

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyne Inc.,
Patent Owner.

Case No. IPR2026-00313
U.S. Patent No. 11,041,149

REPLY TO PATENT OWNER'S DISCRETIONARY DENIAL BRIEF

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I. Introduction

All but one of the claims in challenged U.S. Patent Nos. 11,041,149 (“’149 Patent”), 10,865,400 (“’400 Patent”), and 11,066,656 (“’656 Patent”) (collectively, the “Challenged Patents”) *expressly* require modified PH20 polypeptides that are enzymatically active. When 17 indistinguishable claims in other Halozyme patents were challenged by Petitioner Merck, Sharp & Dohme, LLC (MSD), Halozyme *statutorily disclaimed* every one of them. And the Board has since found comparable claims in each of the Challenged Patents unpatentable under § 112 in four Final Written Decisions (“FWD”).

Recognizing that these claims cannot survive a patentability challenge, Halozyme strains to prevent institution by advancing unfounded assumptions and material misrepresentations at every turn.

First, Halozyme argues that Petitioner MSD has not disclosed all Real-Parties-In-Interest (RPI). But the Board, in a detailed 24-page opinion, *thoroughly rejected* Halozyme’s RPI theory. The Board’s detailed analysis is supported by dozens of documents, a fact-intensive declaration (EX1224) by a high-ranking executive—not cited in Halozyme’s briefing—and an exhaustive 350-page deposition transcript of that same executive (EX2027).

Next, citing a “decade-long investment of substantial resources to develop the claimed invention” (DD Br., 4), Halozyme argues that the relative equities of

the parties warrant discretionary denial. But this argument rests on a falsehood: Halozyme *has never developed or commercialized* a modified PH20 within the scope of any claim of the Challenged Patents. As Halozyme admits, the Challenged Patents are *unrelated* to Halozyme’s actual commercial activities, which are based on Halozyme’s “ENHANZE®” platform first launched in 2005, years before the “MDASE” patents at issue here were filed. Halozyme earns more than a billion dollars annually from ENHANZE® and has told investors that the dispute with MSD has “*absolutely no impact* on [its] ENHANZE business.”¹

Halozyme also complains of “abuse” of the AIA. DD Br., 4. Halozyme again has it backwards—*Halozyme* is the party abusing the patent system through a scheme to capture for itself the entire commercial market for modified recombinant hyaluronidase proteins. Halozyme cannot repurpose its MDASE patents to enforce unpatentable claims against *any* multiply-modified PH20 polypeptide within an incomprehensibly immense genus of possibilities that might have “increased hyaluronidase activity.” Pet., 1-5. MSD’s IPRs are not an “end-run” of the AIA. Under well-established precedent, the claims’ written description and enablement defects—confirmed in four FWDs²—demonstrate the challenged

¹ EX1228; EX1086, 13-14.

² PGR2025-00003, Paper 128; PGR2025-00004, Paper 136; PGR2025-00006,

claims are not entitled to their claimed priority dates, which renders them anticipated by US-275's increased activity PH20 mutants. Pet., 28-29.

Halozyne complains of MSD's "delay" in filing these IPRs, which it says allowed MSD to "repackage and change" its challenges using the PGRs as a "roadmap" while "delay[ing] Halozyne's day in court." DD Br., 2-3. But MSD's § 112 arguments are the same as they were in the PGRs—Halozyne even labels them "recycled." DD Br., 2, 15, 20. MSD did not delay these IPRs. During the sixteen months that preceded the IPRs, MSD was not "sitting on its hands" but was instead actively engaged in preparing, filing, and litigating *fifteen* PGR challenges, all brought within 9-month post-issuance PGR-eligibility windows. And MSD *never* represented that the Challenged Patents would not be subject to IPRs, and there is no evidence the district court had such an understanding.

The Director should deny Halozyne's discretionary denial request.

II. Halozyne's RPI Allegations Are Baseless and Misrepresent the Record

MSD is correctly named the sole "real party-in-interest." Pet., 5. Consistent with the Director's instructions in *Tianma Microelectronics Co., Ltd. v. LG Display Co., Ltd.*, IPR2025-01579, Paper 12, 8 n.6 (March 18, 2026), Petitioner also identified MSD's parent corporation, MCI (Pet., 5), to enable the Board and

Paper 132; PGR2025-00009, Paper 135.

Director to discharge the stated purposes of the RPI requirement.³

Halozyme’s RPI arguments rehash unfounded allegation that MCI “exercised *or could have exercised control*” (RPI Order, 4-5) over MSD’s PTAB proceedings. Citing an abundance of uncontested evidence that Halozyme ignores, the Board rejected Halozyme’s theory, and found that MCI could not do so.⁴ *Id.*, 16-23. Among the facts that the Board found that Halozyme ignores are: (i) [REDACTED] (i.e., 13 (citing EX1224, ¶ 8; EX1244, 2)), (ii) MSD has a separate governance structure from MCI, with separate officers and directors (*id.* (citing EX1224, ¶ 6)); (iii) MSD alone provides all funding, employs all in-house counsel and engaged all outside counsel and experts involved in these proceedings (*id.*, 11-13, 18-20 (citing EX1236, EX1238, EX1240, EX1244, EX1251-1257, EX1258-1276; EX1224, ¶¶ 17–18), and (iv) MSD “alone controls,” and is the only party able to control, these proceedings (RPI Order, 21).⁵ The Board, citing long-standing precedent, also

³ See Trial Practice Guide, § 1.D.1; Memorandum of Director Squires Designating *Corning* Precedential (October 28, 2025).

⁴ PGR2025-00003, Paper 131 (May 12, 2026) (“RPI Order”).

⁵ Petitioner is filing herewith several exhibits cited in the RPI Order. EX1277 correlates exhibit numbers in this proceeding to the related PGR proceedings.

