

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner

v.

HALOZYME, INC.,
Patent Owner

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

PATENT OWNER'S OBJECTIONS TO EVIDENCE

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

Patent Owner Halozyme Inc. (“Halozyme”) objects under the Federal Rules of Evidence (FRE) and 37 C.F.R. § 42.64(b)(1) to the admissibility of Exhibits 1003, 1004, 1010, 1024, 1030, 1034, 1036, 1037, 1040-1044, 1048, 1049, 1053-1058, 1061, 1064-1067, 1069-1075, and 1082-1086 (the “Challenged Evidence”), filed by Petitioner Merck Sharp & Dohme LLC (“Merck”) on January 17, 2025, with Merck’s Petition for PGR. Halozyme’s Objections are timely filed under 37 C.F.R. § 42.64(b)(1), within ten business days of the Board’s September 8, 2025 Decision on Institution. Halozyme files these Objections to provide notice to Merck that Halozyme may move to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c).

Halozyme’s objections apply equally to Merck’s reliance on this evidence in any subsequently filed documents or further proceedings in this matter.

Notwithstanding these objections, Halozyme expressly reserves the right to rely on any evidence submitted by Merck, including on the ground that, *inter alia*, such evidence constitutes a party admission.

I. IDENTIFICATION OF GROUNDS FOR OBJECTIONS

A. Exhibit 1003

Exhibit 1003 purports to be the “Declaration of Michael Hecht, Ph.D.”

Halozyme objects to paragraphs 11-14, 19-22, 33-137, and 138-193 of Exhibit 1003 under FRE 401–403. Dr. Hecht provides opinions assessing the state of the

art and the “common disclosure” as of December 29, 2011, rather than assessing the disclosures as of the ’731 application’s December 28, 2012 filing date. *See e.g.*, EX1003, ¶¶11-14. Accordingly, Dr. Hecht’s opinions lack relevance under FRE 401 and are inadmissible under FRE 402. For the same reason, Halozyme also objects to these paragraphs in Exhibit 1003 under FRE 403 because they have no probative value, create unfair prejudice to Halozyme, and will only confuse issues and waste the Board’s time.

Halozyme also objects to at least paragraphs 20-22, 71-72, 85, 96, 122, 125, and 138-237, and Appendices A1-A9 of Exhibit 1003 under FRE 702. Throughout his declaration, Dr. Hecht provides opinions and analyses without showing that his opinions are based on sufficient facts or data, are the product of reliable principles and methods, or reflect a reliable application of the principles and methods to the facts of this case. *See id.* Moreover, Dr. Hecht repeatedly relies on the testimony of Dr. Park (Exhibit 1004) to form the basis of his opinions in Exhibit 1003. *See e.g.*, EX1003, ¶¶ 20-22, 85, 122, 125, 158, 215-237 (relying on Dr. Park’s testimony in Exhibit 1004). As discussed below, Dr. Park assesses the state of the art, tools, and methodologies as of December 2011—rather than the ’731 application’s December 28, 2012 filing date—and is not qualified to offer opinions on hyaluronidase, as he lacks relevant experience. Accordingly, Halozyme objects to Dr. Hecht’s testimony in Exhibit 1003 because it will not help the trier of fact understand the

evidence or determine a fact in issue. FRE 702; *see also*, 37 C.F.R. § 42.65. Nor does Dr. Hecht's testimony provide any probative value that would substantially outweigh its prejudicial effect.

B. Exhibit 1004

Exhibit 1004 purports to be the "Declaration of Dr. Sheldon Park." Halozyme objects to paragraphs 10-18, 20-112, 113-158, and 159-184 of Exhibit 1004 under FRE 401–403. Dr. Park provides opinions assessing the state of the art, tools, and methodologies as of December 2011, rather than assessing these aspects as of the '731 application's December 28, 2012 filing date. *See e.g.*, EX1004, ¶¶10-14. Accordingly, Dr. Park's opinions lack relevance under FRE 401 and are inadmissible under FRE 402. For the same reason, Halozyme also objects to these paragraphs in Exhibit 1004 under FRE 403 because they have no probative value, create unfair prejudice to Halozyme, and will only confuse issues and waste the Board's time.

