

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyne, Inc.,
Patent Owner.

PGR2025-00017
Patent No. 12,110,520

AUTHORIZED RESPONSE TO DIRECTOR REVIEW REQUEST

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35 U.S.C. § 112	<i>passim</i>
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I. Introduction

Halozyme’s Request for Director Review (Paper 108, “Br.”) fails to identify any abuse of discretion, erroneous finding of fact or conclusion of law, or any other valid basis for review of the Board’s Final Written Decision (Paper 106, “FWD”) or its denial of Halozyme’s motion to terminate (Paper 96, “Order”).

This FWD is the fifth in a series of carefully reasoned Board decisions finding Halozyme’s claims to immense genera of multiply-modified PH20 polypeptides unpatentable under 35 U.S.C. § 112. Halozyme sought (and was correctly denied) Director review of the first four FWDs. In those four Director review requests, Halozyme only disputed the Board’s well-reasoned RPI decision—it raised no issue with the Board’s unpatentability determinations, which are substantively identical to those in this proceeding. *See, e.g.*, PGR2026-00009, Paper 136, 14. Appeals of those unpatentability determinations are now pending before the Federal Circuit.

Halozyme identifies no credible reason for the Director to intervene on the merits now. Its arguments rest on a flawed claim construction: that the Board improperly (1) “read[] function into the claims” by construing a “modified PH20 polypeptide” to have some hyaluronidase activity; (2) departed from Merck’s proposed construction such that its analysis was “agency-led,” and (3) credited expert testimony that did not use its construction. Br. 1, 7-8. But Halozyme’s arguments were thoroughly considered and rejected by the Board in a detailed 16-

page claim construction analysis (FWD, 11-27). And, critically, Halozyne ignores that the Board *independently* found the claims unpatentable, *even under Halozyne’s construction*. FWD, 54-60, 114-115.

The Board’s FWD clearly explains why Halozyne’s theories are wrong. First, after recounting both sides’ positions, the Board correctly noted that the patent’s “Definitions” section expressly states that a “modified PH20 polypeptide can have up to 150 amino acid replacements, *so long as the resulting modified PH20 polypeptide exhibits hyaluronidase activity*.” EX1001, 48:38-53.¹ It separately defines the claim term “PH20” as “a type of hyaluronidase that occurs in sperm and *is neutral-active*.” *Id.*, 45:56-57. The panel appropriately read these definitions together and concluded the claimed “modified PH20 polypeptides” must have hyaluronidase activity. FWD, 17-26. This is not “reading function into the claims”—it is applying the specification’s *express definitions*. As the Board reasoned, to find otherwise would read “PH20” out of the claims. FWD, 25-26; Paper 84, 2-4.

Second, Halozyne’s narrative of a rogue panel crafting its own construction without expert support is fiction. The panel recounted and weighed both parties’ positions and testimony before crediting Merck’s experts, who explained why a POSA would understand the claims were directed to “active” mutants. FWD, 12-16,

¹ All emphasis added unless otherwise noted.

22-27; EX1003, ¶¶98-107, 126-135; EX1133, ¶¶87-110. The Board also quoted *Merck’s Petition*: “the specification describes two mutually exclusive categories of ‘modified PH20 polypeptides’ (i.e., ‘active mutants’ vs. ‘inactive mutants’) **but the claims are limited to one (i.e., ‘active mutants’).**” FWD, 12 (quoting Pet., 22).

Lacking any legitimate basis for review, Halozyme resorts to new arguments about, *inter alia*, the ubiquity of sequence identity claiming, its licensing business, and the development of Merck’s Keytruda QLEX[®] product. Each is irrelevant to the patentability issue, improper for Director Review, and factually incorrect. The Petition did not contend that sequence identity claiming is universally improper — it demonstrated that Halozyme’s claims and disclosure are *uniquely flawed* under § 112. And Halozyme’s assertions that it has licensed the challenged patents and that the novel hyaluronidase in Merck’s product was developed “using” Halozyme’s patent disclosure are *demonstrably false*.

Finally, Halozyme repeats its assertion that Merck & Co., Inc. (“MCI”) is a RPI of Petitioner Merck Sharp & Dohme LLC (“MSD”). But, as the Board found in its 24-page Order, Halozyme’s arguments are *uniformly refuted* by voluminous evidence, briefing, and testimony. The Director has already declined Halozyme’s Director Review requests based solely on this RPI issue in four related PGR proceedings (PGR2025-00003, -004, -006, and -009), and recently granted institution of three related IPRs over Halozyme’s same RPI allegations (IPR2026-

00312, -313, -314). The record and law here is identical.