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.” *Id.*, 18. Indeed, the evidence on every RPI factor Halozyme raised conclusively refutes that MCI is an RPI of these Petitions:

Corporate Resolutions & Governance. The Board rejected Halozyme’s arguments regarding MCI’s corporate resolutions, appointments of MSD managers by the MCI board, and the role of MCI’s board, finding none gave MCI the ability to intervene in the proceedings. *Compare* DD Br., 5-8 *with* RPI Order, 6-9, 18.⁶

SEC Filings. The Board rejected Halozyme’s assertion that the use of

⁶ Halozyme misconstrues “General Corporate Resolution #5” as giving MCI ability to control MSD’s IPRs. DD Br., 5-6. It does not, including because [REDACTED]. EX1224, ¶ 8; EX2002, 22; EX2027, 251:15-252:1, 250:1-8. Consistent with the Board’s findings, there is no evidence “General Corporate Resolution #5” was ever invoked, or could be invoked, by MCI to control MSD PTAB proceedings. *See* Consolidated Trial Practice Guide § I.D.1; *Gonzalez v. Banco Cent. Corp.*, 27 F.3d 751, 759 (1st Cir. 1994) (requiring control “from a practical, as opposed to a purely theoretical, standpoint”).

“Merck” and “the Company” in MCI’s consolidated SEC filings “confirm” MCI “directed the AIA Petitions against Halozyme’s MDASE portfolio.” DD Br., 6-7. The Board credited the testimony of MSD’s declarant, Corporate Secretary Kelly Grez, that “MCI uses collective terms... to refer to actions of MCI’s subsidiaries.” RPI Order, 22-23 (citing EX2019, ¶¶ 31–32). Evaluating Ms. Grez’s testimony and SEC filings, the Board concluded SEC filing language “does not demonstrate that the activities described therein are attributable to MCI specifically, much less that MCI directs, controls, or funds” PTAB proceedings. *Id.*, 23; *see also id.*, 5, 14 (citing EX1224, ¶ 31; EX1257, 183).

Alleged Oversight. Halozyme contends MCI provides “strategic oversight” over these IPRs. DD Br., 7-8. This is inconsistent with established facts that [REDACTED]

[REDACTED]. *Id.*, 13 (citing EX1224, ¶ 8; EX1244, 2). It likewise ignores the Board’s determination that (i) corporate distinctions have been maintained “at all times” (*id.*, 18) (ii) “all the internal counsel involved are employed by MSD—not MCI” (*Id.*, 18 (citing EX1252, 1, 8; EX1272–1276; EX1254, 1; EX1262; EX1266, 1; EX1250, 1; EX1236, 1; EX1242, 1; EX1224, ¶¶ 17–18)) (iii) there is “no evidence that MCI personnel, funds, or other assets were involved” in the proceedings (*id.*, 21 (citing EX1252, 1, 8; EX1272–1276; EX1254, 1; EX1266, 1; EX1224, ¶¶ 17–18; EX1255, 1; EX1256, 1)) (iv) there has

been “no persuasive evidence showing that MCI has any direct relationship” to the PTAB proceedings (*id.*), and (v) [REDACTED] [REDACTED] (*id.*, 20).

Jennifer Zachary. The Board found the evidence confirmed Ms. Zachary (who holds dual roles as General Counsel of MCI and MSD) “wears multiple hats,” with roles that are separate and distinct. RPI Order, 11. For example, Ms. Zachary “may sign on behalf of MCI” when conducting duties for MCI, such as when signing SEC filings. *Id.*, 15 (citing EX2027, 56:145–7:7, 63:20–21). By contrast, Halozyne’s contention that Ms. Zachary [REDACTED] [REDACTED] (DD Br., 7) is false. [REDACTED] [REDACTED]. *Id.*, 20 (citing EX2005, 86; EX1252, 8). Thus, Ms. Zachary is “careful to note which ‘hat’ she is wearing in the relevant documentation” which “allow[s] outsiders to identify when [she] is representing MCI and when she is representing MSD.” *Id.*

Funding. Dispositive evidence cited by the Board refutes Halozyne’s contention that SEC filings “confirm” MCI funds MSD’s PTAB proceedings. DD Br., 8. That evidence (*e.g.*, payment records) proves that all outside counsel, experts, and in-house counsel for these proceedings are paid *only* by MSD. RPI Order, 12-13 (citing EX1252; EX1263-EX1267; EX1272-1276). [REDACTED] [REDACTED] RPI Order, 14 (citing EX1224, ¶

37); *see also id.*, 18, 21, 23.

Blurred Lines. Halozyme alleges “blurred” corporate lines. DD Br., 9. First, it points to MSD employees that hold officer roles at MCI. But the Board found it was appropriate for directors and officers to hold dual roles at a parent and subsidiary, and found that “the management and directors of... MCI and MSD differ significantly.” RPI Order, 17 (citing EX1238; EX1240; EX1224, ¶¶ 6, 10). Next is an erroneous OED filing by MSD’s in-house counsel Mark Stewart (which has since been corrected), and his attendance at a German revocation proceeding. DD Br., 9-10. The Board rejected those too: it found “no indication of any blurred line that would require Mr. Stewart to act directly on behalf of MCI,” including at foreign proceedings “brought by subsidiaries of MCI other than MSD.” *Id.*, 20-21 (citing EX2027, 190:4–20; EX1224, ¶ 34). In fact, as the Board observed, “even [Halozyme] has treated MCI and MSD as distinct entities as it relates to the subject matter of these proceedings,” naming only MSD (and *not* MCI) as the defendant in the district court action. *Id.*, 21 (citing EX2019, 1).

Interest in the Proceedings. The Board found MCI’s interest in these proceedings is merely “incidental to being Petitioner’s corporate parent” and “not sufficient, in and of itself, to make MCI an RPI.” DD Br., 10; RPI Order, 8, 22. (citing EX1224, ¶ 28; EX2027, 322:25–323:3, 326:22–327:14).

Thus, unlike proceedings where institution was denied based on an unnamed

RPI, the Board’s RPI Order rests on *extensive documentary and testimonial evidence* that establishes that *MSD alone can and has controlled and funded* these proceedings, and thus is the sole RPI.⁷ That evidence, again, includes a detailed declaration from a corporate officer that is fully corroborated by documents and *350 pages of the officer’s deposition transcript*.

