UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyme Inc.,
Patent Owner.

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

PETITIONER'S UPDATED EXHIBIT LIST

EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 12,091,692
1002	File History of U.S. Patent No. 12,091,692
1003	Declaration of Dr. Michael Hecht
1004	Declaration of Dr. Sheldon Park
1005	U.S. Patent No. 7,767,429
1006	Chao et al., "Structure of Human Hyaluronidase-1, a Hyaluronan Hydrolyzing Enzyme Involved in Tumor Growth and Angiogenesis," Biochemistry, 46:6911-6920 (2007)
1007	WO 2010/077297, published 8 July 2010
1008	Stern et al., "The Hyaluronidases: Their Genomics, Structures, and Mechanisms of Action," Chem. Rev. 106:818-839 (2006)
1009	Jedrzejas et al., "Structures of Vertebrate Hyaluronidases and Their Unique Enzymatic Mechanism of Hydrolysis," Proteins: Structure, Function and Bioinformatics, 61:227-238 (2005)
1010	Zhang et al., "Hyaluronidase Activity of Human Hyal1 Requires Active Site Acidic and Tyrosine Residues," J. Biol. Chem., 284(14):9433-9442 (2009)
1011	Arming et al., "In vitro mutagenesis of PH-20 hyaluronidase from human sperm," Eur. J. Biochem., 247:810-814 (1997)
1012	Bordoli et al., "Protein structure homology modeling using SWISS-MODEL workspace," Nature Protocols, 4(1):1-13 (2008)
1013	Frost, "Recombinant human hyaluronidase (rHuPH20): an enabling platform for subcutaneous drug and fluid administration," Expert Opinion on Drug Delivery, 4(4):427-440 (2007)
1014	Brandon & Tooze, "Introduction to Protein Structure," Second Ed., Chapters 1-6, 11-12, 17-18 (1999)
1015	Table Associating Citations from the '692 Patent (EX1001) to Corresponding Citations in the '731 Application (EX1026)

No.	Exhibit Description
1016	Steipe, "Consensus-Based Engineering of Protein Stability: From Intrabodies to Thermostable Enzymes," Methods in Enzymology, 388:176-186 (2004)
1017	Green, "Computer Graphics, Homology Modeling, and Bioinformatics," Protein Eng'g & Design, Ch. 10, 223-237 (2010)
1018	Chica et al., "Semi-rational approaches to engineering enzyme activity: combining the benefits of directed evolution and rational design," Curr. Opin. Biotechnol., (4):378-384 (2005)
1019	Hardy et al., "Assessment of contraceptive vaccines based on recombinant mouse sperm protein PH20," Reprod., 127:325-334 (2004)
1020	Pomering et al., "Restricted Entry of IgG into Male and Female Rabbit Reproductive Ducts Following Immunization with Recombinant Rabbit PH-20," Am. J. Reprod. Immunol., (3):174-82 (2002)
1021	Baba et al., "Mouse Sperm Lacking Cell Surface Hyaluronidase PH-20 Can Pass through the Layer of Cumulus Cells and Fertilize the Egg," J. Biol. Chem., 277(33):30310-4 (2002)
1022	Primakoff et al., "Reversible Contraceptive Effect of PH-20 Immunization in Male Guinea Pigs," Biol Reprod., 56(5):1142-6 (1997)
1023	Tung et al., "Mechanism of Infertility in Male Guinea Pigs Immunized with Sperm PH-20," Biol. Reprod., 56(5):1133-41 (1997)
1024	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)
1025	U.S. Patent No. 9,447,401
1026	U.S. Patent Application No. 13/694,731
1027	2024 Chemistry Nobel Prize Background
1028	[Reserved]
1029	Gmachl et al., "The human sperm protein PH-20 has hyaluronidase activity," FEBS Letters, 3:545-548 (1993)

No.	Exhibit Description
1030	Sills, "Retraction," Science, 319:569 (2008)
1031	Yue et al., "Loss of Protein Structure Stability as a Major Causative Factor in Monogenic Disease," J. Mol. Biol., 353:459-473 (2005)
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1037	Benkert et al., "Toward the Estimation of the Absolute Quality of Individual Protein Structure Models," Bioinformatics, 27:343-350 (2010)
1038	Schwede et al., "SWISS-MODEL: An Automated Protein Homology-Modeling Server," Nucleic Acids Rsch., 31:3381-3385 (2003)
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1041	Alexander et al., "A Minimal Sequence Code for Switching Protein Structure and Function," PNAS, 106:21149-21154 (2009)
1042	Ruan et al., "Design and Characterization of a Protein Fold Switching Network," Nature Comm., 14 (2023)
1043	Sievers et al., "Fast, Scalable Generation of High-Quality Protein Multiple Sequence Alignments Using Clustal Omega," Molecular Sys. Biology, 7.1 (2011)
1044	Mihel, "PSAIA – Protein Structure and Interaction Analyzer," BMC Structural Biology, 8:21 (2008)