Halozyme's request for Director review should be denied.

II. Halozyme Fails to Justify Director Review of the FWD

The Board's § 112 determinations flow directly from the grounds, evidence, and expert testimony presented by Merck. They are not, as Halozyme contends, the result of an "agency-led, inquisitorial process" that deprived it of "the benefit of [the] the § 112 bargain." Br. 1-2, 7. Halozyme does not dispute that the claims capture more than 10⁵⁹+ modified PH20 polypeptides with *multiple* modifications, while the record demonstrates that Halozyme's disclosure (i) only describes PH20 mutants with *one* substitution, and (ii) provides insufficient guidance to practice nearly the entirety of the claims' scope. See FWD, 11-27, 31, 60-64, 113-115; Pet., 26-28, 80-84; Paper 84, 2, 7-10.

A. There Was No Error in the Board's Claim Construction

The Board's claim construction analysis was consistent with the intrinsic record. FWD, 17-20. In particular, the disclosure's Definitions section provides:

[A]s used herein, 'modified PH20 polypeptide' or 'variant PH20 polypeptide' refers to a PH20 polypeptide that contains at least one amino acid modification . . . A modified PH20 polypeptide can have up to 150 amino acid replacements, *so long as the resulting modified PH20 polypeptide exhibits hyaluronidase activity.*

EX1001, 48:38-53; FWD, 11. The disclosure also defines "PH20" (a term in every challenged claim) as "a type of hyaluronidase that occurs in sperm and is neutral-active." *Id.* 45:56-57. The panel properly relied on both definitions, reasoning that

“by electing to include the defined term ‘PH20’ in the claims of the ’520 patent, Patent Owner chose to inform the ordinary artisan that the claimed polypeptides would have the properties that the ’520 patent expressly defines as being part of a ‘PH20’ polypeptide, which include hyaluronidase activity.” FWD, 26.

The panel’s construction was further supported by the discussion of hyaluronidase activity in the remainder of the Definitions section, and in the claims. FWD, 20, 24-27. The panel recognized that the Definitions repeatedly associated “modified PH20 polypeptides” with hyaluronidase activity, including its definitions of “increased stability,” “phenophile,” “thermophile,” and “conjugate[d]” products as referencing activity “of the unmodified or reference PH20 hyaluronidase” or retention of “hyaluronidase activity.” FWD, 18-20. It also referenced Halozyme’s statutory disclaimer of dependent claims in response to Merck’s petitions. Those claims required “treating a hyaluronan-associated disease” and “increased hyaluronidase activity,” which necessarily “assume[d] that the underlying ‘modified PH20 polypeptide’ recited in the [independent] base claim has activity.” FWD, 26.

Halozyme’s contention that the panel “selected” hyaluronidase activity because it appeared most frequently in the Definitions section (Br., 9) mischaracterizes the panel’s reasoning. Rather, the panel applied the patent’s express definitional language to conclude that hyaluronidase activity is required for the “modified PH20 polypeptides” being claimed. Consistent with this definition, the

panel further noted that the frequency with which hyaluronidase activity was discussed in the remainder of the disclosure corroborated that construction. FWD, 20, 24-25. And, far from “ignor[ing]” the specification’s discussion of inactive mutants (Br., 9-10), the panel squarely addressed that there were limited references to “inactive” polypeptides in “non-definitional sections” of the patent discussing contraceptive utility that “do[] not modify the definition’s explicit requirement that the claimed ‘modified PH20 polypeptide’ exhibit hyaluronidase activity.” FWD, 20-25 (disclosure’s statement that a modified PH20 “may also be useful to provide a contraceptive effect . . . does not void the definitional language” requiring activity).

Extrinsic evidence confirmed that PH20s were understood by POSAs as having hyaluronidase activity. FWD, 20-21, 25. Halozyme’s expert, Dr. Simpson, conceded that “PH20 is defined as a type of hyaluronidase that occurs in sperm and is neutral-active.” FWD, 23 (quoting EX1130, 62:2-3). Citing this testimony, the panel agreed with Dr. Naismith that “excluding any function from the term ‘PH20’ ‘effectively strikes the word ‘PH20’ out of the claims.’” FWD, 23-26.