III. Halozyme Identifies No Credible Basis for Denying Institution Under Established Criteria Governing Discretionary Denial

A. Halozyme Does Not Practice the Challenged Patents

Halozyme’s brief misrepresents that Halozyme has “spent nearly 13 years and invested millions to develop, and now manufactures in the U.S., a modified human hyaluronidase (PH20) enzyme” and that the Challenged Patents “protect this innovation.” DD Br., 11, 13. Halozyme conceals that it does not make, sell, or license *any* products that practice the challenged claims. Halozyme’s *only* hyaluronidase product is rHuPH20 (Hylenex[®]), the basis of its ENHANZE[®]

⁷ See *Tianma*, Paper 12 at 10 (criticizing “conclusory declaration that simply states that none of the entities Patent Owner identifies funded, controlled, or directed the IPR, or had the ability to control the IPR,” without support by “relevant documents”); *Sun Pham. Indus., Inc. v. Biofrontera Inc.*, PGR2026-00021, Paper 12 at 2-3 (Director, May 26, 2026) (similar).

platform from which it earns more than a billion dollars.⁸ The Challenged Patents do *not* implicate ENHANZE[®] because they require amino acid substitutions not found in rHuPH20, the basis of the ENHANZE[®] platform. In Halozyme’s own words, the MDASE patents challenged by MSD are of *no consequence* to its sales and licensing revenue related to its ENHANZE[®] patent portfolio and product.⁹ Halozyme similarly obscures the facts of its licensing activities, alleging that BMS “licensed Halozyme’s hyaluronidase technology.” DD Br., 13. But BMS licensed ENHANZE[®] in **2017**, before any MDASE patent issued, and its partnership with Halozyme concerns ENHANZE[®].¹⁰

MSD is an innovation-driven U.S. company that invests heavily in US-based manufacturing and R&D infrastructure, including more than \$12 billion since 2017. EX1085. Halozyme seeks to force MSD into a license for its use of a product Halozyme did not invent or develop—an innovative new PH20 enzyme (“ALT-B4”/“BHA”) unlike any of the 6,000+ single substitution PH20 mutants disclosed

⁸ EX1249; EX1248; EX1084; EX1212.

⁹ See 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.”).

¹⁰ EX1247; EX1229, 10-19.

in Halozyme's patent family. Indeed, ALT-B4 includes substitutions Halozyme's patents *say to avoid* in active mutants.¹¹ MSD has made significant investments to develop Keytruda QLEX[®] with ALT-B4, a new product that will improve the lives of cancer patients. Merck's use of the IPR system as "a quick and cost-effective *alternative* to district court patent litigation for resolving disputes over patent validity" is the epitome of a situation for which IPRs were designed.¹²

B. The Merits of MSD's Challenges Are Exceptionally Strong

There is no dispute that the IPRs raise grounds never considered during examination. Pet., 18-19. Nor is there a dispute about the grounds' strong merits. Halozyme concedes the Petitions' lack-of-priority arguments are substantially the same as the § 112 arguments advanced in MSD's PGRs. DD Br., 1-2, 15. Thus far, the PGRs have resulted in four FWDs finding all challenged claims unpatentable, ten other instituted PGRs, and Halozyme's disclaimer of seventeen "increased activity" claims.¹³ Halozyme wrongly suggests that the grounds are "outside the

¹¹ Compare EX1245, with EX1001, 271, Table 10 (positions 319 and 321).

¹² *Magnolia Med. Tech. v. Kurin, Inc.*, IPR2026-00097, Paper 17 at 2 (Director, May 14, 2026) (citing H.R. Rep. No. 112-98 at 48 (2011)).

¹³ PGR2025-00003, EX2003 (claims 5-6); PGR2025-00004, EX2003 (claims 5-6); PGR2025-00006, EX2003 (claims 5-6); PGR2025-00009, EX2003 (claim

core purpose of IPRs.” DD Br., 3. The Office and Federal Circuit have repeatedly confirmed IPRs are appropriate for priority-based unpatentability challenges.¹⁴

C. The Timing of the IPRs Does Not Warrant Discretionary Denial

Halozyme’s assertions about “settled expectations,” “gamesmanship,” and “abuse of AIA trials” are baseless and do not warrant discretionary denial. DD Br., 2-4, 16-17.

1. No Settled Expectations

The “settled expectations” factor weighs *against* discretionary denial here.

4); PGR2025-00017, EX2003 (claim 4); PGR2025-00024, EX2003 (claim 4); PGR2025-00030, EX2003 (claim 4); PGR2025-00033, EX2003 (claim 4); PGR2025-00039, EX2003 (claims 5-6); PGR2025-00042, EX2003 (claim 6); PGR2025-00046, EX2003 (claim 6); PGR2025-00050, EX2003 (claim 4); PGR2025-00053, EX2003 (claim 4).

¹⁴ See Pet., 28-29 (compiling case law); *Motorola Mobility LLC v. Largan Precision Co.*, IPR2022-01170, Paper 11, 10-11 (PTAB Jan. 26, 2023) (compiling precedent rejecting argument that IPR “challenge amounts to a backdoor way of asserting an impermissible challenge under 35 U.S.C. § 112”); *Ajinomoto Co. v. AbTis Co.*, IPR2025-00283, Paper 16, 12-16 (PTAB Aug. 8, 2025).

First, the Challenged Patents have only been in force for 4-5 years.¹⁵

Second, expectations in Halozyme’s MDASE patent family cannot be “settled” when PGRs on fourteen related patents have been instituted, and all claims in four patents have been found unpatentable in FWDs.¹⁶ “It is an appropriate use of Office resources to provide consistency and predictability to the public, and to ensure that a patent applicant or owner does not take action inconsistent with the judgment in a prior Office proceeding.” *POSCO*, 3. Institution of the IPRs here—against three patents asserted in the district court—

¹⁵ See, e.g., *Cambridge Industries USA Inc. et al. v. Applied Optoelectronics, Inc.*, IPR2025-00434, Paper 11 at 2-3 (Acting Director, June 26, 2025) (no settled expectations for 2019 and 2020 patents); *Advanced Micro Devices, Inc. v. XtreamEdge, Inc.*, IPR2025-00223, Paper 12 at 2 (Acting Director, Aug. 14, 2025) (same for 2021 patent).

