

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MERCK SHARP & DOHME LLC,  
Petitioner

v.

HALOZYME, INC.,  
Patent Owner

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Case PGR2025-00017  
U.S. Patent No. 12,110,520

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**PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW OF THE  
FINAL WRITTEN DECISION**

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Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

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## I. INTRODUCTION

Halozyme, Inc. (“Patent Owner”) requests Director Review of the Board’s September 1, 2026 Final Written Decision (“FWD”) finding all claims of U.S. Patent No. 12,110,520 (the “’520 patent”) unpatentable under 35 U.S.C. § 112.

As the Director declared, “intellectual property has become the most dominant and most important asset, not only of companies—but of nations themselves. We know for certain this is true for the United States of America.” Remarks, Protecting U.S. IP and Tech Leadership through International Trade Policy Tools, September 15, 2026. But intellectual property assets are only valuable if they are enforceable, and enforceability requires proper application of the rules governing patentability.

The panel failed to properly apply those rules and instead performed an inappropriate, “agency-led, inquisitorial process” (*SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 364 (2018)) on a pre-AIA patent in reaching its FWD, reading function into the claims where none exists (*see* Section III.B.1) and relying on expert testimony applying a different claim construction entirely (*see* Section III.B.2), among numerous other errors.

Halozyme spent years carefully prosecuting patents through the Patent Office that include commonly used sequence-identity claiming conventions which claim Halozyme’s novel PH20 polypeptides by structure (not by function) to avoid *Amgen*-type §112 problems. But despite Halozyme’s efforts, the panel imported a functional

limitation into the claims in order to apply the *Amgen*-style functional genus law.

Sequence-identity claiming is so common that Petitioner Merck and thousands of other companies hold such claims. [Google Patents Search](#). And they are common because they provide a meaningful scope of protection in exchange for disclosure—the heart of the §112 bargain. Yet the panel here reasoned that the “number of distinct peptides” covered by such claims “is extremely large” due to the basic math of permutations. The panel combined the purported breadth of the claims with its imported functional limitation and found the claims invalid. FWD, 113.

The panel’s decision makes it impossible for Halozyme and companies like it to obtain meaningful patent coverage for their inventions that is commensurate with their disclosure. Halozyme’s disclosure meaningfully advanced the art by providing an unprecedented structure-function mapping of the PH20 protein, which POSAs can indisputably use to generate improved modified PH20s that practice the claims. Having held up its end of the §112 bargain, Halozyme is entitled to a scope of protection commensurate with its disclosure. By disclosing its invention to the public, Halozyme gave fast followers all the information needed to develop a modified PH20 and compete with Halozyme. That is exactly what happened here.

According to the panel, Halozyme is not entitled to the benefit of §112 bargain. Instead, Halozyme must let fast followers take advantage of its disclosure with no consequence, and instead endure competition from copyists. Director review

is warranted here, not just because of the errors in the panel’s analysis, but also to ensure the bargain underlying §112 is respected.

Finally, the panel’s FWD is not the only time the panel failed to follow the rules (*see* Section III.C). The panel’s denial of Halozyme’s motion to terminate for failure to name MCI as a RPI is directly inconsistent 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). It also is inconsistent with the Director discretionarily denying institution in PGR2025-00087, where the failure to name MCI as a RPI was the sole issue raised post-petition. The Director should not let this inconsistency stand.

## **II. FACTUAL BACKGROUND**

Halozyme is an American company. Its inventors initially discovered how to make the PH20 protein soluble such that it could be used in therapeutic products. Many pharmaceutical companies have licensed Halozyme’s invention and use its product in their formulations. Later, and relevant to this proceeding, Halozyme’s inventors discovered that certain amino acid substitutions in the PH20 protein sequence at certain positions improve (or modify or eliminate) hyaluronidase activity. The claims at issue here are directed to certain substitutions at one such position—position 324. *See* EX1001, claim 1, cols. 231-232 (Table 9).