C. Exhibit 1010

Exhibit 1010 purports to be "Zhang *et al.*, 'Hyaluronidase Activity of Human Hyal1 Requires Active Site Acidic and Tyrosine Residues,' *J. Biol. Chem.*, 284(14):9433-9442 (2009)." Halozyme objects to Exhibit 1010 under FRE 1002 and 1003 as being an incomplete document. Exhibit 1010 refers to supplemental Figure S1 and Table S1, which are not provided in Exhibit 1010. *See e.g.*, EX1010,

9433, 9435. Exhibit 1010 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

D. Exhibit 1024

Exhibit 1024 purports to be “Rosengren *et al.*, ‘Recombinant Human PH20: Baseline Analysis of the Reactive Antibody Prevalence in the General Population Using Healthy Subjects,’ *BioDrugs*, 32(1):83-89 (2018).” Halozyme objects to Exhibit 1024 under FRE 401-403 because it is not prior art to the ’520 patent. Exhibit 1024 purports to have published in 2018 and therefore lacks relevance to a POSA’s knowledge and understanding before any of the ’520 patent’s claimed 2011 and 2012 priority dates.

Halozyme also objects to Exhibit 1024 under FRE 1002 and 1003 as an incomplete document. Exhibit 1024 refers to supplemental material, including Table 1 in the supplemental material, which is not provided in Exhibit 1024. *See e.g.*, EX1024, 83-84. Exhibit 1024 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

E. Exhibit 1030

Exhibit 1030 purports to be “Sills, ‘Retraction,’ *Science*, 319:569 (2008).” Halozyme objects to Exhibit 1030 under FRE 801-804 as containing hearsay. Merck relies on Exhibit 1030 to prove the truth of the matter asserted. *See e.g.*, Petition, 73 (“That supposed advancement, however, was later shown to be

false.”). Exhibit 1030 does not fall under any of the hearsay exceptions set forth in FRE 801, 803, or 804.

F. Exhibit 1034

Exhibit 1034 purports to be “‘Negative Results,’ *Nature*: Editorials, 453:258 (2008).” Halozyme objects to Exhibit 1034 under FRE 801-804 as containing hearsay. Merck relies on Exhibit 1034 to prove the truth of the matter asserted. *See e.g.*, Petition, 73 (“That supposed advancement, however, was later shown to be false.”). Exhibit 1034 does not fall under any of the hearsay exceptions set forth in FRE 801, 803, or 804.

G. Exhibit 1036

Exhibit 1036 purports to be “Hayden, ‘Chemistry: Designer Debacle,’ *Nature*, 453:275-278 (2008).” Halozyme objects to Exhibit 1036 under FRE 801-804 as containing hearsay. Merck relies on Exhibit 1036 to prove the truth of the matter asserted. *See e.g.*, Petition, 73 (“That supposed advancement, however, was later shown to be false.”). Exhibit 1036 does not fall under any of the hearsay exceptions set forth in FRE 801, 803, or 804.

H. Exhibit 1037

Exhibit 1037 purports to be “Benkert et al., ‘Toward the Estimation of the Absolute Quality of Individual Protein Structure Models,’ *Bioinformatics*, 27:343-350 (2010).” Halozyme objects to Exhibit 1037 under FRE 1002 and 1003 as an incomplete document. Exhibit 1037 refers to supplementary figures and tables,

which are not provided in Exhibit 1037. *See e.g.*, EX1037, 343-349. Exhibit 1037 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

I. Exhibit 1040

Exhibit 1040 purports to be “He *et al.*, ‘NMR Structures of Two Designed Proteins with High Sequence Identity but Different Fold and Function,’ *PNAS*, 105:14412-14417 (2008).” Halozyme objects to Exhibit 1040 under FRE 1002 and 1003 as an incomplete document. Exhibit 1040 refers to “supporting information,” which is not provided in Exhibit 1040. *See e.g.*, EX1040, 14412. Exhibit 1040 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