¹⁶ *POSCO Co., Ltd. v. ArcelorMittal*, IPR2025-00370, Paper 10 at 2-3 (Acting Director, June 25, 2025) (determination that related claims are unpatentable “tips the balance against discretionary denial”); *Nintendo Co. Ltd. v. Resonant Systems*, IPR2025-00680, Paper 18 at 3 (Acting Director, Aug. 14, 2025) (similar); *Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00217, Paper 10 at 2 (Acting Director, June 13, 2025) (similar).

achieves those objectives.

Finally, Halozyme’s *recent* actions refute there are “settled expectations” for the Challenged Patents—in **2025** Halozyme statutorily disclaimed comparable “increased activity” claims in response to Merck’s challenges to shield them from PTAB scrutiny, rather than defend their patentability.¹⁷

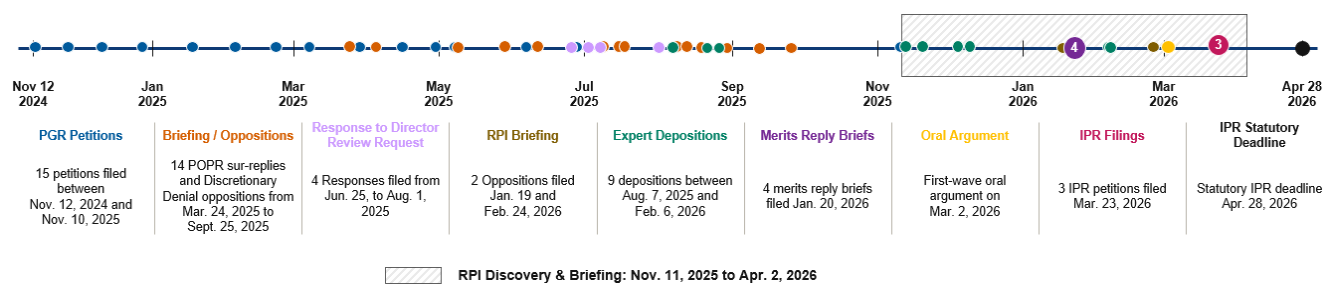
2. MSD Did Not Improperly Delay Filing These IPRs

Since November 2025, MSD has pursued PGRs against *fifteen* related patents. For the ’400, ’149, and ’656 Patents, the 9-month PGR window lapsed years ago, and long before submission of the Keytruda QLEX[®] BLA. Consistent with the Office’s preference, MSD therefore prioritized the PGRs. Pet., 6.¹⁸ Pursuing fifteen concurrent PGRs required a significant deployment of resources by MSD and its outside counsel:

¹⁷ *Nintendo*, at 3 (IPR against patent in force 10+ years warranted where after the Board instituted IPR of continuation patent of the challenged patent, Patent Owner disclaimed substantially similar claims).

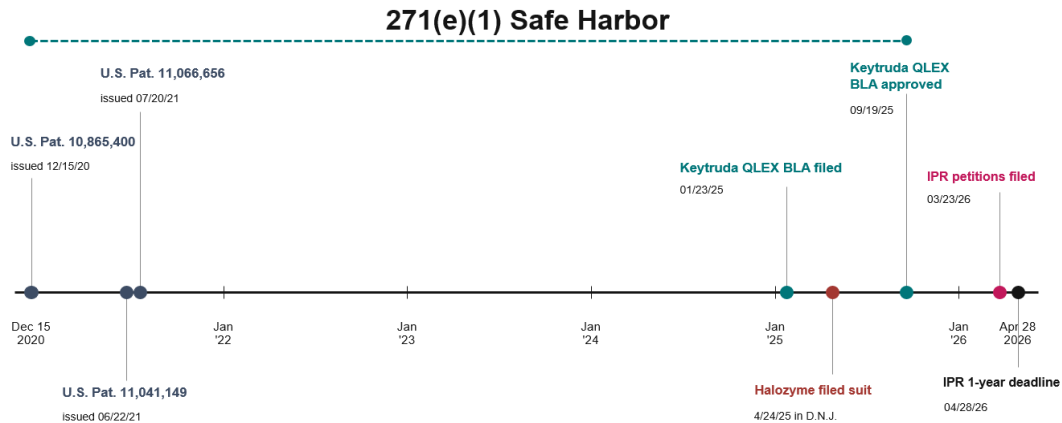
¹⁸ *Multi-Color Corp. v. Brook & Whittle Ltd.*, PGR2025-000025, Paper 10, at 2-3 (Acting Dir., July 16, 2025) (precedential).

16 Months of Constant Activity in Pending PGRs



Halozyne suggests MSD should have filed PGRs against the Challenged Patents when they issued in late 2020 and 2021 after Halozyne approached Merck about licensing discussions. DD Br., 12. But those discussions occurred when *no patents* in Halozyne’s MDASE portfolio had issued. Moreover, at that time, MSD had not filed its BLA for Keytruda QLEX®—that occurred in January of 2025, and was followed by FDA approval in September of 2025. If MSD had filed a PGR challenge to the ’600, ’149, and ’656 patents prior to 2025, MSD would have likely lacked Article III standing in any appeal of a FWD decision before the Federal Circuit due to the 35 U.S.C. § 271(e)(1) safe harbor for pre-approval development activities.¹⁹

¹⁹ See, e.g., *ironSource Ltd. v. Digital Turbine, Inc.*, 171 F.4th 1317, 1320-21 (Fed. Cir. 2026); *Allgenosis Biotherapeutics Inc. v. Cloudbreak Therapeutics, LLC*, 85 F.4th 1377 (Fed. Cir. 2023).



More fundamentally, before and after accusing Merck of infringement based on use of an enzymatically active modified form of PH20, Halozyme statutorily disclaimed seventeen “increased activity” claims in related patents. *Supra* n.13. At the very least, Halozyme’s abandonment of such claims while MSD was filing PGRs with § 112 challenges between February and July of 2025 justified filing these IPRs after the PGRs.

3. MSD Never Represented It Would Not File IPRs

It is not true, as Halozyme contends, that “the parties and the court agreed” to pause proceedings on a “*shared understanding*” that the Challenged Patents would not face IPRs. DD Br., 3-4, 14. MSD acknowledged only that these patents were not eligible for PGR. DD Br., 4; EX2024, 2. It was ***Halozyme’s*** sole position—not MSD’s—that “no matter the outcome of the PGRs, this case will move forward with at least” the ’400, ’149, and ’656 patents. EX2025, 3; EX2026, 2-3. MSD proposed that the parties should “provide an update to the Court ... with the outcomes of each of the PGRs and the Parties’ positions with respect to

whether or not the case should be restored to the active docket.” EX2025, 8-9; EX2026, 1-2. MSD never said it would not file IPRs.

