S.-based, innovation driven company—to take a license for a product Halozyme did not invent or develop. Merck is using the IPR system for the reason it was created: as a cost-effective alternative to Halozyme's aggressive licensing and litigation tactics.[3]

III. Halozyme's RPI Arguments Were Already Considered and Rejected

Halozyme re-argues that the Institution Decision conflicts with the denial of institution in PGR2025-00087 and the Director's decisions in *Viance* and *Sun*, and that Petitioner's parent company, Merck & Co., Inc. ("MCI") has the "ability to control" these proceedings. Br., 6-10. Notwithstanding the fact that the Board had already fully considered and rejected all of Halozyme's theories about MCI's alleged "ability to control," that RPI issue was briefed again here. DD Br., 4-11; POPR, 12-19; DD Reply, 3-9. The Director correctly denied Halozyme's request for

[3] Halozyme continues to harass Merck by pursuing 14+ continuation applications claiming comparably immense genera of modified PH20s with the same § 112 flaws as the 17 patents undergoing PTAB review. *See* Paper 19. Halozyme's failure to promptly provide the Examiners with the full records of the eleven FWDs to date calls into question Halozyme's duty of candor to the Patent Office.

discretionary denial (Paper 22) and found that "no other non-discretionary considerations warrant denial of institution" (ID, 2). That decision was fully consistent with the Board's RPI Order, and with the Director's denial of Halozyme's four prior requests to review that Order in PGR2025-00003, -004, -006, and -009.

Halozyme recites the same corporate-governance allegations the Board thoroughly considered and rejected in its RPI analysis. The Board's 24-page Order rested on four rounds of briefing, a detailed declaration (EX1224) and a roughly 350-page deposition of Merck's corporate secretary, Kelly Grez (EX2027), and numerous corroborating internal records. DD Reply, 1, 9. The Board found, among other things, that: (i) MCI is a holding company with no employees, legal department, or products; (ii) Petitioner MSD has a separate governance structure with separate officers and directors; (iii) MSD alone funds these proceedings and employs and engaged all in-house and outside counsel and experts; and (iv) MSD "alone controls," and is the only party able to control, them. DD Reply, 4 (citing Order, 11-13, 16-23). The Board also found that subsidiary 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." Order, 18. Each of the points re-raised by Halozyme here have been thoroughly addressed by Merck and the Board, including Halozyme's reference to corporate resolutions, appointment of managers, dual-role officers, and

MCI's general interest in the outcome of this dispute. DD Reply, 5-8 (compiling the Board's findings and corroborating evidence). As Halozyme concedes, the record here is "identical" (Br., 2, 6-7) and thus warrants the identical result.

The relevant law is also identical. Halozyme contends that *Viance, LLC v. Koppers Performance Chemicals, Inc.*, PGR2026-00023, Paper 32 (Dir. Aug. 19, 2026), and *Sun Pharmaceutical Industries, Inc. v. Biofrontera Inc.*, PGR2026-00021, Paper 12 (Dir. May 26, 2026) require treating MCI as an RPI. Br., 7-10. They do not. These are the Director's own decisions; *Viance* issued the same day as the Director's rejection of Halozyme's discretionary denial arguments (Paper 22), and three weeks before the Director instituted (ID). There is no reason to believe the Director overlooked his own authority in rejecting Halozyme's RPI arguments.

Nor are the decisions inconsistent with institution. *Sun* was already raised in discretionary denial briefing, where Merck explained that, unlike in *Sun*, its declarant demonstrated that MCI does not have the ability to control these proceedings. DD Reply, 8-9 & n.7. That evidence likewise distinguishes *Viance*, where a limited evidentiary record failed to show that the petitioner's corporate parents lacked the ability to control the proceedings. *Viance*, Paper 32 at 3-4. The Office has criticized "conclusory" declarations unsupported by "relevant documents." *Tianma Microelectronics Co. v. LG Display Co.*, IPR2025-01579, Paper 12 at 10 (PTAB Mar. 18, 2026); *see also Sun*, Paper 12 at 2-3 (similar).

