

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

**PETITIONER'S MOTION
FOR *PRO HAC VICE* ADMISSION OF LEIF E. PETERSON, II**

Petitioner Merck Sharp & Dohme LLC (“Merck”) respectfully requests that the Board recognize Leif E. Peterson, II, Esq. as *pro hac vice* and as an associate agent of Merck’s counsel of record designated under its Power of Attorney (Paper 2) for Merck in this proceeding.

I. BACKGROUND

Merck’s Motion for *Pro Hac Vice* Admission is being filed pursuant to and in compliance with the Notice of Filing Date Accorded to Petition, which was filed March 11, 2025 (Paper 8) (the “Notice”). Patent Owner has confirmed it does not oppose this Motion.

II. TIME OF FILING

This Motion for *Pro Hac Vice* Admission is being filed in accordance with the Notice, and is filed greater than 21 days after service of the Petition.

III. STATEMENT OF FACTS

As required by the Order, the following statement of facts, supported by the attached Declaration of Leif E. Peterson, II in Support of Motion for *Pro Hac Vice* Admission (Ex. 1076, “Peterson Declaration”), shows that there is good cause for the Patent Trial and Appeal Board (“Board”) to recognize Mr. Peterson *pro hac vice* in this proceeding. As required by 37 C.F.R. § 42.10(c), Merck’s lead counsel, Jeffrey P. Kushan, is a registered practitioner and experienced in proceedings before the USPTO.

Mr. Peterson is an experienced litigation attorney. Mr. Peterson has been a litigating attorney for more than 10 years and has been involved in numerous patent litigation cases in federal courts. Mr. Peterson's experience includes representing a wide range of clients in complex intellectual property litigation, and he has appeared in a number of litigation matters before various Appellate and District Courts. Mr. Peterson previously appeared *pro hac vice* before the Board in *Apple Inc. v. MemoryWeb, LLC*, Case No. IPR2022-00031.

Mr. Peterson is a member in good standing of the Illinois State Bar, with no suspensions or disbarments from practice, nor any application for admission to practice denied, nor any sanctions or contempt citations. Mr. Peterson is admitted to practice before the United States Court of Appeals for the Federal Circuit, the United States District Court for the Northern District of Illinois, and the United States District Court for the Western District of Michigan.

Mr. Peterson's mailing address is: Sidley Austin LLP, 1 South Dearborn, Chicago, IL 60603; his email address is: leif.peterson@sidley.com; and his direct dial is: (312) 853-7190.

Mr. Peterson has worked with lead counsel in connection with this proceeding. As such, he has reviewed and is familiar with (i) U.S. Patent No. 12,110,520, the patent at issue in this proceeding, (ii) the legal and factual

arguments that have been put forth by Petitioner, and (iii) the developments in this proceeding since the filing of the Petition. Mr. Peterson has fully familiarized himself with the Board's established practices. Accordingly, he has established familiarity with the subject matter at issue in these proceedings and the conduct of these proceedings to date.

Mr. Peterson has read and will comply with the Office Patent Trial Practice Guide and the Board's Rules for Practice for Trials set forth in part 42 of 37 C.F.R., and he agrees to be subject to the USPTO Rules of Professional Conduct set forth in 37 C.F.R. §§ 11.01 *et seq.*, and to disciplinary jurisdiction under 37 C.F.R. § 11.19(a).

IV. ANALYSIS

The facts contained in the Statement of Facts above, and contained in the Peterson Declaration, establish that there is good cause to admit Mr. Peterson *pro hac vice* in this proceeding under 37 C.F.R. § 42.10(c). Merck's lead counsel is a registered practitioner, and Mr. Peterson is an experienced litigating attorney with an established familiarity with the subject matter at issue in this proceeding.

V. CONCLUSION

Therefore, Petitioner respectfully submits that there is good cause for the Board to recognize Mr. Peterson as *Pro Hac Vice* counsel and as an associate agent

for Petitioner during these proceedings. Merck's Motion for *Pro Hac Vice* Admission is accompanied by a Declaration of Leif E. Peterson, II, as required by the Order.

Dated: March 24, 2025

Respectfully Submitted,

/Jeffrey P. Kushan/
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EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 12,110,520
1002	File History of U.S. Patent No. 12,110,520
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," <i>Biochemistry</i> , 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," <i>Chem. Rev.</i> 106:818-839 (2006)
1009	Jedzrejas et al., "Structures of Vertebrate Hyaluronidases and Their Unique Enzymatic Mechanism of Hydrolysis," <i>Proteins: Structure, Function and Bioinformatics</i> , 61:227-238 (2005)
1010	Zhang et al., "Hyaluronidase Activity of Human Hyal1 Requires Active Site Acidic and Tyrosine Residues," <i>J. Biol. Chem.</i> , 284(14):9433-9442 (2009)
1011	Arming et al., "In vitro mutagenesis of PH-20 hyaluronidase from human sperm," <i>Eur. J. Biochem.</i> , 247:810-814 (1997)
1012	Bordoli et al., "Protein structure homology modeling using SWISS-MODEL workspace," <i>Nature Protocols</i> , 4(1):1-13 (2008)
1013	Frost, "Recombinant human hyaluronidase (rHuPH20): an enabling platform for subcutaneous drug and fluid administration," <i>Expert Opinion on Drug Delivery</i> , 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 '520 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,” <i>Methods in Enzymology</i> , 388:176-186 (2004)
1017	Green, “Computer Graphics, Homology Modeling, and Bioinformatics,” <i>Protein Eng’g & Design</i> , 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,” <i>Curr. Opin. Biotechnol.</i> , (4):378-384 (2005)
1019	Hardy et al., “Assessment of contraceptive vaccines based on recombinant mouse sperm protein PH20,” <i>Reprod.</i> , 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,” <i>Am. J. Reprod. Immunol.</i> , (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,” <i>J. Biol. Chem.</i> , 277(33):30310-4 (2002)
1022	Primakoff et al., “Reversible Contraceptive Effect of PH-20 Immunization in Male Guinea Pigs,” <i>Biol Reprod.</i> , 56(5):1142-6 (1997)
1023	Tung et al., “Mechanism of Infertility in Male Guinea Pigs Immunized with Sperm PH-20,” <i>Biol. Reprod.</i> , 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,” <i>BioDrugs</i> , 32(1):83-89 (2018)
1025	U.S. Patent No. 9,447,401
1026	U.S. Patent Application No. 13/694,731
1027	[Reserved]
1028	[Reserved]