The IPRs also have not “disrupt[ed] the agreed-upon litigation schedule” or risked “duplicative proceedings” (DD Br., 14-15, 19)—there is *no schedule* and the *litigation is stayed*. See EX1246. Premising the litigation pause on no IPRs of the ’400, ’149, and ’656 patents (DD Br., 13-14) also would have been illogical. It is much more efficient for the district court to allow the Office to consider the patentability of *all* asserted patents.

4. MSD Did Not Improperly Use the PGRs As a Roadmap

Road-mapping concerns are minimal when a later-filed petition raises grounds “substantially overlapping with those in a previously-filed petition and the later petition is not refined based on lessons learned from later developments.”²⁰

²⁰ *Code200, UAB et al v. Bright Data Ltd.*, IPR2022-00861, Paper 18 (Director, Aug. 23, 2022) (precedential); *see also Qualcomm Inc. v. Cobblestone Wireless, LLC*, IPR2024-01336, Paper 15, 10, 17-18 (PTAB Mar. 7, 2025) (“lack of ‘road-mapping’” where petition “substantively identical” to prior IPR, “raised the identical prior art, arguments, and evidence,” and Board “already invested significant resources” in related proceedings); *Intel Corp. v. VLSI Technology LLC*, IPR2022-00366, Paper 14, 11 (PTAB June 8, 2022).

Halozyme maintains that the petitions “repackage[] recycled § 112 assertions from the PGRs” and “cite[] no new prior art.” DD Br., 2. It cannot simultaneously claim these same grounds are materially changed relative to the ones in the PGRs.

Indeed, Halozyme’s attempts to recast MSD’s petitions as “changed” blatantly mischaracterize the PGR record and IPR petitions (DD Br., 17-19):

- MSD did not “abandon[] the obviousness grounds.” *Id.*, 3, 20. MSD has never raised obviousness challenges against “increased activity” claims.²¹
- Halozyme asserts MSD “abandoned” its position that “‘modified PH20 polypeptide’ was limited to ‘active mutants’” (DD Br., 18), but MSD’s position is the same here as in the first-filed PGR:

PGR2025-00003, Petition at 22	3. The Claims Are Restricted to One of Two Alternative Embodiments in the Patents: “Active Mutants” When a specification discloses alternative embodiments, the language used in the claims may cause them to be limited to only one.⁵³ That is the case here: the specification describes two mutually exclusive categories of “modified PH20 polypeptides” (<i>i.e.</i>, “active mutants” vs. “inactive mutants”) but the claims are limited to one of them: “active mutants.”
IPR2026-000313, Petition at 23	2. The Claims Expressly Require “Active Mutants” The claims are expressly limited to a subset of one of what the disclosure portrays as two mutually exclusive types of modified PH20s: “active mutants” with “increased activity.”⁶⁰ Specifically, all claims require $\geq 120\%$ of the unmodified PH20’s activity, while dependent claim 6 requires $\geq 200\%$ activity. None of the claims encompass “inactive mutants.”

²¹ See, e.g., PGR2025-00003, Pet., 7; PGR2025-00050, Pet., 7.

- MSD’s expert, Dr. Naismith, is not a “different expert” than in the PGRs. DD Br., 19. He was an expert for MSD in *all* 14 instituted PGRs.
- In his IPR declarations, Dr. Naismith made the factual statement that in connection with the PGRs he had reviewed the testimony of Drs. Park, Hecht, Petsko, and Simpson. EX1003, ¶ 20. However, Dr. Naismith did not rely on Drs. Park or Hecht’s PGR declarations in his IPR declarations.
- Like Dr. Naismith, Dr. Hecht assessed § 112 using *both* December 29, 2011 and December 28, 2012 as reference points, as the Board correctly found.²²
- Halozyme falsely claims MSD “jettisoned” its argument that “‘homology models’ were a well-known ‘accurate computational method to generate reliable structural [protein] models.’” DD Br., 18 (citing EX2031, ¶ 36). But Dr. Naismith provides the *same opinion* in the IPRs. EX1003, ¶¶ 103-104.
- The petitions do not “rel[y] on” Drs. Petsko and Simpson to “fill in gaps in the art.” DD Br., 17. MSD’s position has always been that the claims are restricted to “active” mutants, which requires proper folding; Drs. Petsko and Simpson’s testimony simply *confirms* that activity requires folding, and that unconstrained mutations (permitted by the claims) impact the folding

²² PGR2025-00003, Paper 16, 5-6; PGR2025-00003, Paper 25, 5-6, 35-36.

process unpredictably.²³

This case is thus nothing like *Videndum Prod. Sols., Inc. v. Rotolight Ltd.*, which concerned an abandoned first petition and a second later petition raising additional art petitioner knew of at the time of the first petition.²⁴ It is also different from *General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, *ResMed Corp. v. Cleveland Med. Devices, Inc.*, and *Metal Zug AG v. Carl Zeiss Meditec AG* where petitioners relied on entirely new unpatentability grounds in follow-on IPRs against the same patents challenged in earlier denied petitions institution.²⁵

IV. Conclusion

Halozyme has identified no legitimate basis to deny institution based on any discretionary or other factors, and institution is therefore appropriate.

Dated: June 29, 2026

Respectfully Submitted,

/Jeffrey P. Kushan/

²³ See PGR2025-00003, EX1003 (Hecht), ¶¶ 50, 59, 127-129, 142; PGR2025-00003, Pet., 10-11, 19-20, 25-26, 52-53.

²⁴ IPR2023-01219, Paper 9 at 14-16 (PTAB Jan. 24, 2024).

²⁵ IPR2016-01357, Paper 19 at 6-8, 11 (PTAB Sept. 6, 2017) (precedential); IPR2025-00157, Paper 10 at 11 (PTAB June 10, 2025); IPR2020-01074, Paper 8 at 8 (PTAB Jan. 5, 2021).

