

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK, SHARP & DOHME LLC,
Petitioner

v.

HALOZYME, INC.,
Patent Owner

Case PGR2025-00009
U.S. Patent No. 12,123,035

**PATENT OWNER'S NOTICE OF INTENT TO DESIGNATE A
PROVISIONALLY RECOGNIZED PTAB ATTORNEY AS BACK-UP
COUNSEL UNDER 37 C.F.R. § 42.10(c)**

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PATENT OWNER'S UPDATED EXHIBIT LIST

Exhibit No.	Description
2001	Declaration of Barbara Triggs-Raine, Ph.D. in support of Patent Owner Preliminary Response (WITHDRAWN)
2002	<i>Curriculum Vitae</i> of Barbara Triggs-Raine, Ph.D.
2003	Disclaimer in a Patent under 37 C.F.R. § 1.321(a), filed in U.S. Patent Application No. 18/068,327, April 8, 2025
2004	"Halozyme Therapeutics to Present Data on PEGPH20 at the Upcoming 2011 EORTC-NCIASCO Annual Meeting," Halozyme Therapeutics, Inc. Press Release, October 24, 2011
2005	LinkedIn profiles of Michael Shepard, Robert Connor, Ge (Gina) Wei, and Qiping Zhao
2006	Sequence listing of U.S. Patent Application No. 18/068,327
2007	Gifre, L., et al., "Trends in recombinant protein use in animal production," <i>Microb Cell Fact</i> 16:40 (2017)
2008	"Recombinant Drugs," Smithsonian Institution, accessible at https://www.si.edu/spotlight/birth-of-biotech/recombinant-drugs (last accessed February 27, 2025)
2009	Naz, R., "Antisperm Contraceptive Vaccines: Where We Are and Where We Are Going?," <i>American Journal of Reproductive Immunology</i> 66:5-12 (2011)
2010	Primakoff, P., et al., "Fully effective contraception in male and female guinea pigs immunized with the sperm protein PH-20," <i>Nature</i> 335:543-546 (October 6, 1988)
2011	Definition of "guinea pig," Merriam-Webster OnLine, archived by the Internet Archive on February 21, 2010, accessible at https://web.archive.org/web/20100221175034/http://www.merriam-webster.com/dictionary/guinea%20pig (last accessed February 27, 2025)
2012	"A decade in numbers," <i>Nature Materials</i> 11:743-744 (September 2012)
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2019	Atmuri, V., <i>et al.</i> , “Hyaluronidase 3 (<i>HYAL3</i>) knockout mice do not display evidence of hyaluronan accumulation,” <i>Matrix Biology</i> 27:653-660 (2008)
2020	Hemming, R., <i>et al.</i> , “Mouse Hyal3 encodes a 45- to 56-kDa glycoprotein whose overexpression increases hyaluronidase 1 activity in cultured cells,” <i>Glycobiology</i> 18(4):280-289 (2008)
2021	Miller, A., “Hyaluronidase 2 and its intriguing role as a cell-entry receptor for oncogenic sheep retroviruses,” <i>Seminars in Cancer Biology</i> 18:296-301 (2008)
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2024	Petition for Post-Grant Review, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00006 (P.T.A.B.), December 10, 2024
2025	Petition for Post-Grant Review, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00003 (P.T.A.B.), November 12, 2024
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2027	Petition for Post-Grant Review, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00030 (P.T.A.B.), February 4, 2025
2028	Petition for Post-Grant Review, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00024 (P.T.A.B.), February 21, 2025
2029	Declaration of Michael Hecht, Ph.D. (Exhibit 1003), <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00004 (P.T.A.B.), November 26, 2024
2030	Declaration of Michael Hecht, Ph.D. (Exhibit 1003), <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00006 (P.T.A.B.), December 10, 2024
2031	Declaration of Michael Hecht, Ph.D. (Exhibit 1003), <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00003 (P.T.A.B.), November 12, 2024
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2035	Lokeshwar, V., <i>et al.</i> , “Regulation of Hyaluronidase Activity by Alternative mRNA Splicing,” <i>The Journal of Biological Chemistry</i> 277(37):33654-33663 (2002)
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2038	Declaration of Michael Hecht, Ph.D. (Exhibit 1003), <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00039 (P.T.A.B.), March 28, 2025

