UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner

v.

HALOZYME INC.,
Patent Owner

Case PGR2025-00046
U.S. Patent No. 12,091,692

PATENT OWNER'S OBJECTIONS TO EVIDENCE

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Patent Owner Halozyme, Inc. ("Patent Owner") objects under the Federal Rules of Evidence (FRE) and 37 C.F.R. § 42.64(b)(1) to the admissibility of Exhibits 1133–34, 1120, 1122, 1126, 1141, 1144, 1145–47, 1151, 1155, 1157, 1173, 1175, and 1190 (the "Challenged Evidence"), filed by Petitioner Merck, Sharp & Dohme LLC ("Petitioner") on May 4, 2026, with Petitioner's Reply. Patent Owner's Objections are timely filed under 37 C.F.R. § 42.64(b)(1), within five business days of May 4, 2026. Patent Owner files these Objections to provide notice to Petitioner that Patent Owner 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. EX1120

Exhibit 1120 ("EX1120") purports to be "Huo, Z. et al., "Systemic and Mucosal Immune Responses to Sublingual or Intramuscular Human Papilloma Virus Antigens in Healthy Female Volunteers," PLoS ONE 7(3):e33736 (2012)."

Halozyme objects to EX1120 under FRE 1002 and 1003 as being an

incomplete document. EX1120 refers to supporting information, which is not provided in EX1120. *See e.g.,* EX1120, 1 and 8. EX1120 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

Halozyme also objects to EX1120 under FRE 401–403 because it is not prior art to the '520 patent. EX1120 purports to have published in March 2012 and therefore lacks relevance to a POSA's knowledge and understanding before the '520 patent's claimed 2011 priority date.

B. EX1122

EX1122 purports to be "Printz, M. et al., "Risk Factors, Hyaluronidase Expression, and Clinical Immunogenicity of Recombinant Human Hyaluronidase PH20, an Enzyme Enabling Subcutaneous Drug Administration," AAPS 24(6):110 (2022)."

Halozyme objects to EX1122 under FRE 1002 and 1003 as being an incomplete document. EX1122 refers to supplementary information, which is not provided in EX1122. *See e.g.,* EX1122, 13. EX1122 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

Halozyme also objects to EX1122 under FRE 401–403 because it is not prior art to the '520 patent. EX1122 purports to have published in in 2022 and therefore lacks relevance to a POSA's knowledge and understanding before any of the '520 patent's claimed 2011 and 2012 priority dates.

C. EX1126

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 '520 patent. EX1126 purports to have published in 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.

D. EX1133

EX1133 purports to be the "Declaration of James Naismith, Ph.D."

Halozyme objects to at least paragraphs 1–16, 18–39, 47, 62–63, 81–82, 90–91, 111, 113, 135, 164, 194, 196, 220, 231, 243–245, 279–280, 285-290, 335–337 of EX1133 under FRE 401–403. At least paragraphs 1–16, 18–39, 47, 62–63, 81–82, 90–91, 111, 113, 135, 164, 194, 196, 220, 231, 243–245, 279–280, 285-290, 335–337 of EX1133 are not cited in Petitioner's Reply. In addition, at least paragraphs 46–47, 58–76, 102–110, 113–119, 121–140, 142–143, 163–174, 176, 206–207, 222, 243–251, 253–263, and 283–317 are irrelevant to the substance of Petitioner's positions and arguments in this proceeding. Accordingly, Dr. Naismith's testimony in the foregoing paragraphs of EX1133 lacks relevance under FRE 401 and is inadmissible under FRE 402. For the same reason,

Halozyme also objects to these paragraphs in EX1133 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 EX1133 under FRE 702 and 703. Dr. Naismith repeatedly relies on EX1135 to form the basis of his opinions in EX1133. *See e.g.,* EX1133, ¶¶242, 310, 316 (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 EX1133 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.

E. EX1134

EX1134 purports to be the "Declaration of Dr. Garnett Kelsoe."