In the process of making their discovery, Halozyme’s inventors performed a complete structural mapping of a soluble PH20, evaluating on average 13 substitutions at every single position in the 447 amino acid PH20 sequence. EX2070, ¶¶264-296; EX2068, ¶ 196. “This level of structure-function detail for an individual protein of this size was virtually unheard of as of 2012” and is “extraordinarily useful to a POSA seeking to make and use modified PH20 polypeptides.” EX2068, ¶¶ 163-164; EX2070, ¶234; EX1131, 113:8-18.

Consistent with the scope of their disclosure and what the inventors discovered, the inventors claimed modified PH20 polypeptides with the specified change at position 324 as well as at least 91% identical variants of those modified PH20s. *See* claim 1, reproduced below. Sequence identity limitations, such as those recited in the claims, are a common mechanism for ensuring that the Patent Office grants a meaningful scope of patent protection for protein sequence inventions in return for public disclosure. Without them, it would be easy for others to make use of the disclosed invention while making trivial changes to avoid claims limited to an exact sequence. This is not a theoretical concern: in fact, Alteogen, the South Korean company that makes the modified PH20 in Merck’s product, has publicly admitted to using Halozyme’s patents—which include the vast mutagenesis study supporting the claims—to develop its modified PH20. 2:25-cv-03179-ES-JRA, 48-1 at 3, 48-5.

Nor is it a trivial concern: there are well over 10,000 currently issued patents

using similar types of claims, and numerous American companies hold hundreds of such patents across multiple fields. *See* [hyperlink]. For instance, Pioneer Hi-Bred International, Inc., Genentech and Regeneron each hold 50 or more patents with claims including some form of sequence identity.

Instead of respecting Halozyme's patent rights, however, Merck elected to license Alteogen's copycat product. Merck should not be rewarded for such conduct, and other jurisdictions with strong intellectual property systems, like Germany, have enjoined Merck's use of Alteogen's product. But here, the panel issued a fifth FWD in a string of FWDs holding Halozyme's claims unpatentable.

Claim 1, which is representative of the claims at issue here, recites the invention in structural terms, defining the modifications allowed to PH20 in reference to known PH20 amino acid sequences (EX1001, claim 1):

1. A modified PH20 polypeptide, comprising one or more amino acid modifications in an unmodified PH20 polypeptide, wherein:

the unmodified PH20 polypeptide consists of the amino acid sequence selected from the group consisting of SEQ ID NO: 3, 7 and 32-66;

amino acid modifications are selected from the group consisting of amino acid replacements(s), deletion(s), and/or insertion(s);

the modified PH20 polypeptide comprises an amino acid replacement at a position corresponding to residue 324, with reference to amino acid positions set forth in SEQ ID NO: 3;

the replacement at the position corresponding to residue 324 is selected

from the group consisting of A, D, H, M, N, R and S;

corresponding amino acid positions are identified by alignment of the PH20 polypeptide with the polypeptide having the amino acid sequence of SEQ ID NO: 3; and

the modified PH20 polypeptide has at least 91% sequence identity to a polypeptide having the amino acid sequence selected from the group consisting of SEQ ID NO: 3, 7 and 32-66.

### III. ARGUMENT

#### A. The Challenged Claims Are Patentable

The claims recite only structure, as set out above (and in Section III.B.1). The legal standard for determining whether a structural claim complies with §112's written description requirement is straightforward. For a claimed genus, it “*may be satisfied through sufficient description of...relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties....*” MPEP 2163. And for a species, it is satisfied where “a complete structure is disclosed.” *Id.*

The application of written description law to the '520 claims also should have been straightforward. The claims identify the genus of proteins by their amino acid sequence structure, not function, as Merck's experts admitted. EX2070, ¶ 68; EX1003, ¶ 36; EX2301, 57:5-8. There is no dispute that every amino acid sequence within the claim scope was sufficiently described: Merck's experts admitted POSAs would know exactly which amino acid sequences are covered by the claims based on the specification's teaching. EX2076, 203:18-204:10; *see also* EX2068, ¶¶36,

161-164, 278-317; EX2070, ¶¶44. That is all that written description requires.