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EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 11,041,149
1002	File History of U.S. Patent No. 11,041,149
1003	Declaration of Dr. James Naismith
1004	United States Patent Publication No. 2013/03032275
1005	U.S. Patent No. 7,767,429
1006	Chao et al., "Structure of Human Hyaluronidase-1, a Hyaluronan Hydrolyzing Enzyme Involved in Tumor Growth and Angiogenesis," <i>Biochemistry</i> , 46:6911-6920 (2007)
1007	WO 2010/077297, published 8 July 2010
1008	Stern et al., "Hyaluronidases: Their Genomics, Structures, and Mechanisms of Action," <i>Chem. Rev.</i> 106:818-839 (2006)
1009	Jedzrejas et al., "Structures of Vertebrate Hyaluronidases and Their Unique Enzymatic Mechanism of Hydrolysis," <i>Proteins: Structure, Function and Bioinformatics</i> , 61:227-238 (2005)
1010	Zhang et al., "Hyaluronidase Activity of Human Hyal1 Requires Active Site Acidic and Tyrosine Residues," <i>J. Biol. Chem.</i> , 284(14):9433-9442 (2009)
1011	Arming et al., "In vitro mutagenesis of PH-20 hyaluronidase from human sperm," <i>Eur. J. Biochem.</i> , 247:810-814 (1997)
1012	Bordoli et al., "Protein structure homology modeling using SWISSMODEL workspace," <i>Nature Protocols</i> , 4(1):1-13 (2008)
1013	Frost, "Recombinant human hyaluronidase (rHuPH20): an enabling platform for subcutaneous drug and fluid administration," <i>Expert Opinion on Drug Delivery</i> , 4(4):427-440 (2007)
1014	Branden & Tooze, "Introduction to Protein Structure," Second Ed., Chapters 1-6, 11-12, 17-18 (1999)
1015	Table Associating Citations from the '149 Patent (EX1001) to Corresponding Citations in the '731 Application (EX1026) and US-275 (EX1004)

No.	Exhibit Description
1016	Steipe, “Consensus-Based Engineering of Protein Stability: From Intrabodies to Thermostable Enzymes,” <i>Methods in Enzymology</i> , 388:176-186 (2004)
1017	Green, “Computer Graphics, Homology Modeling, and Bioinformatics,” <i>Protein Eng’g & Design</i> , Ch. 10, 223-237 (2010)
1018	Chica et al., “Semi-rational approaches to engineering enzyme activity: combining the benefits of directed evolution and rational design,” <i>Curr. Opin. Biotechnol.</i> , (4):378-384 (2005)
1019	Hardy et al., “Assessment of contraceptive vaccines based on recombinant mouse sperm protein PH20,” <i>Reprod.</i> , 127:325-334 (2004)
1020	Pomering et al., “Restricted Entry of IgG into Male and Female Rabbit Reproductive Ducts Following Immunization with Recombinant Rabbit PH-20,” <i>Am. J. Reprod. Immunol.</i> , (3):174-82 (2002)
1021	Baba et al., “Mouse Sperm Lacking Cell Surface Hyaluronidase PH-20 Can Pass through the Layer of Cumulus Cells and Fertilize the Egg,” <i>J. Biol. Chem.</i> , 277(33):30310-4 (2002)
1022	Primakoff et., “Reversible Contraceptive Effect of PH-20 Immunization In Male Guinea Pigs,” <i>Biol Reprod.</i> , 56(5): 1142-6 (1997)
1023	Tung et al., “Mechanism of Infertility in Male Guinea Pigs Immunized with Sperm PH-20,” <i>Biol. Reprod.</i> , 56(5): 1133-41 (1997)
1024	Rosengren et al., “Recombinant Human PH20: Baseline Analysis of the Reactive Antibody Prevalence in the General Population Using Healthy Subjects,” <i>BioDrugs</i> , 32(1):83-89 (2018)
1025	[Reserved]
1026	U.S. Patent Application No. 13/694,731
1027	2024 Chemistry Nobel Prize Background
1028	Bordier, “Phase separation of integral membrane proteins in Triton X-114 solution.” <i>J. Bio. Chem.</i> 256 (4):1604-1607 (1981)

No.	Exhibit Description
1029	Gmachl et al., “The human sperm protein PH-20 has hyaluronidase activity,” FEBS Letters, 3:545-548 (1993)
1030	Sills, “Retraction,” Science, 319:569 (2008)
1031	Yue et al., “Loss of Protein Structure Stability as a Major Causative Factor in Monogenic Disease,” J. Mol. Biol., 353:459-473 (2005)
1032	Wang & Moul, “SNPs, Protein Structure, and Disease,” Hum. Mutation, 17:263-270 (2001)
1033	Marković-Housley et al., “Crystal Structure of Hyaluronidase, a Major Allergen of Bee Venom,” Structure, 8:1025-1035 (2000)
1034	“Negative Results,” Nature: Editorials, 453:258 (2008)
1035	[Reserved]
1036	Hayden, “Chemistry: Designer Debacle,” Nature, 453:275-278 (2008)
1037-1038	[Reserved]
1039	Alberts, “Molecular Biology of the Cell,” Fifth Edition, Chapter 3 (2007)
1040	He et al., “NMR Structures of Two Designed Proteins with High Sequence Identity but Different Fold and Function,” PNAS, 105:14412-14417 (2008)
1041	Alexander et al., “A Minimal Sequence Code for Switching Protein Structure and Function,” PNAS, 106:21149-21154 (2009)
1042	Ruan et al., “Design and Characterization of a Protein Fold Switching Network,” Nature Comm., 14 (2023)
1043-1044	[Reserved]
1045	Redline Comparison of the '731 Application and '149 Patent Specifications
1046	Beasley & Hecht, “Protein Design: The Choice of <i>de Novo</i> Sequences,” J. Biological Chemistry, 272:2031-2034 (1997)