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2039	Petition for Post-Grant Review, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00039 (P.T.A.B.), March 28, 2025
2040	Wilson, C., <i>et al.</i> , “A critical assessment of the secondary structure prediction of α -helices and their termini in proteins,” <i>Protein Engineering</i> , 15(7):545-554 (2002)
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2042	Cochran D., <i>et al.</i> , “Effect of the N1 residue on the stability of the α -helix for all 20 amino acids,” <i>Protein Science</i> , 10:463-470 (2001)
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2056	Petition for Post-Grant Review, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00042 (P.T.A.B.), April 15, 2025
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2058	Complaint for Patent Infringement and Declaratory Judgment of Patent Infringement, <i>Halozyme, Inc. v. Merck Sharp & Dohme Corp.</i> , Civil Action No. 2:25-cv-03179-ES (D.N.J.), filed April 24, 2025
2059	“Alteogen announces amendment to license agreement with MSD,” Alteogen Press Release, February 22, 2025, accessible at https://www.alteogen.com/en/ir_1/?uid=2223&mod=document&pageid=1 (last accessed April 28, 2025)
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2062	Petition for Post-Grant Review, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00046 (P.T.A.B.), April 29, 2025

Exhibit No.	Description
2063	Petition for Post-Grant Review, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00053 (P.T.A.B.), June 6, 2025
2064	Petition for Post-Grant Review, <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00052 (P.T.A.B.), June 27, 2025
2065	Declaration of Michael Hecht, Ph.D. (Exhibit 1003), <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00046 (P.T.A.B.), April 29, 2025
2066	Declaration of Michael Hecht, Ph.D. (Exhibit 1003), <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00053 (P.T.A.B.), June 6, 2025
2067	Declaration of Michael Hecht, Ph.D. (Exhibit 1003), <i>Merck Sharp & Dohme LLC v. Halozyme Inc.</i> , Case No. PGR2025-00052 (P.T.A.B.), June 27, 2025
2068	Declaration of Melanie A. Simpson, Ph.D. in Support of Patent Owner's Response
2069	<i>Curriculum Vitae</i> of Melanie A. Simpson, Ph.D.
2070	Declaration of Gregory A. Petsko, Ph.D. in Support of Patent Owner's Response
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2072	Declaration of Gary N. Cherr, Ph.D. in Support of Patent Owner's Response
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2076	Transcript of the Deposition of Michael Hecht, Ph.D., August 26, 2025
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2092	Marković-Housley, Z. et al., “Crystal Structure of Hyaluronidase, a Major Allergen of Bee Venom,” <i>Structure</i> , 8:1025-1035 (October 2000)
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2157	Tomita, M. et al., “Hybridoma technologies for antibody production,” <i>Immunotherapy</i> , 3(3):371-380 (2011)
2158	Excerpts from <i>Antibody Methods and Protocols</i> , Proetzel G. and Ebersbach H. eds., Humana Press (2012) (including Zhang, C., “Hybridoma Technology for the Generation of Monoclonal Antibodies,” Chapter 7; and Lee, E. et al., “The Application of Transgenic Mice for Therapeutic Antibody Discovery,” Chapter 8)