The Board thus correctly adopted Merck’s construction: “we agree with Petitioner that the term, interpreted in light of the Specification, requires at least some hyaluronidase activity.” *Id.*, 24. Halozyme’s suggestion that “Merck never advocated for... the construction supplied by the panel” (Br. 11) is simply wrong.

But the Board’s decision did not limit its unpatentability conclusion to

Merck’s construction. It explained that “*even if [it] were to accept Patent Owner’s position* that the term is broader and includes inactive versions of such peptides that can be used as antigens to provide a contraceptive effect, the preponderance of the evidence before us does not demonstrate this to be a credible utility” and “*it does not demonstrate that the inventors were in possession of the full scope of the claimed polypeptides.*” FWD, 54-60. The Board thus found the claims unpatentable for inadequate written description and enablement even under Halozyne’s reading. *Id.* 60, 114-115. Even if credited, Halozyne’s claim construction arguments would not have changed the Board’s conclusions, and thus do not warrant Director review.

B. Halozyne Misrepresents the Testimony of Merck’s Experts

Halozyne contends that Merck’s experts applied “entirely different construction[s] than that adopted by the panel.” Br., 7-8. That is false. Consistent with the Board’s construction, each of Merck’s experts—Dr. Hecht and Dr. Naismith—testified that a POSA, reviewing the intrinsic record as a whole, would conclude that the claims are directed to “active” mutants that exhibit hyaluronidase activity. EX1133, ¶109 (POSA “would have concluded that the claims are directed to the ‘active mutant’ alternative of ‘modified PH20 polypeptides,’ which are forms of modified PH20 polypeptides that exhibit hyaluronidase activity”); EX1003, ¶134 (POSA “would have understood the claims to necessarily cover modified PH20 polypeptides that are active mutants and would not view them as including inactive

mutants”). In reaching their conclusions, the experts pointed to much of the same evidence as the Board, including recognizing that the “as used herein” language in the Definitions section “is a definition of how it is used herein,” and that the language stating “so long as the resulting polypeptides exhibit hyaluronidase activity” was “a pretty strong statement... in terms of how it is used herein.” FWD, 22-24 (quoting EX2076, 191:18-192:1; EX1133, ¶¶103-104; EX2301, 64:20-22).

Halozyme attacks Dr. Naismith’s explanation that hyaluronidase activity requires “proper folding” of the protein. Br. 12. But this is an area of *agreement* between Dr. Naismith and Halozyme’s expert, Dr. Petsko, who testified that active PH20s must be “properly folded.” EX2070, ¶128 n.12. Dr. Naismith agreed, stating that “[a] modified PH20 polypeptide must preserve many aspects of the tertiary fold of the wild-type PH20 protein to exhibit hyaluronidase activity.” EX1133, ¶¶96, 109.

Also contrary to Halozyme’s assertions (Br. 11), Merck and its experts never contended the *claims* require 40% activity. Merck’s position is, and always has been, “that the claims require PH20s *with hyaluronidase activity*.” Paper 84, 2-4 n.12; *see also, e.g.,* Pet., 2, 41; EX1003, ¶134. Merck merely referred to 40% as the disclosure’s threshold for its classification of mutants in its mutagenesis study, not as definitional to the claims. *See* Pet. 22-23; EX1003, ¶¶98, 100; Paper 84, 4 n.12.

Finally, Halozyme misrepresents that “Merck’s experts admitted” that “[t]he claims identify the genus of proteins by their amino acid sequence structure, not

function” and that “POSAs would know exactly which amino acid sequences are covered by the claims based on the specification’s teachings” Br., 6 (citing EX2070, ¶¶68; EX1003, ¶36; EX2301, 57:5-8; EX2076, 203:18-204:10; EX2068, ¶¶36, 161-164, 278-307; EX2070, ¶44). But nearly all of these cited “admissions” are to Halozyme’s *own experts’ testimony* (EX2068, EX2070). The cited testimony from Merck’s experts’ (EX1003, ¶36; EX2301, 57:5-8; EX2076, 203:18-204:10) simply explains that proteins are formed by sequences of amino acids and that a POSA can determine sequence identity—it says nothing about construction of the claims.

Merck’s experts fully support the Board’s § 112 determinations.

III. Halozyme’s Other Arguments Should be Disregarded or Rejected

Halozyme’s request raises new evidence and arguments it never presented in this proceeding. This violates of the rules governing Director Review. *See* [Director Review Process](#), 2.B.