No.	Exhibit Description
1029	Gmachl et al., “The human sperm protein PH-20 has hyaluronidase activity,” <i>FEBS Letters</i> , 3:545-548 (1993)
1030	Sills, “Retraction,” <i>Science</i> , 319:569 (2008)
1031	Yue et al., “Loss of Protein Structure Stability as a Major Causative Factor in Monogenic Disease,” <i>J. Mol. Biol.</i> , 353:459-473 (2005)
1032	Wang & Moulton, “SNPs, Protein Structure, and Disease,” <i>Hum. Mutation</i> , 17:263-270 (2001)
1033	Marković-Housley et al., “Crystal Structure of Hyaluronidase, a Major Allergen of Bee Venom,” <i>Structure</i> , 8:1025-1035 (2000)
1034	“Negative Results,” <i>Nature: Editorials</i> , 453:258 (2008)
1035	Lins et al., “Analysis of Accessible Surface of Residues in Proteins,” <i>Protein Sci.</i> , 12:1406-1417 (2003)
1036	Hayden, “Chemistry: Designer Debacle,” <i>Nature</i> , 453:275-278 (2008)
1037	Benkert et al., “Toward the Estimation of the Absolute Quality of Individual Protein Structure Models,” <i>Bioinformatics</i> , 27:343-350 (2010)
1038	Schwede et al., “SWISS-MODEL: An Automated Protein Homology-Modeling Server,” <i>Nucleic Acids Res.</i> , 31:3381-3385 (2003)
1039	Alberts, “Molecular Biology of the Cell,” Fifth Edition, Chapter 3 (2007).
1040	He et al., “NMR Structures of Two Designed Proteins with High Sequence Identity but Different Fold and Function,” <i>PNAS</i> , 105:14412-14417 (2008)
1041	Alexander et al., “A Minimal Sequence Code for Switching Protein Structure and Function,” <i>PNAS</i> , 106:21149-21154 (2009)
1042	Ruan et al., “Design and Characterization of a Protein Fold Switching Network,” <i>Nature Comm.</i> , 14 (2023)

No.	Exhibit Description
1043	Sievers et al., “Fast, Scalable Generation of High-Quality Protein Multiple Sequence Alignments Using Clustal Omega,” <i>Molecular Sys. Biology</i> , 7.1 (2011)
1044	Mihel, “PSAIA – Protein Structure and Interaction Analyzer,” <i>BMC Structural Biology</i> , 8:21 (2008)
1045	Redline Comparison of the '731 and '520 Specifications
1046	Beasley & Hecht, “Protein Design: The Choice of <i>de Novo</i> Sequences,” <i>J. Biological Chemistry</i> , 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,” <i>PNAS</i> , 92: 6349-6353 (1995)
1048	Hayden, “Key Protein-Design Papers Challenged,” <i>Nature</i> , 461:859 (2009)
1049	KEGG, <i>DRUG: Hyaluronidase (human recombinant)</i> , available at: https://www.genome.jp/entry/D06604
1050	Pace & Scholtz, “A Helix Propensity Scale Based on Experimental Studies of Peptides and Proteins,” <i>Biophysical J.</i> 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
1056	Hom_pre2011.fasta
1057	Ph20_pre2011.aln-clustal_num
1058	Ph20_pre2011 Alignment html
1059	Leisola & Turunen, “Protein Engineering: Opportunities and Challenges,” <i>Appl. Microbiol. Biotechnol.</i> 75:1225-1232 (2007)

No.	Exhibit Description
1060	Hecht et al., “De Novo Proteins from Designed Combinatorial Libraries,” <i>Protein Sci.</i> , 13:1711-1723 (2004)
1061	Rosengren et al., “Clinical Immunogenicity of rHuPH20, a Hyaluronidase Enabling Subcutaneous Drug Administration,” <i>AAPS J.</i> , 17:1144-1156 (2015)
1062	[Reserved]
1063	[Reserved]
1064	Collection of BLAST Webpages from the Internet Archive, navigable from: 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 E324D Mutation
1071	Swiss Model Printout of PH20 Model with E324N Mutation
1072	Swiss Model Printout of PH20 Model with E324R Mutation
1073	Swiss Model Printout of PH20 Model with E324A Mutation
1074	Swiss Model Printout of PH20 Model with E324H Mutation
1075	Swiss Model Printout of PH20 Model with E324S Mutation

No.	Exhibit Description
1076 [NEW]	Declaration of Leif E. Peterson, II

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 24th day of March, 2025, I caused to be served a true and correct copy of the foregoing and any accompanying exhibits by electronic mail on the following counsel:

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