Exhibit No.	Description
2159	Zeitlin, L. et al., “Topically Applied Human Recombinant Monoclonal IgG1 Antibody and Its Fab and F(ab') ₂ Fragments Protect Mice from Vaginal Transmission of HSV-2,” <i>Virology</i> , 225:213-215 (1996)
2160	Sherwood, J. et al., “Controlled release of antibodies for long-term topical passive immunoprotection of female mice against genital herpes,” <i>Nature Biotechnology</i> , 14:468-471 (April 1996)
2161	Veselinovic, M. et al., “Topical gel formulation of broadly neutralizing anti-HIV-1 monoclonal antibody VRC01 confers protection against HIV-1 vaginal challenge in a humanized mouse model,” <i>Virology</i> , 432:505-510 (2012)
2162	Schweitzer, M. et al., “Microscopic, chemical and molecular methods for examining fossil preservation,” <i>Comptes Rendus Palevol</i> , 7:159-184 (2008)
2163	<u>National Medal of Science in Medicine Citation for Gregory Petsko, 2022 (accessible at https://nationalmedals.org/laureate/gregory-petsko/?amp=1, last accessed September 19, 2025)</u>
2164	Petsko, G., et al., <i>Protein Structure and Function</i> , New Science Press (2004)
2165	U.S. Patent Application Publication No. 2010/0143457 A1 to Wei et al., published June 10, 2010
2166	Petsko Patent Analysis Data
2167	Huang, C. et al., “Effect of sublingual administration with a native or denatured protein allergen and adjuvant CpG oligodeoxynucleotides or cholera toxin on systemic TH2 immune responses and mucosal immunity in mice,” <i>Annals of Allergy, Asthma, and Immunology</i> , 99:443-452 (November 2007)
2168	<u>Profile of Gregory A. Petsko, American Academy of Arts and Sciences (accessible at https://www.amacad.org/person/gregory-petsko, last accessed September 22, 2025)</u>
2169	<u>“BLAST Topics,” National Institutes of Health (accessible at https://blast.ncbi.nlm.nih.gov/doc/blast-topics, last accessed September 22, 2025)</u>
2170	Chain, E. et al., “Identity of Hyaluronidase and Spreading Factor,” <i>British Journal of Experimental Pathology</i> , 21(6):324-338 (1940)

Exhibit No.	Description
2171	Tollner, T. et al., “Macaque Sperm Release ESP13.2 and PSP94 During Capacitation: The Absence of ESP13.2 Is Linked to Sperm-Zona Recognition and Binding,” <i>Molecular Reproduction and Development</i> , 69:325-337 (2004)
2172	Yudin, A. et al., “Characterization of the active site of monkey sperm hyaluronidase,” <i>Reproduction</i> , 121:735-743 (2001)
2173	Yudin, A. et al., “PH-20 but Not Acrosin Is Involved in Sperm Penetration of the Macaque Zona Pellucida,” <i>Molecular Reproduction and Development</i> , 53:350-362 (1999)
2174	Errata from Park Deposition (introduced during Park deposition and marked by court reporter as “Park 2068”)
2175	Mutational Analysis Table, 2024-11-7, Native Excel File (introduced during Park deposition and marked by court reporter as “Park 2069”)
2176	Mutational Analysis Table, 2024-11-7, PDF File (introduced during Park deposition and marked by court reporter as “Park 2070”)
2177	E-mail Correspondence dated August 14, 2025
2178	1LOH pdb file
2179	1FCV pdb file
2180	2PE4 pdb file
2181	8SMN pdb file
2182	S312G Swiss Model
2183	S312K Swiss Model
2184	S312L Swiss Model
2185	S312N Swiss Model
2186	N47 N219A S312T Swiss Model
2187	N47A N131A S312T Swiss Model
2188	N47A N313A N219A S312T Swiss Model
2189	N131A N219A S312T Swiss Model
2190	Orangutan S312T Swiss Model
2191	PH20 Swiss Model
2192	S312T Swiss Model
2193	Chimpanzee S312N Swiss Model
2194	Gibbon S312N Swiss Model
2195	Chimpanzee S312T Swiss Model
2196	Gibbon S312T Swiss Model
2197	N47A N219A S312N Swiss Model

