

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALVOTECH USA INC. and ALVOTECH HF,
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case: PGR2025-00085
U.S. Patent No. 12,168,036

**REGENERON PHARMACEUTICALS, INC.'S MOTION FOR PRO HAC
VICE ADMISSION OF KATHRYN S. KAYALI PURSUANT TO 37 C.F.R.
§ 42.10(c)**

I. RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.10(c) and the Board’s Notice of Filing Date Accorded to Petition and Time for Filing Patent Order Preliminary Response (Paper 3, dated September 26, 2025) (hereinafter “Authorizing Order”), Patent Owner Regeneron Pharmaceuticals, Inc. (“Regeneron”) respectfully requests *pro hac vice* admission of Kathryn S. Kayali in this proceeding. Petitioner does not oppose this motion.

II. GOVERNING LAW, RULES AND PRECEDENT

The Board is authorized to recognize counsel *pro hac vice* pursuant to 37 C.F.R. § 42.10(c), which provides that:

The Board may recognize counsel *pro hac vice* during a proceeding upon a showing of good cause, subject to the condition that lead counsel be a registered practitioner and to any other conditions as the Board may impose. For example, where the lead counsel is a registered practitioner, a motion to appear *pro hac vice* by counsel who is not a registered practitioner may be granted upon showing that counsel is an experienced litigating attorney and has an established familiarity with the subject matter at issue in the proceeding.

The Authorizing Order requires that any motion for *pro hac vice* admission motion “[c]ontain a statement of facts showing there is good cause for the Board to recognize counsel *pro hac vice* during the proceeding.” See Authorizing Order at 4.

The Authorizing Order also requires that the *pro hac vice* motion “[b]e accompanied by an affidavit or declaration in which the individual seeking *pro hac vice* recognition attests to the following:

- i. Membership in good standing of the Bar of at least one State or the District of Columbia;
- ii. No suspensions or disbarments from practice before any court or administrative body;
- iii. No application for admission to practice before any court or administrative body ever denied;
- iv. No sanctions or contempt citations imposed by any court or administrative body;
- v. The individual seeking to appear has read and will comply with the Office Patent Trial Practice Guide and the Board’s Rules of Practice for Trials set forth in 37 C.F.R. part 42;
- vi. The individual will be subject to the USPTO Rules of Professional Conduct set forth in 37 C.F.R. 11.101 *et seq.* and disciplinary jurisdiction under 37 C.F.R. 11.19(a);
- vii. All other proceedings before the Office for which the individual has applied to appear *pro hac vice* in the last three years; and
- viii. Familiarity with the subject matter at issue in the proceeding.”

Authorizing Order at 4-5.

Regeneron hereby files a motion for *pro hac vice* admission of Kathryn S. Kayali.

III. STATEMENT OF FACTS

Based on the following facts, and supported by the Declaration of Ms. Kayali (Ex. 2037) submitted herewith, which attests to each of the items required by the Authorizing Order, Regeneron requests the *pro hac vice* admission of Kathryn S. Kayali in this proceeding:

1. Regeneron's counsel, David I. Berl and Andrew V. Trask are registered practitioners (Berl, Reg. No. 72,751); (Trask, Reg. No. 59,239).
2. Ms. Kayali has established familiarity with the subject matter at issue in this proceeding. As detailed below, Ms. Kayali has a Master's degree in molecular biology, which is related to the technical subject matter of the challenged patent. Ms. Kayali also has engaged in extensive strategic discussions with Patent Owner's lead and backup counsel regarding the matters at issue in this proceeding. (Ex. 2037 ¶ 11).
3. Ms. Kayali is a member in good standing of the bars of Massachusetts and the District of Columbia and has been admitted to practice before

the United States Court of Appeals for the Federal Circuit. (Ex. 2037 ¶ 3).