J. Exhibit 1041

Exhibit 1041 purports to be “Alexander *et al.*, ‘A Minimal Sequence Code for Switching Protein Structure and Function,’ *PNAS*, 106:21149-21154 (2009).” Halozyme objects to Exhibit 1041 under FRE 1002 and 1003 as an incomplete document. Exhibit 1041 refers to “supporting information,” which is not provided in Exhibit 1041. *See e.g.*, EX1041, 21149. Exhibit 1041 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

K. Exhibit 1042

Exhibit 1042 purports to be “Ruan *et al.*, ‘Design and Characterization of a Protein Fold Switching Network,’ *Nature Comm.*, 14 (2023).” Halozyme objects to Exhibit 1042 under FRE 401-403 because it is not prior art to the ’520 patent. Exhibit 1042 purports to have published in 2023 and therefore lacks relevance to a

POSA's knowledge and understanding before any of the '520 patent's claimed 2011 and 2012 priority dates.

Halozyme also objects to Exhibit 1042 under FRE 1002 and 1003 as an incomplete document. Exhibit 1042 refers to supplementary figures and tables throughout, which are not provided in Exhibit 1042. *See e.g.*, EX1042, 2-9, 11, 14. Exhibit 1042 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

L. Exhibit 1043

Exhibit 1043 purports to be "Sievers *et al.*, 'Fast, Scalable Generation of High-Quality Protein Multiple Sequence Alignments Using Clustal Omega,' *Molecular Sys. Biology*, 7.1 (2011)." Halozyme objects to Exhibit 1043 under FRE 1002 and 1003 as an incomplete document. Exhibit 1043 refers to "Supplementary Information," which is not provided in Exhibit 1043. *See e.g.*, EX1043, 3, 6. Exhibit 1043 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

M. Exhibit 1044

Exhibit 1044 purports to be "Mihel, 'PSAIA – Protein Structure and Interaction Analyzer,' *BMC Structural Biology*, 8:21 (2008)." Halozyme objects to Exhibit 1044 under FRE 401-403 because it is not cited in the Petition, Hecht declaration, or Park declaration. Therefore, Exhibit 1044 lacks relevance.

Halozyme also objects to Exhibit 1044 under FRE 1002 and 1003 as being an incomplete document. Exhibit 1044 refers to “Additional material” files 1-20, which are not provided in Exhibit 1044. *See e.g.*, EX1044, 9-11. Exhibit 1044 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

N. Exhibit 1048

Exhibit 1048 purports to be “Hayden, ‘Key Protein-Design Papers Challenged,’ *Nature*, 461:859 (2009).” Halozyme objects to Exhibit 1048 under FRE 801-804 as containing hearsay. Merck relies on Exhibit 1048 for the truth of the matter asserted. *See e.g.*, Petition, 73 (“That supposed advancement, however, was later shown to be false.”). Exhibit 1048 does not fall under any of the hearsay exceptions set forth in FRE 801, 803, or 804.

O. Exhibit 1049

Exhibit 1049 purports to be “KEGG, DRUG: Hyaluronidase (human recombinant), available at: <https://www.genome.jp/entry/D06604>.” Halozyme objects to Exhibit 1049 under FRE 401-403 because it is not prior art to the ’520 patent. Exhibit 1049 indicates it was prepared on “10/5/2024,” and therefore lacks relevance to a POSA’s knowledge and understanding before any of the ’520 patent’s claimed priority dates. *See* EX1049, 1.

Halozyme also objects to Exhibit 1049 under FRE 901-903 as lacking authentication. Exhibit 1049 does not qualify as a self-authenticating document

under FRE 902.

P. Exhibits 1053-1058

Exhibits 1053-1058 purport to be various pieces of evidence supporting Dr. Park's sequence analysis and script writing. Halozyme objects to each of Exhibits 1053-1058 under FRE 901-903 as lacking authentication. None of Exhibits 1053-1058 qualifies as a self-authenticating document under FRE 902.