Exhibit No.	Description
2198	N47A N131A S312N Swiss Model
2199	N47A N131A N219A S312N Swiss Model
2200	N131A N219A S312N Swiss Model
2201	Orangutan S312N Swiss Model
2202-2213	<i>Intentionally Left Blank</i>
2214	Declaration of Zachariah Summers in Support of <i>Pro Hac Vice</i> Admission
2215-2399	<i>Intentionally Left Blank</i>
2400	Merck & Co., Inc. Form 10-Q, Securities and Exchange Commission, November 5, 2025
2401	E-mail Correspondence between Counsel for Petitioner and Patent Owner, January 6, 2026 (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2402	MERCK_PGR00006 - 30November2023 Merck 031988 Master Agreement - executed 4932-6153-3216 1_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2403	MERCK_PGR00056 - MSA - Term 4 - Dechert LLP_Signed_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2404	MERCK_PGR00467 - Mark Stewart Offer Letter_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2405	MERCK_PGR00052 - Hecht Engagement Letter (7-19)_Signed (Redacted)_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2406	MERCK_PGR00086 - Park Engagement Letter with signature - sjp (redacted)_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2407	“Executive team,” MSD, accessible at http://www.msd.com/company-overview/leadership/executive-team/ (last accessed January 5, 2026)
2408	“Executive team,” Merck, accessible at http://www.merck.com/company-overview/leadership/executive-team/ (last accessed January 5, 2026)
2409	“Board of directors,” MSD, accessible at http://www.msd.com/company-overview/leadership/board-of-directors/ (last accessed January 5, 2026)

Exhibit No.	Description
2410	“Board of directors,” Merck, accessible at http://www.merck.com/company-overview/leadership/board-of-directors/ (last accessed January 5, 2026)
2411	“Contact us,” MSD, accessible at http://www.msd.com/contact-us/ (last accessed January 5, 2026)
2412	“Contact us,” Merck, accessible at http://www.merck.com/contact-us/ (last accessed January 5, 2026)
2413	“Who we are,” MSD, accessible at http://www.msd.com/company-overview/ (last accessed January 5, 2026)
2414	“Who we are,” Merck, accessible at http://www.merck.com/company-overview/ (last accessed January 5, 2026)
2415	Merck & Co., Inc. Form 10-K, Securities and Exchange Commission, February 25, 2025
2416	USPTO OED Practitioner Search - Mark J. Stewart
2417	Petition for <i>Inter Partes</i> Review, <i>Merck Sharp & Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00240 (P.T.A.B.), November 30, 2023
2418	Petition for <i>Inter Partes</i> Review, <i>Merck Sharp & Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00622 (P.T.A.B.), March 4, 2024
2419	Petition for <i>Inter Partes</i> Review, <i>Merck Sharp & Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00623 (P.T.A.B.), March 4, 2024
2420	Petition for <i>Inter Partes</i> Review, <i>Merck Sharp & Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00624 (P.T.A.B.), March 4, 2024
2421	Petition for <i>Inter Partes</i> Review, <i>Merck Sharp & Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00625 (P.T.A.B.), March 4, 2024
2422	Petition for <i>Inter Partes</i> Review, <i>Merck Sharp & Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00647 (P.T.A.B.), March 13, 2024
2423	Petition for <i>Inter Partes</i> Review, <i>Merck Sharp & Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00648 (P.T.A.B.), March 13, 2024

Exhibit No.	Description
2424	Petition for <i>Inter Partes</i> Review, <i>Merck Sharp & Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00649 (P.T.A.B.), March 13, 2024
2425	Petition for <i>Inter Partes</i> Review, <i>Merck Sharp & Dohme LLC v. The Johns Hopkins University</i> , IPR2024-00650 (P.T.A.B.), March 13, 2024
2426	MERCK_PGR00035 - 20250813 Payment Remittance_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2427	MERCK_PGR00042 - Dechert T360 Halozyme - 202500327_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2428	MERCK_PGR00045 - FW_Atnn_Accounts Receivable Dept - PAYMENT REMITTANCE DETAIL (Nov 2025)_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2429	MERCK_PGR00049 - Halozyme - 202000447 - Invoices 5_1_2024-12_22_2025_1 of 3_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2430	MERCK_PGR00465 - Mark Stewart Payroll Statement for Dec 12 2025_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2431	MERCK_PGR00001 - Workday - Ginkel Organization Screen Shot (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2432	MERCK_PGR00002 - Workday - Lally Organization Screen Shot (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2433	MERCK_PGR00003 - Workday - Majchrzak Organization Screen Shot (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2434	MERCK_PGR00004 - Workday - Stewart Organization Screen Shot (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2435	MERCK_PGR00005 - Workday - Su Organization Screen Shot (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2436	MERCK_PGR00036 - 20250903 Payment Remittance_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2437	MERCK_PGR00037 - 20251001 Payment Remittance_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2438	MERCK_PGR00038 - 20251203 Payment Remittance_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)

