UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner

v.

HALOZYME, INC.,
Patent Owner

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

PATENT OWNER'S OBJECTIONS TO EVIDENCE

Mail Stop "PATENT BOARD"
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, 1010, 1024, 1030, 1034, 1036, 1040-1042, 1048, 1061, 1066, 1084-1086, 1101, 1126, 1135, 1141, 1144, 1146, 1147, 1151, 1155, and 1157 (the "Challenged Evidence"), filed by Petitioner Merck Sharp & Dohme LLC ("Merck") on March 23, 2026, with Merck's Petition for IPR and on June 29, 2026 with Merck's Reply to Patent Owner's Discretionary Denial Brief. Halozyme's Objections are timely filed under 37 C.F.R. § 42.64(b)(1), within ten business days of the Board's September 9, 2026 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

EX1003 purports to be the "Declaration of James Naismith, Ph.D."

Halozyme objects to at least paragraphs 1–11, 14–15, 17–21, 33, 110–118,

160–162, 167–172, 176, 194–199, 203–207, 215, 247–248, 252, and 281-289 of EX1003 under FRE 401–403. At least paragraphs 1–11, 14–15, 17–21, and 33 of EX1003 are not specifically cited in the Petition. In addition, at least paragraphs 110–118, 160–162, 167–172, 176, 194–199, 203–207, 215, 247–248, 252, and 281-289 are irrelevant to the substance of Petitioner's positions and arguments in this proceeding. Accordingly, Dr. Naismith's testimony in the foregoing paragraphs of EX1003 lacks relevance under FRE 401 and is inadmissible under FRE 402. For the same reason, Halozyme also objects to these paragraphs in EX1003 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 further objects to the entirety of EX1003 under FRE 702 and 703. Dr. Naismith repeatedly relies on EX1135 to form the basis of his opinions in EX1003. *See e.g.*, EX1003, ¶¶163–164, 166 (citing EX1135). As discussed below, EX1135 lacks authentication and does not qualify as a self-authenticating document under FRE 902. Accordingly, Halozyme objects to Dr. Naismith's testimony in EX1003 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. Naismith's testimony provide any probative value that would substantially outweigh its prejudicial effect.

B. 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.

C. 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 '149 patent. Exhibit 1024 purports to have published in 2018 and therefore lacks relevance to a POSA's knowledge and understanding before any of the '149 patent's claimed 2011 and 2012 priority dates.

D. 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, 69-70 ("Chica credited a 'ground-breaking' predictive molecular

modeling technique that 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.

E. 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, 69-70 ("Chica credited a 'ground-breaking' predictive molecular modeling technique that 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.

F. 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, 69-70 ("Chica credited a 'ground-breaking' predictive molecular modeling technique that 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.

G. 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.

H. 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.

I. 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 '149 patent. Exhibit 1042 purports to have published in 2023 and therefore lacks relevance to a POSA's knowledge and understanding before any of the '149 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.

J. 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, 69-70 ("Chica credited a 'ground-breaking' predictive molecular modeling technique that 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.

K. 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 '149 patent. Exhibit 1061 purports to have published in 2015 and therefore lacks relevance to a POSA's knowledge and understanding before any of the '149 patent's claimed 2011 and 2012 priority dates.

L. Exhibit 1066

Exhibit 1066 purports to be a collection of various web pages. Halozyme objects to Exhibit 1066 under FRE 401-403 because the document is not prior art

to the ’149 patent as lacking relevance. Exhibit 1066 indicates it was produced in 2024, and therefore lacks relevance to a POSA’s knowledge and understanding before any of the ’149 patent’s claimed 2011 and 2012 priority dates. EX1066, 1.

M. 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.

N. 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.

O. 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.

P. Exhibit 1101

Exhibit 1101 purports to be Halozyme Therapeutics, Inc., Morgan Stanley Global Healthcare Conference: Questions. Halozyme objects to Exhibit 1101 under

FRE 901-903 as lacking authentication. Exhibit 1101 does not qualify as a self-authenticating document under FRE 902.

Q. Exhibit 1126

EX1126 purports to be "Im, S. et al., "Cryo-EM Structure of Human Hyaluronidase PH-20," Proteins: Structure, Function, and Bioinformatics 93:1067-1073 (2025)."

Halozyme objects to EX1126 under FRE 401–403 because it is not prior art to the '149 patent. EX1126 purports to have published in 2025 and therefore lacks relevance to a POSA's knowledge and understanding before any of the '149 patent's claimed 2011 and 2012 priority dates.