The legal standards for determining whether a claim such as claim 1 complies with §112's enablement requirement are similarly straightforward: the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Application of this test to the facts should have been simple. The panel found that a POSA would have been able to modify proteins from their amino acid sequences as a routine matter: "Based on the evidence of record, we find that simply making and expressing modified PH20 polypeptides was well within the state of the prior art." FWD, 86. Moreover, the patent moved the state of the art far forward, making further modification of PH20 routine. EX2068, ¶¶ 43-45, 163-164; EX1130, 95:5-10, 98:3-10. The claims are enabled.

**B. The Panel Clearly Erred In Finding The Claims Unpatentable**

Post-grant review proceedings are supposed to be "a party-directed, adversarial process," not an "agency-led, inquisitorial process for reconsidering patents." *Zhuhai Cosmx Battery Co., Ltd. v. Ningde Amperex Tech. Ltd.*, IPR2025-00524, Paper No. 17, 3 (quoting *SAS*, 584 U.S. at 364). As set out below, however, the panel here performed its own inquisition. At Merck's insistence, it read function into the claims where none exists to shoehorn Halozyme's claims into the body of inapplicable §112 law invalidating *functional* genus claims, and relied on expert

testimony applying an entirely different construction than that adopted by the panel, even after the panel provided its preliminary claim construction opinion.

### 1. The Panel Erred in Reading Function Into the Claims

The panel's first error, which set into motion several others, was to invent a claim construction for "modified PH20 polypeptide" that read a specific function ("some hyaluronidase activity") into claim 1, despite no such function being recited in the claims (*see* Section B.2). The panel's construction, which is at clear odds with the claims and intrinsic evidence, is wrong.

The claim language (above) says nothing about any function. And, as the panel acknowledged, the specification describes at length multiple *different* functions for PH20, including modified PH20s that are enzymatically inactive, stable, soluble, antigenic, or immunogenic. FWD, 18, 24-25. For instance, as just one of many examples, the specification explains that "[p]rovided herein are modified PH20 polypeptides... *that are inactive, whereby the polypeptides do not exhibit hyaluronidase activity* or exhibit low or diminished hyaluronidase activity." EX1001, 79:27-29, 119:13-17. As another example, the patent teaches modified PH20s that are stable in the presence of a phenolic preservative. EX1001, 6:39-43.

The panel, however, appeared to reason that it *must* select a specific function for the claims: "*some type* of activity is required for a polypeptide to be a 'modified PH20 polypeptide.'" FWD, 20 (emphasis added). It thus evaluated which function

was mentioned the most often in the “definitions” section of the specification—hyaluronidase activity—and disregarded (1) the other functions specifically presented in the specification and (2) the fact that the specification uses the phrase “modified PH20 polypeptides” to refer to polypeptides *without* enzymatic activity:

Analyzing all of the intrinsic evidence, a consistent reading of the term “modified PH20 polypeptide” in the ’520 patent supports the understanding that some type of activity is required for a polypeptide to be a “modified PH20 polypeptide,” and that *the enzymatic activity of hyaluronidase is the most frequently identified activity recited in the definitions section of the ’520 patent.*

FWD, 20 (emphasis added) (“In contrast, the discussion regarding the potential use of ‘modified PH20 polypeptides that are inactive’ as antigens in contraception vaccines appears only in non-definitional sections...”).

The law is clear that unrecited functional limitations cannot be read into the claims. As explained in MPEP section 2111.01, the Federal Circuit has repeatedly emphasized that “it is important not to import into a claim limitations that are not part of the claim.” *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). That a function is the “most frequently identified” in a particular section of the patent is no reason to ignore this well-settled law.

The panel also ignored that the express definition of “modified PH20 polypeptide” in the specification is structural and not limited to a particular function. The specification defines it as: “a PH20 polypeptide that contains at least one amino

acid modification, such as at least one amino acid replacement as described herein, in its sequence of amino acids compared to a reference unmodified PH20 polypeptide.” EX1001, 48:38-43.