No.	Exhibit Description
1047	Xiong et al., “Periodicity of Polar and Nonpolar Amino Acids is the Major Determinant of Secondary Structure in Self-Assembling Oligomeric Peptides,” PNAS, 92: 6349-6353 (1995)
1048	Hayden, “Key Protein-Design Papers Challenged,” Nature, 461:859 (2009)
1049-1050	[Reserved]
1051	U.S. Patent Application No. 61/631,313
1052	U.S. Patent Application No. 61/796,208
1053-1058	[Reserved]
1059	Leisola & Turunen, “Protein Engineering: Opportunities and Challenges,” Appl. Microbiol. Biotechnol. 75:1225-1232 (2007)
1060	[Reserved]
1061	Rosengren et al., “Clinical Immunogenicity of rHuPH20, a Hyaluronidase Enabling Subcutaneous Drug Administration,” AAPS J. 5:1144-56 (2015)
1062-1065	[Reserved]
1066	Collection of SWISS-MODEL Webpages from the Internet Archive, navigable from: https://web.archive.org/web/20110519141121/http://swissmodel.expasy.org/?pid=smh01&uid=&token=
1067	[Reserved]
1068	Declaration of Jeffrey P. Kushan
1069-1075	[Reserved]
1076	Declaration of Leif E. Peterson, II
1077-1078	[Reserved]
1079	Hunnicuttt et al., “Sperm Surface Protein PH-20 Is Bifunctional: One Activity Is a Hyaluronidase and a Second, Distinct Activity Is Required in Secondary Sperm-Zona Binding,” Biol. Reprod., 55(1):80-86 (1996)

No.	Exhibit Description
1080	Bookbinder et al., “A Recombinant Human Enzyme for Enhanced Interstitial Transport of Therapeutics,” J. Controlled Release, 114:230-241 (2006)
1081	Goldberg, “Protein degradation and protection against misfolded or damaged proteins,” Nature, 426:895-899 (2003)
1082-1083	[Reserved]
1084 [NEW]	Halozyme Raises 2025 Financial Guidance Ranges and Reports Strong First Quarter 2025 Results
1085 [NEW]	Merck Breaks Ground on New \$1 Billion Biologics Center of Excellence in Wilmington, Delaware
1086 [NEW]	Halozyme Therapeutics_1Q25 Transcript_May 2025
1087	Vembar & Brodsky, “One Step at a Time: Endoplasmic Reticulum-Associated Degradation,” Nature, 9:944-958 (2008)
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1101 [NEW]	Halozyme Therapeutics_Morgan Stanley Global Healthcare Conference_8 September
1102-1104	[Reserved]
1105	United States Patent Publication No. 2010/0143457
1106-1111	[Reserved]
1112	Primakoff, P., et al., “Fully effective contraception in male and female guinea pigs immunized with the sperm protein PH-20,” Nature 335:543-546 (October 6, 1988)
1113	Declaration of Sue Wang
1114	Declaration of Brian M. Goldberg
1115	Declaration of Katherine A. Helm, Ph.D.
1116	Declaration of Christine M. Engen
1117	Declaration of Amit Bhatla

No.	Exhibit Description
1118-1125	[Reserved]
1126	Im, S. et al., “Cryo-EM Structure of Human Hyaluronidase PH20,” Proteins: Structure, Function, and Bioinformatics 93:10671073 (2025)
1127-1129	[Reserved]
1130	Melanie Ann Simpson, Ph.D. Deposition Transcript
1131	Gregory Petsko, Ph.D. Deposition Transcript
1132-1134	[Reserved]
1135	Dr. Naismith Disclosure Analysis Spreadsheet
1136	Dobson, “Principles of protein folding, misfolding and aggregation” Semin. Cell. Dev. Biol. 15(1):3-16 (2004)
1137	Dobson, “Protein folding and misfolding” Nature. 18;426(6968):884-90 (2003)
1138	Dobson, “Experimental investigation of protein folding and misfolding” Methods 34(1):4-14 (2004)
1139	Chiti & Dobson, “Protein Misfolding, Functional Amyloid, and Human Disease” Annu. Rev. Biochem. 75:333–66 (2006)
1140	Dobson, “Protein misfolding, evolution and Disease” Trends Biochem. Sci. (9):329-32 (1999)
1141	Goldsmith & Tawfik, “Directed enzyme evolution: beyond the low-hanging fruit” Curr. Opin. Struct. Biol. 22(4):406-12 (2012)
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1145	[Reserved]
1146	Pal et al., “Comprehensive and Quantitative Mapping of Energy Landscapes for Protein-Protein Interactions by Rapid

No.	Exhibit Description
	Combinatorial Scanning” J. Biol. Chem. 4;281(31):22378-22385 (2006)
1147	van Rossum et al., “Reporter-based screening and selection of enzymes” FEBS J. 280:2979-96 (2013)
1148	Reed et al., “Use of Coefficient of Variation in Assessing Variability of Quantitative Assays” Clin. Diagn. Lab Immunol. 9(6):1235-9 (2002)
1149	Ten Have et al., “Cloning and characterization of the cDNA encoding the PH20 protein in the European red fox <i>Vulpes</i> ” Reprod. Fertil. Dev. 10(2):165-72 (1998)
1150	Chowpongpan et al., “Cloning and characterization of the bovine testicular PH-20 hyaluronidase core domain” Biotechnol. Lett. 26(15):1247-52 (2004)
1151	Fowler et al., “High-resolution mapping of protein sequence function relationships” Nature Methods 7, 741–746 (2010)
1152	Ringe & Petsko, “Q&A: What are pharmacological chaperones and why are they interesting?” J. Biol. 8:80 (2009)
1153-1154	[Reserved]
1155	Calloni et al., “Investigating the Effects of Mutations on Protein Aggregation in the Cell” J. Biol. Chem. 10607-13 (2005)
1156	Chiti et al., “Studies of aggregation of mutant proteins in vitro provided insights into genetics of amyloid diseases” PNAS 99:16419-26 (2002)
1157	Chiti et al., “Rationalization of the effects of mutations on peptide and protein aggregation rates” Nature, 424:805-808 (2003)
1158	Wang et al., “Immunogenicity of protein aggregates-Concerns and Realities” Int. J. Pharmaceutics 431:1-11, (2012)
1159	[Reserved]
1160	Poelwijk, Frank J., et al., “Empirical fitness landscapes reveal accessible evolutionary paths” Nature 445.7126 (2007): 383-386