No.	Exhibit Description
1045	Redline Comparison of the ’731 and ’692 Specifications
1046	Beasley & Hecht, “Protein Design: The Choice of *de Novo* Sequences,” J. Biological Chemistry, 272:2031-2034 (1997)
1047	Xiong et al., “Periodicity of Polar and Nonpolar Amino Acids is the Major Determinant of Secondary Structure in Self-Assembling Oligomeric Peptides,” PNAS, 92: 6349-6353 (1995)
1048	Hayden, “Key Protein-Design Papers Challenged,” Nature, 461:859 (2009)
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1050	Pace & Scholtz, “A Helix Propensity Scale Based on Experimental Studies of Peptides and Proteins,” Biophysical J. 75:422-427 (1998)
1051	U.S. Patent Application No. 61/631,313
1052	U.S. Patent Application No. 61/796,208
1053	Hom_pre2011
1054	Hom_pre2011_header
1055	Hom_pre2011_header_clean
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1057	Ph20_pre2011.aln-clustal_num
1058	Ph20_pre2011 Alignment html
1059	Leisola & Turunen, “Protein Engineering: Opportunities and Challenges,” Appl. Microbiol. Biotechnol. 75:1225-1232 (2007)
1060	Hecht et al., “De Novo Proteins from Designed Combinatorial Libraries,” Protein Sci., 13:1711-1723 (2004)
1061	Rosengren et al., “Clinical Immunogenicity of rHuPH20, a Hyaluronidase Enabling Subcutaneous Drug Administration,” AAPS J., 17:1144-1156 (2015)
1062-1063	[Reserved]
1064	Collection of BLAST Webpages from the Internet Archive, navigable from:

No.	Exhibit Description
	https://web.archive.org/web/20111022151531/http://www.clustal.org/omega/
1065	Collection of Clustal Omega Webpages from the Internet Archive, navigable from: https://web.archive.org/web/20111022151531/http://www.clustal.org/omega/
1066	Collection of SWISS-MODEL Webpages from the Internet Archive, navigable from: https://web.archive.org/web/20110519141121/http://swissmodel.expasy.org/?pid=smh01&uid=&token=
1067	Collection of PyMol Webpages from the Internet Archive, navigable from: https://web.archive.org/web/20110701072314/http://pymol.org/
1068	Declaration of Jeffrey P. Kushan
1069	Swiss Model Printout of PH20 Model
1070	Swiss Model Printout of PH20 Model with M313K Mutation
1071	Swiss Model Printout of PH20 Model with M313A Mutation
1072	Swiss Model Printout of PH20 Model with M313R Mutation
1073	Swiss Model Printout of PH20 Model with M313Y Mutation
1074	Swiss Model Printout of PH20 Model with M313P Mutation
1075	Swiss Model Printout of PH20 Model with M313L Mutation
1076	Declaration of Leif E. Peterson, II
1077-1078	[Reserved]
1079	Hunnicutt et al., "Sperm Surface Protein PH-20 Is Bifunctional: One Activity Is a Hyaluronidase and a Second, Distinct Activity Is Required in Secondary Sperm-Zona Binding," Biol. Reprod., 55(1):80-86 (1996)
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1081	Goldberg, "Protein degradation and protection of against misfolded or damaged proteins," Nature, 426:895-899 (2003)