First, citing and hyperlinking to “Google Patents,” Halozyme argues sequence-identity claims are “so common that Petitioner Merck and thousands of other companies hold such claims” and that the FWD will “make[] it impossible for Halozyme and companies like it to obtain meaningful patent coverage.” Br. 2, 4-5. To the extent the Director considers this untimely and improper argument, it is irrelevant. Neither Merck’s PGRs nor the Board’s FWD suggest the use of sequence identity in patent claims is improper. Instead, both contrasted the scope of these

claims (which encompass an immense and heterogenous genus of $10^{59}+$ multiply modified PH20s that in the aggregate weighs more than Earth and would have taken billions of lifetimes of a POSA to make and test) with Halozyme's *uniquely deficient disclosure*, which describes *zero* multiply-modified PH20s in the claim scope. FWD, 60-62, 73-81, 97-101; EX1133, ¶132.

The Board also squarely rejected Halozyme's characterization of the disclosure as providing a "structure-function mapping of the PH20 protein" that can be used to "generate improved modified PH20s that practice the claims." Br. 2, 4. It correctly found that "the effects observed from single amino acid modifications [i.e., all the disclosure purports to show] are not necessarily additive when combined in [the] same polypeptide" and "the functional and other characteristics of a PH20 protein that incorporates a first single amino acid substitution... cannot be extrapolated to modified PH20 polypeptides that incorporate myriad sets of combinations of multiple substitutions in addition to the first." FWD, 100-101 (quoting EX1003, ¶140). Halozyme's failure to satisfy "the heart of the § 112 bargain" (Br., 2) is why the Board found its claims unpatentable.

Halozyme is also wrong on the law. It contends (incorrectly) that it could "avoid *Amgen*-type § 112 problems" by "carefully prosecuting patents" to avoid use of functional language. Br. 1-2, 10. But claims that define immense chemical genera in purely structural terms are not exempt from the enablement and written

description requirements of § 112. In *Ariad*, the Federal Circuit noted that written description problems stem from “merely drawing a fence around the outer limits of a purported genus” and are “*especially acute* with genus claims that use functional language.” *Ariad Pharms. v. Eli Lilly*, 598 F.3d 1336, 1349-50 (Fed. Cir. 2010). Such written description problems, however, are not only present in claims that define the genus with functional language. The Federal Circuit made this crystal clear in *Regents of University of Minnesota v. Gilead Sciences*, which found claims that defined chemical genera in purely structural language unpatentable. 61 F.4th 1350, 1356 (Fed. Cir. 2023) (a “broad outline of a genus’s perimeter is insufficient.”). And just last week, the Federal Circuit again confirmed that where, as here, the disclosure lacks adequate guidance regarding which enzymes captured by sequence identity claims will exhibit activity, “[t]he massive disparity between the amount claimed and the amount disclosed supports the Board’s finding of lack of enablement.” *Pioneer Hi-Bred Int’l, Inc. v. Inari Agric., Inc.*, No. 2025-1287, 2026 WL 2969664, at *3 (Fed. Cir. Oct. 2, 2026).

Next, Halozyme raises new and false allegations about the development history of the modified PH20 in Merck’s Keytruda QLEX[®] product, which was developed by a third party, Alteogen. Br. 4. Halozyme contends Alteogen “publicly admitted to using Halozyme’s patents—which include the vast mutagenesis study supporting the claims—to develop its modified PH20.” Br., 4 (citing 2:25-cv-03179-

ES-JRA, 48-1 at 3, 48-5). Alteogen said no such thing. What Halozyme cites are *Halozyme’s attorney arguments* in the district court. The underlying documents Halozyme cites simply state that Alteogen had analyzed Halozyme’s patents and concluded they were invalid and not infringed—Alteogen did not suggest (much less admit) using Halozyme’s patents to develop their novel hyaluronidase (“BHA”).

Halozyme also consciously disregards facts and its own arguments in this proceeding to advance this false narrative. In its district court complaint, Halozyme included a sequence alignment that *confirms* that BHA contains *two mutations* to native human PH20 that Halozyme’s disclosure states render human PH20 *inactive*, and affirmatively instructs that such changes *should not be made in active mutants*.