The panel fundamentally changed this express definition by adding to its construction the sentence immediately following the definition, which discusses PH20s with “up to 150 modifications” “so long as” they retain hyaluronidase activity. EX1001, 48:38-43. That was error. For example, it is incompatible with the specification’s use of “modified PH20 polypeptide” to describe both active and inactive PH20s, and at odds with the specification’s description of modified PH20 polypeptides as having multiple functions.<sup>1</sup> *E.g.*, EX1001, 75:45-60; *id.* at 43:48-44:52. And the second sentence uses “non-limiting terms” instead of “refers to” or “as used herein,” a clear signal that it is not definitional. *Alnylam*, 138 F.4th at 1333.

Yet despite the plain language of the claim and disclosure of the specification, the panel was determined to read function into the claims in order to analogize them to *Amgen* and *Idenix*, decisions which invalidated ***functional*** claims. FWD, 101, 111. That plain error formed the basis of the panel’s analysis and warrants reversal. *See, e.g.*, FWD, 63 (“the claims of the ’520 patent fail to satisfy the written

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<sup>1</sup> The panel’s argument that the word “PH20” requires activity fails for this same reason—the patent uses the word “PH20” to refer to both actives and inactives.

description requirement because they ... ‘recite a description of the problem to be solved while claiming all solutions to it and . . . cover any compound later actually invented and determined to fall within the claim’s functional boundaries...’”).

## **2. The Panel Relied on Expert Evidence Applying the Wrong Claim Construction**

Even if the panel’s construction were correct (it was not), the panel erred by inventing expert testimony on Merck’s behalf and ignoring the only relevant expert testimony under the panel’s construction—that of Patent Owner’s experts.

Specifically, despite being the Petitioner, Merck never advocated for or adopted the construction supplied by the panel, nor did its experts ever apply it. Instead, on filing its petition, Merck’s experts provided testimony that required a “modified PH20 polypeptide” to exhibit 40% activity. Paper 1, 25-26, 53-54, 108-109; EX1003 ¶¶126, 134, 190. In other words, Merck’s petition was founded on the argument that the specification did not provide §112 support for claims that required at least 40% enzymatic activity—not “some hyaluronidase activity,” as required by the panel’s construction.

These are two significantly different evidentiary questions, and expert testimony on whether a POSA could, for example, reasonably predict whether a given modified PH20 will have at least 40% activity is very different from whether a POSA could reasonably predict that a PH20 will have any activity. Yet whether Merck’s expert supporting its petition—Dr. Hecht—would have maintained his

position in view of the panel’s construction is a question unanswered on the record. That is because Dr. Hecht was replaced on reply during the trial.

Merck’s failure to put in *any* evidence that addresses the panel’s construction is particularly egregious considering that the Institution Decision put Merck on notice of the preliminary construction requiring “some” hyaluronidase activity (Paper 31, 17). Rather than address that construction, Merck submitted a 390-page declaration from a new expert, Dr. Naismith, who offered a new construction. Dr. Naismith opined that “modified PH20 polypeptide” requires “proper folding” (or stable folding) of the PH20, in addition to hyaluronidase activity (EX1133, ¶¶ 101, 104) – substituting one erroneous requirement not adopted by the panel (40% activity) for another (proper folding). Whether the specification sufficiently describes and enables a POSA to predict “proper” or “stable” folding (at 8 or 12 hours) is a completely different question. Merck also continued to advocate for a construction requiring “proper folding” at the hearing (EX1278, 19-22, 66-69)—as, of course, Merck had provided no testimony under the panel’s construction.

Despite Merck offering (with its Petition or otherwise) no expert testimony actually addressing the panel’s ultimate construction, the panel time and again credited Merck’s experts’ testimony. FWD, 51, 53 (“To the extent the experts disagree on this point, we credit the testimony of Petitioner’s experts over that of

Patent Owner's.”). The panel did not address how Merck's testimony applying a claim construction with different requirements was or remained relevant.