No.	Exhibit Description
1082	United States District Court – National Judicial Caseload Profile, navigable from: https://www.uscourts.gov/data-news/reports/statistical-reports/federal-court-management-statistics/federal-court-management-statistics-december-2024
1083	Table Showing Outcomes of Disputed Motions to Stay Pending IPRs in DNJ
1084	News Release: "Halozyme Raises 2025 Financial Guidance Ranges and Reports Strong First Quarter 2025 Results," navigable from: https://www.prnewswire.com/news-releases/halozyme-raises-2025-financial-guidance-ranges-and-reports-strong-first-quarter-2025-results-302447541.html
1085	News Release: "Merck Breaks Ground on New $1 Billion Biologics Center of Excellence in Wilmington, Delaware," navigable from: https://www.merck.com/news/merck-breaks-ground-on-new-1-billion-biologics-center-of-excellence-in-wilmington-delaware/
1086	Halozyme Therapeutics, Inc. Q1 2025 Earnings Call Transcript (May 6, 2025)
1087-1112	[Reserved]
1113	Declaration of Sue Wang
1114	Declaration of Brian M. Goldberg
1115	Declaration of Katherine A. Helm
1116-1118	[Reserved]
1119	Csoka, A. et al., "The Six Hyaluronidase-Like Genes in the Human and Mouse Genomes" Matrix Biology 20:499-508 (2001)
1120	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)
1121	[Reserved]
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1123-1124	[Reserved]
1125	Emails re: AutoDock Vina (Sept. 9, 2025 - Oct. 27, 2025)
1126	Im, S. et al., "Cryo-EM Structure of Human Hyaluronidase PH-20," Proteins: Structure, Function, and Bioinformatics 93:1067-1073 (2025)
1127-1128	[Reserved]
1129	Transcript of the Deposition of Dr. Gary Cherr, Ph.D., November 12, 2025
1130	Melanie Ann Simpson, Ph.D. Deposition Transcript
1131	Gregory Petsko, Ph.D. Deposition Transcript
1132	Transcript of the Deposition of Dr. James Moon, Ph.D., November 18, 2025
1133	Declaration of James Naismith, Ph.D.
1134	Declaration of Dr. Garnett Kelsoe
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1144	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)
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1148	Reed et al., "Use of Coefficient of Variation in Assessing Variability of Quantitative Assays" Clin. Diagn. Lab Immunol. 9(6):1235-9 (2002)
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1152	Ringe & Petsko, "Q&A: What are pharmacological chaperones and why are they interesting?" J. Biol. 8:80 (2009)
1153	Petsko, "Herding CATS" Sci. Transl. Med. 24;3(97):97 (2011)
1154	Second Table Associating Citations from the '692 Patent (EX1001) to Corresponding Citations in the '731 Application (EX1026)
1155	Calloni et al., "Investigating the Effects of Mutations on Protein Aggregation in the Cell" J. Biol. Chem. 10607-13 (2005)
1156	Chiti et al., "Studies of aggregation of mutant proteins in vitro provided insights into genetics of amyloid diseases" PNAS 99:16419-26 (2002)
1157	Chiti et al., "Rationalization of the effects of mutations on peptide and protein aggregation rates" Nature, 424:805-808 (2003)

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1159	Brachmann et al., "Genetic selection of intragenic suppressor mutations that reverse the effect of common p53 cancer mutations" EMBO Journal 17:1847–59 (1998)
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1165	MERCK_PGR00458 - PTAB-PGR2021-00036-16 Merck-Genentech PGR
1166	MERCK_PGR00462 - RE_ 2_25-cv-03179-ES-JRA_ HALOZYME, INC. v. MERCK SHARP & DOHME CORP.
1167	MERCK_PGR00094 - DNJ-2-25-cv-03179 Stipulation to Substitute Parties
1168	MERCK_PGR00090 - DNJ-2-25-cv-03179 2025-07-14 [019] Corporate Disclosure Statement
1169	Declaration of Jeffrey P. Kushan (Petitioner's Reply)
1170	Murphy, K., "Janeway's Immuno Biology," (8th 2012), Chapters 1, 4, 8, 10, 11, 12, 15, and Appx I
1171	Yang, X. et al., "An Introduction to Epitope Prediction Methods and Software," Rev. Med. Virol., 19: 77–96 (2009)

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1179	Dormitzer, P. et al., "Influenza Vaccine Immunology," Immunol Rev., 239(1):167-77 (2011)
1180	Mantis, NJ., et al., "Secretory IgA ' s Complex Roles in Immunity and Mucosal Homeostasis in the Gut," Mucosal Immunol., 4(6):603-11 (2011)
1181	Siskind, G. and Eisen, H., "Effect of Variation in Antibody-Hapten Association Constant upon the Biologic Activity of the Antibody," J Immunol., 95(3):436-41 (1965)
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1183	Fauci, A. et al., "The Relationship between Antibody Affinity and the Efficiency of Complement Fixation," J Immunol., 105(1):215-20 (1970)
1184	Laver, W. et al., "Epitopes on Protein Antigens: Misconceptions and Realities," Cell 61:553-556 (1990)
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1188	Cherr, G. et al., "The Dual Functions of GPI-Anchored PH-20: Hyaluronidase and Intracellular Signaling," Matrix Biol., 20(8):515-25 (2001)
1189	Martin-Deleon, "Epididymal SPAM1 and its Impact on Sperm Function" Molecular and Cellular Endocrinology 250:114-121 (2006)
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1191	McCutcheon, J. et al., "HLA-B*0702 Antibody Epitopes are Affected Indirectly by Distant Antigen Residues," Hum Immunol., 36(2):69-75 (1993)
1192	Nobusawa, E. et al., "Comparison of Complete Amino Acid Sequences and Receptor-Binding Properties among 13 Serotypes of Hemagglutinins of Influenza A Viruses," Virology, 182(2):475-85 (1991)