No.	Exhibit Description
1161-1188	[Reserved]
1189	Martin-Deleon, P., “Epididymal SPAM1 and its Impact on Sperm Function,” Molecular and Cellular Endocrinology 250:114-121 (2006)
1190-1205	[Reserved]
1206	U.S. Food and Drug Administration, Medical Review: Hylenex, App. No. 21-859 (2005)
1207	US Patent No. 12,091,692
1208	Redline of the '731 App. and US-275 Publication
1209	Petsko & Ringe, Protein Structure and Function, New Science Press (2004)
1210	Nelson & Cox, Lehninger Principles of Biochemistry, W.H. Freeman, 4th ed. (2005)
1211	Halozyme Therapeutics, Inc., Hylenex Label, U.S. Food and Drug Administration; AccessData (2005)
-	Declaration of Gregory A. Petsko, PGR2025-00003 (U.S. Patent No. 11,952,600), EX2070 (Sept. 22, 2025)
1212 [NEW]	ENHANZE Drug Delivery Technology Halozyme
1213-1223	[Reserved]
1224 [NEW]	Declaration of Kelly Grez
1225-1227	[Reserved]
1228 [NEW]	PGR2025-00050 EX2009 - Halozyme News Revenue
1229 [NEW]	Halozyme Form 10-K (Feb 2026)
1230-1235	[Reserved]

No.	Exhibit Description
1236 [NEW]	[PROTECTIVE ORDER MATERIAL] Jennifer_Zachary WD_Redacted
1237	[Reserved]
1238 [NEW]	Merck Co. Inc.- NJ Certificate of Long Form Standing with Officers and Directors
1239	[Reserved]
1240 [NEW]	Merck Sharp Dohme LLC - NJ Certificate of Long Form Standing with Officers and Directors
1241	[Reserved]
1242 [NEW]	[PROTECTIVE ORDER MATERIAL] - ZACHARYJENNIFER ADP_Redacted
1243	[Reserved]
1244 [NEW]	[PROTECTIVE ORDER MATERIAL] 2024 Form 851 Affiliations Schedule -50
1245 [NEW]	District Court Complaint - Exhibit T
1246 [NEW]	June 10, 2026 [60] Letter Order
1247 [NEW]	Bristol Myers Squibb and Halozyme Enter Global Collaboration and License Agreement for ENHANZE
1248 [NEW]	Commercial Products Halozyme
1249 [NEW]	Drug Delivery Technologies Halozyme
1250 [NEW]	PGR2025-00003 EX2451 - Employment Letter

1251 [NEW]	PGR2025-00003 EX2401 - E-mail (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1252 [NEW]	PGR2025-00003 EX2402 - MERCK_PGR00006 - Sidley MSA (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1253 [NEW]	PGR2025-00003 EX2403 - MERCK_PGR00056 - Dechert MSA (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1254 [NEW]	PGR2025-00003 EX2404 - MERCK_PGR00467 - Mark Stewart Offer Letter (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1255 [NEW]	PGR2025-00003 EX2405 - MERCK_PGR00052 - Hecht Engagement Letter (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1256 [NEW]	PGR2025-00003 EX2406 - MERCK_PGR00086 - Park Engagement Letter (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1257 [NEW]	PGR2025-00003 EX2415 - Merck Co - 10k - year 2024
1258 [NEW]	PGR2025-00003 EX2426 - MERCK_PGR00035 - 20250813 Payment Remittance (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1259 [NEW]	PGR2025-00003 EX2427 - MERCK_PGR00042 - Dechert T360 Halozyme (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1260 [NEW]	PGR2025-00003 EX2428 - MERCK_PGR00045 - FW_Attn_Accounts Receivable Dept (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1261 [NEW]	PGR2025-00003 EX2429 - MERCK_PGR00049 - Halozyme - 202000447 - Invoices (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)

1262 [NEW]	PGR2025-00003 EX2430 - MERCK_PGR00465 - Mark Stewart Payroll Statement (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1263 [NEW]	PGR2025-00003 EX2431 - MERCK_PGR00001 - Ginkel Organization Screen Shot (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1264 [NEW]	PGR2025-00003 EX2432 - MERCK_PGR00002 - Lally Organization Screen Shot (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1265 [NEW]	PGR2025-00003 EX2433 - MERCK_PGR00003 - Majchrzak Organization Screen Shot (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1266 [NEW]	PGR2025-00003 EX2434 - MERCK_PGR00004 - Stewart Organization Screen Shot (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1267 [NEW]	PGR2025-00003 EX2435 - MERCK_PGR00005 - Su Organization Screen Shot (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1268 [NEW]	PGR2025-00003 EX2436 - MERCK_PGR00036 - 20250903 Payment Remittance_Redacted (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1269 [NEW]	PGR2025-00003 EX2437 - MERCK_PGR00037 - 20251001 Payment Remittance_Redacted (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1270 [NEW]	PGR2025-00003 EX2438 - MERCK_PGR00038 - 20251203 Payment Remittance_Redacted (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1271 [NEW]	PGR2025-00003 EX2439 - MERCK_PGR00040 - 20251215 Payment Remittance_Redacted (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)

1272 [NEW]	PGR2025-00003 EX2440 - MERCK_PGR00046 - PAYMENT REMITTANCE DETAIL (Oct 2025) (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1273 [NEW]	PGR2025-00003 EX2441 - MERCK_PGR00047 - PAYMENT REMITTANCE DETAIL (Sep 2025) (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1274 [NEW]	PGR2025-00003 EX2442 - MERCK_PGR00048 - Invoice IN00125072310 Review History (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1275 [NEW]	PGR2025-00003 EX2443 - MERCK_PGR00050 - Invoices 5_1_2024-12_22_2025_2 of 3 (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1276 [NEW]	PGR2025-00003 EX2444 - MERCK_PGR00051 - Invoices 5_1_2024-12_22_2025_3 of 3 (CONFIDENTIAL - PROTECTIVE ORDER MATERIAL)
1277 [NEW]	RPI Order Exhibit Correlation Table

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume set by the Director's Interim Discretionary Process dated March 26, 2025, because it is no more than 20 pages, excluding the parts of the brief exempted by 37 C.F.R. § 42.24. See <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>.

Dated: June 29, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 29th day of June, 2026, I caused to be served a true and correct copy of the foregoing and any accompanying exhibits by e-mail on the following counsel:

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