4. Ms. Kayali has never been suspended or disbarred from practice before any court or administrative body. (Ex. 2037 ¶ 4).
5. No court or administrative body has ever denied Ms. Kayali's application for admission to practice before it. (Ex. 2037 ¶ 5).
6. No court or administrative body has ever imposed sanctions or contempt citations on Ms. Kayali. (Ex. 2037 ¶ 6).
7. Ms. Kayali has read and will comply with the Office of Patent Trial Practice Guide and the Board's Rules of Practice for Trials set forth in part 42 of 37 C.F.R. (Ex. 2037 ¶ 7).
8. Ms. Kayali understands and agrees that she will be subject to the USPTO Code of Professional Responsibility set forth in 37 C.F.R. §§ 11.101 *et seq.* and will be subject to disciplinary jurisdiction under 37 C.F.R. § 11.19(a). (Ex. 2037 ¶ 8).
9. Ms. Kayali's applications to appear *pro hac vice* have been granted in the following matters in the last three years:
 - a. *Biontech SE & Pfizer Inc. v. Modernatx, Inc.*, IPR2023-01358
(regarding U.S. Patent No. 10,702,600)
 - b. *Biontech SE & Pfizer Inc. v. Modernatx, Inc.*, IPR2023-01359

(regarding U.S. Patent No. 10,933,127)

Ms. Kayali has not applied to appear *pro hac vice* in any other proceedings before the Office in the last three (3) years. (Ex. 2037 ¶ 9).

IV. GOOD CAUSE EXISTS FOR THE PRO HAC VICE ADMISSION OF MS. KAYALI IN THIS PROCEEDING

The Board may recognize counsel *pro hac vice* during a proceeding upon a showing of good cause, subject to the condition that lead counsel be a registered practitioner and to any other conditions as the Board may impose. 37 C.F.R. § 42.10(c). Regeneron's counsel, David I. Berl and Andrew V. Trask, are registered practitioners before the Board. Based on the facts contained herein, as supported by Ms. Kayali's declaration, good cause exists to admit Ms. Kayali *pro hac vice* in this proceeding.

As set forth in her declaration, Ms. Kayali has established familiarity with the subject matter at issue in the proceeding. Ms. Kayali has a Master's degree in molecular biology, which is related to the subject matter of the challenged patent. To that end, Ms. Kayali has reviewed Petitioner's Petition, Patent Owner's Discretionary Denial Brief, Patent Owner's Preliminary Response, and the Board's Notices in this proceeding and engaged in strategic discussions with Patent Owner's lead and backup counsel regarding the conduct of this proceeding. Ms. Kayali's admission *pro hac vice* will permit her to participate in depositions in this matter.

For these reasons, Regeneron has a substantial need for Ms. Kayali's *pro hac vice* admission and her involvement in the continued prosecution of this proceeding.

V. CONCLUSION

For the foregoing reasons, Regeneron respectfully requests that Ms. Kayali be admitted *pro hac vice* in this proceeding.

The Patent Trial and Appeal Board is hereby authorized to charge any fees associated with this filing to Deposit Account No. 506403.

May 22, 2026

/Andrew V. Trask/

Andrew V. Trask

Reg. No. 59,239

Backup Counsel for Patent Owner

UPDATED EXHIBIT LIST

Exhibit	Description	Previously Submitted
2001	Excerpts from the File History of U.S. Appl. No. 17/384,070	X
2002	US 2018/0326126 (“Fiedler ’126”)	X
2003	Australian Dep’t of Health & Human Aging, Australian Public Assessment Report for Aflibercept (July 2012) (“AusPAR”)	X
2004	Ameya U. Borwankar et al., <i>Viscosity Reduction of a Concentrated Monoclonal Antibody with Arginine.HCl and Arginine.Glutamate</i> , 55 Ind. Eng. Chem. Rsch. 11225 (2016) (“Borwankar”)	X
2005	Neal Whitaker et al., <i>A Formulation Development Approach to Identify and Select Stable Ultra-High-Concentration Monoclonal Antibody Formulations with Reduced Viscosities</i> , 106 J. Pharmaceutical Scis. 3230 (2017) (“Whitaker”)	X
2006	Ameya U. Borwankar et al., <i>Viscosity Reduction of a Concentrated Monoclonal Antibody with Arginine.HCl and Arginine.Glutamate: Supplementary Information</i> , 55 Ind. Eng. Chem. Rsch. 11225 (2016) (“Borwankar SI”)	X
2007	Eylea HD [®] Highlights of Prescribing Information (Oct. 2024)	X
2008	AbbVie, Allergan, an AbbVie Company, and Molecular Partners Receive Complete Response Letter from FDA on Biologics License Application for Abicipar Pegol, AbbVie News Center (June 26, 2020), https://news.abbvie.com/2020-06-26-Allergan-an-AbbVie-Company-and-Molecular-Partners-Receive-Complete-Response-Letter-from-FDA-on-Biologics-	X