No.	Exhibit Description
1193	CDC on H5N1 CDC Press Release: "Highly Pathogenic Avian Influenza A (H5N1) Virus Infection Reported in a Person in the U.S." (Apr. 1, 2024)
1194	Lin, Y., et al., "Molecular cloning of the human and monkey sperm surface protein PH-20," Proc. Natl. Acad. Sci USA 90:10071-10075 (November 1993) (EX2013 in Proceedings PGR2025-00003, -00004, -00006, -00009, -00017, -00024, -00030, -00033, and -00039)
1195	Zhang, H. et al., "Mouse Spam1 (PH-20) Is a Multifunctional Protein: Evidence for Its Expression in the Female Reproductive Tract," Biol Reprod., 69(2):446-54 (2003)
1196	Dunn, C. et al., "Transcription of the Human and Rodent SPAM1 / PH-20 Genes Initiates Within an Ancient Endogenous Retrovirus," BMC Genomics, 6:47 (2005)
1197	Hirsch, C. et al., "The Ubiquitylation Machinery of the Endoplasmic Reticulum," Nature, 458(7237):453-60 (2009)
1198	Singh, S., et al., "Solubilization and Refolding of Bacterial Inclusion Body Proteins," Journal of Bioscience and Bioengineering 99:303-310 (2005)
1199	Li, M. et al., "Importance of Glycosylation and Disulfide Bonds in Hyaluronidase Activity of Macaque Sperm Surface PH-20," J Androl., 23(2):211-9 (2002)
1200	[Reserved]
1201	Rodriguez, L. et al., "Foot and mouth disease virus vaccines," Vaccine 27:D90-D94 (2009)
1202	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)
1203	Russell, M. et al., "Complement-Fixing Properties of Human IgA Antibodies. Alternative Pathway Complement Activation by Plastic-Bound, but not Specific Antigen-Bound, IgA," Scand J Immunol., 30(2):175-83 (1989)

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1204	Nikolova E. et al., "All Forms of Human IgA Antibodies Bound to Antigen Interfere with Complement (C3) Fixation Induced by IgG or by Antigen Alone," Scand J Immunol., 39(3):275-80 (1994)
1205	Goodey, N. et al., "Allosteric Regulation and Catalysis Emerge via a Common Route," Nat Chem Biol. 4(8):474-82 (2008)
1206-1223	[Reserved]
1224	Declaration of Kelly Grez – Protective Order Material
1225	Transcript of the Deposition of Kelly Grez, March 26, 2026
1226	Kelly Grez Deposition Transcript Errata
1227-1233	[Reserved]
1234	MSD Netherlands Capital B.V., Preliminary Prospectus Supplement (May 14, 2024)
1235	Merck & Co., Inc., Form 8-K (Nov. 4, 2009)
1236	Jennifer_Zachary WD_Redacted – Protective Order Material
1237	Merck & Co., Inc. Subsidiaries (Dec. 31, 2024)
1238	State of New Jersey, Certificate of Long Form Standing with Officers and Directors, Merck & Co., Inc. (Feb. 18, 2026)
1239	Press Release: "Merck and Schering-Plough to Merge" (Mar. 9, 2009)
1240	State of New Jersey, Certificate of Long Form Standing with Officers and Directors, Merck Sharp & Dohme LLC (Feb. 18, 2026)
1241	Company Statement: "Merck Sues Merck KGaA, Darmstadt, Germany for Improper Use of "Merck"" (Jan. 15, 2016)
1242	ZacharyJennifer ADP_Redacted – Protective Order Material
1243	Table Comparing the Boards of Directors for Merck & Co., Inc. and Merck Sharp & Dohme LLC
1244	Merck & Co., Inc., Form 851 – Affiliations Schedule for Tax Year Ending Dec. 31, 2024

No.	Exhibit Description
1245-1277	[Reserved]
1278 [NEW]	Petitioner's Demonstratives

Dated: July 20, 2026

Respectfully Submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 20th day of July, 2026, I caused to be served a true and correct copy of the foregoing and any accompanying exhibits by e-mail on the following counsel of record for Patent Owner:

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