Exhibit No.	Description
2439	MERCK_PGR00040 - 20251215 Payment Remittance_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2440	MERCK_PGR00046 - FW_Attn_Accounts Receivable Dept - PAYMENT REMITTANCE DETAIL (Oct 2025)_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2441	MERCK_PGR00047 - FW_Attn_Accounts Receivable Dept - PAYMENT REMITTANCE DETAIL (Sept 2025)_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2442	MERCK_PGR00048 - Halozyme - 202000447 - Invoice IN00125072310 Review History (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2443	MERCK_PGR00050 - Halozyme - 202000447 - Invoices 5_1_2024-12_22_2025_2 of 3_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2444	MERCK_PGR00051 - Halozyme - 202000447 - Invoices 5_1_2024-12_22_2025_3 of 3_Redacted (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
2445	By-Laws of Merck & Co., Inc., Effective as of November 19, 2024

Pursuant to 37 C.F.R. § 42.10(c), Patent Owner Halozyme, Inc. (“Patent Owner”) hereby gives notice of its intent to designate provisionally recognized PTAB attorney Zachariah Summers as its back-up counsel in this proceeding.

Pursuant to 37 C.F.R. § 42.10(c)(2)(ii)(B), this Notice is accompanied by the Declaration of Zachariah Summers (Exhibit 2214), in which Mr. Summers attests to satisfying all requirements set forth by the Board for *pro hac vice* recognition of a provisionally recognized PTAB attorney and agrees to be subject to the USPTO Rules of Professional Conduct set forth in §§ 11.101 *et seq.* of Title 37 of the Code of Federal Regulations and disciplinary jurisdiction under § 11.19(a) of the same.

I. STATEMENT OF FACTS SHOWING MR. SUMMER’S ELIGIBILITY FOR AUTOMATIC *PRO HAC VICE* ADMISSION AS BACK-UP COUNSEL

In accordance with 37 C.F.R. § 42.10(c), a party may designate as back-up counsel during a proceeding “[a]ny counsel who is not a registered practitioner, who has been previously recognized *pro hac vice* in a Board proceeding, and who has not subsequently been denied permission to appear *pro hac vice* in a Board proceeding.” 37 C.F.R. § 42.10(c)(2)(i).

Patent Owner sets forth these facts in support of this Notice:

1. Lead counsel for Patent Owner in this matter, Eldora L. Ellison, is a registered practitioner (Reg. No. 39,967).

2. The most recent prior proceeding in which Mr. Summers was recognized *pro hac vice* by order of the Patent Trial and Appeal Board pursuant to a motion of the type described in 37 C.F.R. § 42.10(c)(1) was IPR2023-00739. EX2214, ¶7. Mr. Summers has never been denied permission to appear *pro hac vice* in a Board proceeding. *Id.*

3. Accompanying this Notice is Exhibit 2214, the Declaration of Zachariah Summers in Support of Admission *Pro Hac Vice* in this proceeding. In his Declaration, Mr. Summers attests, among other things, that he satisfies all requirements of the Board for automatic admission *pro hac vice*.

See EX2214 *generally*; Paper 5 at 5-6; 37 C.F.R. 42.10(c)(2).

II. CONCLUSION

For the foregoing reasons, Patent Owner gives notice that it intends to designate provisionally recognized PTAB attorney Zachariah Summers as back-up counsel in this proceeding.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

/Eldora L. Ellison/

Eldora L. Ellison, Ph.D.
Registration No. 39,967
Lead Attorney for Patent Owner

Date: January 28, 2026

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

I certify that the above-captioned **PATENT OWNER'S NOTICE OF INTENT TO DESIGNATE A PROVISIONALLY RECOGNIZED PTAB ATTORNEY AS BACK-UP COUNSEL UNDER 37 C.F.R. § 42.10(c)** and Exhibit 2214 were served in their entireties on January 28, 2026, upon the following parties via electronic mail:

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