Merck's showing is the opposite: a fact-intensive declaration corroborated by internal documents and 350 pages of deposition testimony establishing that MSD alone can, and does, control and fund these proceedings. DD Reply, 8-9 & n.7.

Finally, the Director's 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. Br., 1-2. The -087 decision is silent as to the Director's reasoning; it references unidentified "discretionary and non-merits" reasons. PGR2025-00087, Paper 22, 1. Those may include that the patent at issue in that proceeding was not asserted by Halozyme in litigation (Paper 19, 2) or other considerations unrelated to the RPI issue. Whatever the basis, it does not warrant re-opening the RPI issue here, which has been decided consistently across all instituted PGR and IPR proceedings.

IV. Halozyme Mischaracterizes The Record on Claim Construction

Halozyme's final argument is that the Petitions allegedly rest on a "properly folded" construction the Board "rejected" in the PGRs, and that Merck supplied no evidence under the Board's construction that requires "some hyaluronidase activity." Br., 10-13. This argument grossly misstates the record at every step, and in any event was already rejected by the Director by his grant of institution. *See* POPR, 11-12.

Initially, Halozyme incorrectly portrays "proper folding" as an extra limitation that Merck added. It is not. Merck's position "has always been that the

claims are restricted to 'active' mutants, which requires proper folding." DD Reply, 19-20. This fact is actually ***undisputed***—both Dr. Naismith and Halozyme's own expert, Dr. Petsko testified that only properly folded PH20s exhibit activity. PGR2025-00003, EX2070, ¶128 n.12 ("I am using enzymatic activity as a proxy for a properly folded protein."). And because the '149 Patent claims explicitly require PH20s that exhibit activity, those "active" modified PH20s must be properly folded.

Dr. Naismith explained why Halozyme's disclosure fails to adequately support "active" mutants as § 112 requires. *See, e.g.*, EX1003, ¶¶194-207. Neither Dr. Naismith nor Merck propose a construction that adds an additional requirement beyond the activity requirement that the Board correctly found is required by all challenged claims considered to date. EX1003, ¶¶179, 200-203.

The Board also did not "reject[]" Merck's construction; it adopted it. *See, e.g.*, PGR2025-00003, Paper 128 (FWD), 23 (agreeing "with Petitioner that the term, interpreted in light of the Specification, requires at least some hyaluronidase activity."). Merck's position is, and always has been, that the claims require PH20s with hyaluronidase activity; as Merck explained previously, its position here is the same as in the first-filed PGR. DD Reply, 18 (comparing PGR2025-00003, Pet., 22 ("the claims are limited to one of them: 'active mutants'") with IPR2026-00313, Pet., 23 ("The Claims Expressly Require 'Active Mutants'"). The only claim construction the Board rejected was ***Halozyme's*** (*i.e.*, that the claims include

inactive mutants). PGR2025-00003, Paper 128 (FWD) at 26, 103.[4] Halozyme's premise ignores both the claim language and the record of earlier proceedings.

Finally, Halozyme alleges "gamesmanship," asserting that Merck altered its claim construction positions to "preserve a non-infringement position" in district court. Br., 13-14. But Halozyme's speculation is completely unfounded—Merck's construction here is the one it advanced in each PGR petition, and the one the Board adopted, and Halozyme ignores that the district court proceedings have been effectively stayed since inception, have no schedule, and are nowhere near claim construction. *See, e.g.*, 2:25-cv-03179-ES-JRA, Dkt. 65; DD Reply, 17 (citing EX1246). Halozyme's cited authority is thus irrelevant, as it concerns petitioners who have advanced different constructions in the two forums. Br., 14.

V. Conclusion

Halozyme has identified no basis for the Director to review his own recent decision instituting these IPRs. Halozyme's Request should be denied.

Dated: October 19, 2026

Respectfully Submitted,
/*Jeffrey P. Kushan*/
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[4] Halozyme ignores that the Board found similar claims unpatentable under § 112 ***even under Halozyme's proposed construction***. *E.g.*, PGR2025-00017, Paper 106 (FWD), 54-60, 114-115.

Reg. No. 43,401
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 19th day of October 2026, I caused to be served a true and correct copy of the foregoing by email on the following counsel:

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