Excerpt of Halozyme Complaint, Exhibit T (Annotated)

Needleman-Wunsch Global Sequence Alignment Between SEQ ID NO: 3 (Query) and BHA (Sbjct)							
Query	301	IVIWGTL SIMRSMKSCLLLDNYMETILNPYIINVTLAAKMCSQVLCQEQGVCIRKNWNSS					360
Sbjct	299	SWENT.TKE..QAIKE..D.T.....					358
				↑	↑		
				L319I	N321E		

Excerpt of EX1001 (520 Patent) (Annotated)

TABLE 10-continued							
Inactive Mutants							
F040G	Y099G	R176C	A223G	F266T	N321E	S360L	D413H
F038L	D095Y	K173S	E220R	V265N	L319I	S359A	C408R

Halozyme also argued *in this proceeding* that “inactivating” mutations (including the two in BHA) must be *avoided* in enzymatically active PH20s. Paper 101, 20-21 (“the specification discloses the common structural features based on [the] primary

structure and the related mutagenesis data,” including “for actives... “*[l]ack of the inactivating changes identified in the disclosure.*”). In other words, according to Halozyme, the patent's disclosure does **not** describe and **cannot** lead one to (much less enable) BHA’s unique structure.

Halozyme’s arguments about parallel infringement proceedings also have no relevance to the FWD. Halozyme baselessly speculates there will be “shifting claim constructions” in the district court (Br. 13-14), but conceals that those proceedings have been effectively stayed since their inception, do not have a schedule, and thus are nowhere near claim construction. *See, e.g.,* 2:25-cv-03179-ES-JRA, Dkt. 65 (order staying case “pending the outcome of the patent reviews before the [PTAB] and, if applicable, the [Federal Circuit]”). Halozyme’s assertions regarding the status of proceedings in Germany are similarly irrelevant and unsubstantiated.

Finally, Halozyme argues it is an “American company” whose PH20 innovations have been licensed to “[m]any pharmaceutical companies” that “use its product in their formulations.” Br. 1, 3. These arguments were previously rejected. Paper 17, 11-13; Paper 25 (Acting Director, July 2, 2025). They are also misleading: Halozyme does not make, sell, or license any products that ***practice the challenged claims***. In Halozyme’s own words, Merck’s PGR challenges are of ***no consequence*** to its patents on rHuPH20 (Hylenex[®]), its only commercial product. *See* IPR2026-00312, Exhibit 1101, 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.”). Halozyme is the opportunistic 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 PGR system for the reason it was created: as a cost-effective alternative to Halozyme's aggressive licensing and litigation tactics.²

IV. Halozyme Provides No Basis for Review of the Board's RPI Order

Halozyme again seeks Director review of the Board's RPI Order. Br., 3. The Director has already considered and *denied four prior requests* by Halozyme to review that Order. The Board's Order addressed every factor relevant to RPI, and provided an exhaustive review of the *entire* evidentiary record submitted by both parties. Paper 87. This included four rounds of briefing, a detailed declaration and protracted deposition testimony from a corporate deponent, Kelly Grez, and numerous corroborating internal records MSD produced. The evidence conclusively

² 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. FWD, 4-5. Halozyme's failure to promptly provide the Examiners with the full records of the nine FWDs to date calls into question Halozyme's duty of candor to the Patent Office.

and uniformly disproved Halozyme's RPI theory.

Halozyme now points to two decisions, *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), as allegedly "directly inconsistent" with the Order. Br., 3. They are not. *Sun* was already addressed in Halozyme's prior Director review requests, where Merck relied on evidence showing that (unlike in *Sun*) its declarant demonstrated MCI does not have the ability to control these proceedings. PGR2025-00003, Paper 144, 14-15. That evidence likewise distinguishes *Viance*, where a limited evidentiary record failed to show *Viance's* corporate parents lacked the ability to control the proceedings. *Viance*, 3-4. Neither decision raises any new issue.

Halozyme's speculation about the basis of the Director's discretionary denial decision in PGR2025-00087 are belied by the Director's decision to deny review of the same RPI theory in PGR2025-00003, -4, -6, and -9, and the Director's recent institution of IPRs 2026-00312, -313, and -314. *See, e.g.*, IPR2026-00312, Paper 10, 4-11; Paper 14, 12-19; Paper 22 (Director Denial of Request for Discretionary Denial, Aug. 19, 2026); Paper 23 (Director Institution Decision, Sept. 9, 2026). There is no reason to disturb the Board's RPI Order or its FWD.

V. Conclusion

Halozyme's Request for review of the Board's decisions should be denied.

Dated: October 9, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 9th 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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