Q. Exhibit 1061

Exhibit 1061 purports to be "Rosengren *et al.*, 'Clinical Immunogenicity of rHuPH20, a Hyaluronidase Enabling Subcutaneous Drug Administration,' *AAPS J.*, 17:1144-1156 (2015)." Halozyme objects to Exhibit 1061 under FRE 401-403 because it is not prior art to the '520 patent. Exhibit 1061 purports to have published in 2015 and therefore lacks relevance to a POSA's knowledge and understanding before any of the '520 patent's claimed 2011 and 2012 priority dates.

Halozyme also objects to Exhibit 1061 under FRE 1002 and 1003 as an incomplete document. Exhibit 1061 refers to "supplementary material," which is not provided in Exhibit 1061. *See e.g.*, EX1061, 1144-1145. Exhibit 1061 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

R. Exhibits 1064-1067

Exhibits 1064-1067 purport to be collections of various web pages. Halozyme objects to each of Exhibits 1064-1067 under FRE 401-403 because the

documents are not prior art to the '520 patent as lacking relevance. Each of Exhibits 1064-1067 indicates it was produced in 2024, and therefore lacks relevance to a POSA's knowledge and understanding before any of the '520 patent's claimed 2011 and 2012 priority dates. EX1064, 1; EX1065, 1; EX1066, 1; EX1067, 1.

S. Exhibits 1069-1075

Exhibits 1069-1075 purport to be Swiss Model Printouts of PH20 Models. Halozyme objects to Exhibits 1069-1075 under FRE 401-403 as lacking relevance because the documents are not prior art to the '520 patent. Each of Exhibits 1069-1075 indicates it was produced in 2024 or 2025, and therefore lacks relevance to a POSA's knowledge and understanding before any of the '520 patent's claimed 2011 and 2012 priority dates. EX1069, 1; EX1070, 1; EX1071, 1; EX1072, 1; EX1073, 1; EX1074, 1; EX1075, 1. Halozyme additionally objects to Exhibits 1070-1075 as lacking relevance because these exhibits are not cited in the Petition.

Halozyme also objects to Exhibits 1069-1075 under FRE 901-903 as lacking authentication. None of Exhibits 1069-1075 qualifies as a self-authenticating document under FRE 902.

T. Exhibit 1082

Exhibit 1082 purports to be United States – National Judicial Caseload Profile. Halozyme objects to Exhibit 1082 under FRE 901-903 as lacking

authentication. Exhibit 1082 does not qualify as a self-authenticating document under FRE 902.

U. Exhibit 1083

Exhibit 1083 purports to be a Table Showing Outcomes of Disputed Motions to Stay Pending IPRs in DNJ. Halozyme objects to Exhibit 1083 under FRE 901-903 as lacking authentication. Exhibit 1083 does not qualify as a self-authenticating document under FRE 902.

V. Exhibit 1084

Exhibit 1084 purports to be a News Release: “Halozyme Raises 2025 Financial Guidance Ranges and Reports Strong First Quarter 2025 Results.” Halozyme objects to Exhibit 1084 under FRE 901-903 as lacking authentication. Exhibits 1084 does not qualify as a self-authenticating document under FRE 902.

W. Exhibit 1085

Exhibit 1085 purports to be a News Release: “Merck Breaks Ground on New \$1 Billion Biologics Center of Excellence in Wilmington, Delaware.” Halozyme objects to Exhibit 1085 under FRE 901-903 as lacking authentication. Exhibits 1085 does not qualify as a self-authenticating document under FRE 902.

X. Exhibit 1086

Exhibit 1086 purports to be Halozyme Therapeutics, Inc. Q1 2025 Earnings Call Transcript (May 6, 2025). Halozyme objects to Exhibit 1086 under FRE 901-903 as lacking authentication. Exhibits 1086 does not qualify as a self-

authenticating document under FRE 902.

II. CONCLUSION

In view of the Objections set forth above, Patent Owner may file a motion to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c).

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

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CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

I certify that the above-captioned **PATENT OWNER'S OBJECTIONS TO EVIDENCE** was served in its entirety on September 22, 2025, upon the following parties via electronic mail:

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