Simply put, the panel abused its discretion by crediting Merck's experts with testimony they never gave to support findings under a construction they never addressed. *See, e.g., Interactive Commc'ns Int'l, Inc. v. Blackhawk Network Inc.*, IPR2024-00465, Paper 40 (Oct. 9, 2025) (vacating a FWD because “the Board abused its discretion by improperly crediting expert testimony that has multiple material contradictions” on an issue that was “central to Petitioner's analysis”).

Compounding its error, the panel also ignored the fact that the *only* expert testimony of record that addressed its initial and ultimate construction was Patent Owner's. Despite disagreeing with the panel's construction (EX2068, ¶ 276), both of Halozyne's experts provided patentability opinions, assuming that the claims required “some hyaluronidase activity.” EX 2068, at ¶ 350; EX 2070, ¶¶ 245, 247.

Petitioner bore the burden of proving unpatentability under the operative construction, and under that construction, only Patent Owner provided testimony. It was clear error to credit expert testimony that did not apply the panel's own construction over testimony that did. But, acting as inquisitor, that is what the panel did, because the record could not otherwise support its FWD.

Merck's inconsistent claim constructions raise an additional issue. Merck and Halozyne are involved in an associated district court case, and Merck's shifting

claim constructions suggest it is trying to preserve a non-infringement position for that case. Merck’s gamesmanship should not be rewarded. “When the party with the burden of proof...rests its case on an expert’s self-contradictory testimony, [the court] may conclude the evidence is insufficient to satisfy that standard.” *Finesse Wireless LLC v. AT&T Mobility LLC*, 156 F.4th 1221, 1227 (Fed. Cir. 2025).

**C. The Panel’s Decision Ignores RPI Law**

As an additional ground for review, the panel erred in denying Halozyme’s motion to terminate based on failure to name MCI as an RPI. Under the recent decisions in *Viance* and *Sun*, Merck’s parent MCI plainly qualifies as an RPI.

In fact, in the -087 PGR, the Director discretionarily denied institution after considering full briefing from both parties and the complete evidentiary record on the RPI issue. The post-petition briefing in that proceeding addressed only RPI—nothing else—and the parties advanced the same arguments and relied on the same evidence as they do here. In denying institution, the Director must have found (correctly) that MCI is an RPI. But the panel failed to do so. To let the inconsistency stand would be to apparently treat Merck as both RPI and not RPI on the same set of facts, eroding the clarity the Director’s recent RPI decisions have given.

MCI is a “global pharmaceutical company with more than \$200 billion in market cap.” EX1225, 57:16-19. MCI “is responsible for the global enterprise ... [and] the business of that enterprise is conducted through subsidiaries.” *Id.*, 106:21-

107:6; EX2410. MSD is the “main U.S. operating entity for [MCI’s] human health business,” (EX1225, 58:10-13), and MCI operates through MSD. MCI also has **actual control** over MSD. MCI is the “sole owner” of MSD and appoints (and can remove) the board of managers that controls MSD. EX1225, 63:17-25, 65:8-67:12.

MCI controls MSD with respect to these PGRs. MCI passed resolutions authorizing MCI’s CEO Robert Davis and general counsel Jennifer Zachary to “execute and to revoke” documents related to patent matters on behalf of MCI and MSD which cover the PGR proceedings. *Id.*, 241:20–248:4. Ms. Zachary in particular has the authority to settle the PGRs. *Id.*, 295:3-21, 305:12-15. Thus, MCI has authorized ***its CEO and general counsel*** to control these PGR proceedings.

In denying the motion to terminate, the panel concluded that MCI is not an RPI because MCI has not actually controlled the proceedings, for example by paying for them or retaining counsel. According to the panel, MCI’s purportedly “theoretical” ability to control the PGRs is insufficient. But that is directly contrary to *Sun* and *Viance*: “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.” *Sun*, Paper 12 at 2-3; *Viance* Paper, 32 at 3. MCI has the ability to control the proceeding and thus should have been named as an RPI.

Patent Owner respectfully requests that the Director grant this request for Director Review, vacate the Board’s Final Written Decision and terminate this PGR.

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 FINAL WRITTEN DECISION** was served in its entirety on October 1, 2026, upon the following parties via electronic mail:

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