Halozyme objects to at least paragraphs 1–14 of EX1134 under FRE 401–403. Paragraphs 1–14 of EX1134 are not cited in Petitioner's Reply. Accordingly, Dr. Kelsoe's testimony in the foregoing paragraphs of EX1134 lacks relevance under FRE 401 and is inadmissible under FRE 402. For the same reason, Halozyme also objects to these paragraphs in EX1134 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.

F. EX1135

EX1135 purports to be various spreadsheets ("Dr. Naismith Analysis Spreadsheet") supporting Dr. Naismith's analysis. *See* EX1135, ¶242.

Halozyme objects to EX1135 under FRE 901–903 as lacking authentication. Regarding EX1135, Dr. Naismith states, "I relied upon spreadsheets made with the assistance of counsel." EX1135, ¶242. Dr. Naismith does not provide further explanation regarding how EX1135 was prepared. EX1135 does not qualify as a self-authenticating document under FRE 902.

G. EX1141

EX1141 purports to be "Huo, Z. et al., "Systemic and Mucosal Immune Responses to Sublingual or Intramuscular Human Papilloma Virus Antigens in Healthy Female Volunteers," PLoS ONE 7(3):e33736 (2012)."

Halozyme objects to EX1141 under FRE 401–403 because it is not prior art to the '520 patent. EX1141 purports to have published online on May 12, 2012 and therefore lacks relevance to a POSA's knowledge and understanding before the '520 patent's claimed 2011 priority date.

H. 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.

I. EX1145

EX1145 purports to be "AutoDock Vina Tutorial 2011."

Halozyme objects to EX1145 under FRE 1002 and 1003 as being an incomplete document. A portion of page 31 of EX1145 appears to be missing. *See e.g.,* EX1145, 31. EX1145 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

J. 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.

K. 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 ’520 patent. EX1147 purports to have published in 2013 and therefore lacks relevance to a POSA’s knowledge and understanding before any of the ’520 patent’s claimed 2011 and 2012 priority dates.

L. 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.

M. 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.

N. 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.

O. EX1173

EX1173 purports to be "Anderson, M. et al., "Projection of an Immunological Self Shadow Within the Thymus by the Aire Protein," Science, 298(5597):1395-401 (2002)."

Halozyme objects to EX1173 under FRE 1002 and 1003 as being an incomplete document. EX1173 refers to supporting online material, which is not provided in EX1173. *See e.g.,* EX1173, 1401. EX1173 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

P. EX1175

EX1175 purports to be "Popova, L. et al., "Immunodominance of Antigenic Site B over Site A of Hemagglutinin of Recent H3N2 Influenza Viruses," PLoS One, 7(7):e41895 (2012)."

Halozyme objects to EX1175 under FRE 1002 and 1003 as being an incomplete document. EX1175 refers to supporting information, which is not provided in EX1175. *See e.g.,* EX1175, 10. EX1175 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

Q. EX1190

EX1190 purports to be "Nolan et al., "The Safety of Recombinant Human Hyaluronidase PH20 in Nonclinical Models: An Overview of Toxicology, Pharmacology, and Impact of Anti-PH20 Antibodies," Journal of Controlled Release, 374:369-383 (2024)."

Halozyme objects to EX1190 under FRE 1002 and 1003 as being an incomplete document. EX1190 refers to supplementary data, which is not provided in EX1190. *See e.g.,* EX1190, 382. EX1190 is therefore not an original under FRE 1002 or a duplicate under FRE 1003.

Halozyme also objects to EX1190 under FRE 401–403 because it is not prior art to the '520 patent. EX1190 purports to have published 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.

R. EX1202

EX1202 purports to be "Redwood, A. et al., "Viral Vectored Immunocontraception: Screening of Multiple Fertility Antigens using Murine Cytomegalovirus as a Vaccine Vector," Vaccine, 25(4):698-708 (2007)."

Halozyme objects to EX1202 under FRE 1002 and 1003. EX1202 is marked "Provided for non-commercial research and educational use only. Not for reproduction or distribution or commercial use." EX1202, Cover. EX1202 is also

marked "Author's personal copy." EX1202, 698–708. EX1202 is therefore not an acceptable original under FRE 1002 or an acceptable 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,

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/Eldora L. Ellison/

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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 May 11, 2026, upon the following parties via electronic mail:

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