R. Exhibit 1135

EX1135 purports to be various spreadsheets ("Dr. Naismith Analysis Spreadsheet") supporting Dr. Naismith's analysis. *See* EX1003, ¶¶163-166.

Halozyme objects to EX1135 under FRE 901–903 as lacking authentication. Dr. Naismith does not provide explanation regarding how EX1135 was prepared. EX1135 does not qualify as a self-authenticating document under FRE 902.

S. Exhibit 1141

EX1141 purports to be Goldsmith, M. & Tawfik, D. S., "Directed enzyme evolution: beyond the low-hanging fruit," Current Opinion in Structural Biology 22(4):406–412 (2012).

Halozyme objects to EX1141 under FRE 401–403 because it is not prior art

to the ’149 patent. EX1141 purports to have published online on May 12, 2012 and therefore lacks relevance to a POSA’s knowledge and understanding before the ’149 patent’s claimed 2011 and 2012 priority dates.

T. EX1144

EX1144 purports to be “Ochoa-Levya et al., “Protein Design through Systematic Catalytic Loop Exchange in the (beta/alpha)8 Fold” J. Mol. Biol. 10 387(4):949-64 (2009).”

Halozyme objects to EX1144 under FRE 1002 and 1003 as being an incomplete document. EX1144 refers to supplementary data, which is not provided in EX1144. *See e.g.,* EX1144, 962. EX1144 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

U. EX1146

EX1146 purports to be “Pal et al., “Comprehensive and Quantitative Mapping of Energy Landscapes for Protein-Protein Interactions by Rapid Combinatorial Scanning” J. Biol. Chem. 4;281(31):22378-22385 (2006).”

Halozyme objects to EX1146 under FRE 1002 and 1003 as being an incomplete document. EX1146 refers to supplemental material, which is not provided in EX1146. See e.g., EX1146, 22378–79, 22386. EX1146 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

V. EX1147

EX1147 purports to be “Van Rossum et al., “Reporter-based screening and

selection of enzymes" FEBS J. 280:2979-96 (2013)."

Halozyme also objects to EX1147 under FRE 401–403 because it is not prior art to the '149 patent. EX1147 purports to have published in 2013 and therefore lacks relevance to a POSA's knowledge and understanding before any of the '149 patent's claimed 2011 and 2012 priority dates.

W. EX1151

EX1151 purports to be "Fowler et al., "High-resolution mapping of protein sequence function relationships" Nature Methods 7, 741–746 (2010)."

Halozyme objects to EX1151 under FRE 1002 and 1003 as being an incomplete document. EX1151 refers to supplementary information, which is not provided in EX1151. *See e.g.,* EX1151, 742–46. EX1151 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

X. EX1155

EX1155 purports to be "Calloni et al., "Investigating the Effects of Mutations on Protein Aggregation in the Cell" J. Biol. Chem. 10607-13 (2005)."

Halozyme objects to EX1155 under FRE 1002 and 1003 as being an incomplete document. EX1155 refers to supplemental figures, which are not provided in EX1155. *See e.g.,* EX1155, 10609–10. EX1155 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

Y. EX1157

EX1157 purports to be "Chiti et al., "Rationalization of the effects of

mutations on peptide and protein aggregation rates" Nature, 424:805-808 (2003)."

Halozyme objects to EX1157 under FRE 1002 and 1003 as being an incomplete document. EX1157 refers to supplementary information, which is not provided in EX1157. *See e.g.,* EX1157, 806–808. EX1157 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

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

/Tyler C. Liu/

Tyler C. Liu
Registration No. 72,126
Attorney for Patent Owner

Date: September 23, 2026

1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600

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 23, 2026, upon the following parties via electronic mail:

Jeffrey P. Kushan (Lead Counsel)	jkushan@sidley.com
Leif Peterson (Back-up Counsel)	leif.peterson@sidley.com
Sue Wang (Back-up Counsel)	sue.wang@sidley.com
Katherine A. Helm (Back-up Counsel)	khelm@dechert.com
Amy Mahan (Back-up Counsel)	amy.mahan@sidley.com
Blaine Hackman (Back-up Counsel)	Blaine.Hackman@dechert.com
Christine M. Engen (Back-up Counsel)	christine.engen@sidley.com
Amit Bhatla (Back-up Counsel)	abhatla@sidley.com
Brian M. Goldberg (Back-up Counsel)	Brian.Goldberg@dechert.com
Mark Stewart (Back-up Counsel)	mark.stewart@merck.com

HalozymePGRs@sidley.com
Merck-Halozyme-Dechert@dechert.com

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

/Tyler C. Liu/

Tyler C. Liu
Registration No. 72,126
Attorney for Patent Owner

Date: September 23, 2026

1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600