	License-Application-for-Abicipar-pegol (“AbbVie Press Release”)	
2009	Rod McNeil, <i>Advances and Developments in Medical Retina</i> , 25 Eye News 1 (2019) (“McNeil”)	X
2010	Rehan M. Hussain & Thomas A. Ciulla, <i>Emerging Vascular Endothelial Growth Factor Antagonists to Treat Neovascular Age-Related Macular Degeneration</i> , 22 Expert Op. Emerging Drugs 235 (2017) (“Hussain”)	X
2011	Angus Liu, <i>Novartis Calls off 3 Beovu Trials Testing More Frequent Dosing on Concerns of Vision-Threatening Side Effect</i> , FiercePharma (June 1, 2021) (“Liu 2021”)	X
2012	Beovu Label (2024)	X
2013	Philip J. Rosenfeld & David J. Browning, <i>Editorial: Is This a 737 Max Moment for Brolucizumab?</i> , 216 Am. J. Ophthalmology A7 (2020) (“Rosenfeld”)	X
2014	J. Gaudreault et al., <i>Preclinical Pharmacokinetics of Ranibizumab (rhuFabV2) After a Single Intravitreal Administration</i> , 46 Invest. Ophthalmol Vis. Sci. 726 (2005) (“Gaudreault”)	X
2015	Public Trial Transcript Excerpts, <i>Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.</i> , No. 22-cv-61 (N.D.W. Va.)	X
2016	Wang, <i>Protein Aggregation and Its Inhibition in Biopharmaceuticals</i> , 289 Int. J. Pharm. 1 (2005) (“Wang 2005”)	X
2017	Wang, <i>Instability, Stabilization, and Formulation of Liquid Protein Pharmaceuticals</i> , 1856 Int. J. Pharm. 129 (1999) (“Wang 1999”)	X

X2018	Philip J. Rosenfeld et al., <i>Maximum Tolerated Dose of a Humanized Anti-Vascular Endothelial Growth Factor Antibody Fragment for Treating Neovascular Age-Related Macular Degeneration</i> , 112 Ophthalmology 1048 (2005) (“Rosenfeld 2005”)	X
2019	U.S. Patent Application Publication No. 2004/0197324 (“Liu 2004”)	X
2020	U.S. Patent No. 7,087,411 (“Daly”)	X
2021	WO 2006/138181 (“Gokarn”)	X
2022	Rahul N. Khurana et al., <i>Two-Year Results of the Phase 3 Randomized Controlled Study of Abicipar in Neovascular Age-Related Macular Degeneration</i> , 128 Ophthalmology 1027 (2021) (“Khurana 2021”)	X
2023	James A. Dixon et al., <i>VEGF Trap-Eye for the Treatment of Neovascular Age-Related Macular Degeneration</i> , 18 Expert Opinion Investigational Drugs 1573 (2009) (“Dixon 2009”)	X
2024	Pravin U. Dugel et al., <i>HAWK and HARRIER: Ninety-Six-Week Outcomes from the Phase 3 Trials of Brolucizumab for Neovascular Age-Related Macular Degeneration</i> , 128 Ophthalmology 89 (2021) (“Dugel”)	X
2025	John S.Y. Park & David R. Chow, <i>Clinical Primer on Eylea HD: Review of the Current Data</i> , Retina Specialist (Apr. 13, 2024), https://www.retina-specialist.com/article/clinical-primer-on-eylea-hd-review-of-the-current-data (“Park”)	X
2026	Vabysmo Label 2024 (“Vabysmo Label”)	X
2027	Jonas L. Fast et al., <i>Physical Instability of a Therapeutic Fc Fusion Protein: Domain Contributions to</i>	X

	<i>Conformational and Colloidal Stability</i> , 48 Biochemistry 11724 (2009) (“Fast”)	
2028	Zaltrap Label 2023 (“Zaltrap Label”)	X
2029	Michael Thomas, <i>Comparative Effectiveness of Aflibercept for the Treatment of Patients with Neovascular Age-related Macular Degeneration</i> , 7 Clinical Ophthalmology 495 (2013) (“Thomas”)	X
2030	Alvotech, Report of Foreign Private Issuer (Form 6-K) (June 23, 2025) (“Alvotech Press Release”)	X
2031	Molecular Partners, Molecular Partners to Regain Global Rights to Abicipar, Molecular Partners News Release Details (Aug. 8, 2021) https://investors.molecularpartners.com/news-releases/news-release-details/molecular-partners-regain-global-rights-abicipar (“Molecular Partners Press Release”)	X
2032	Novartis, <i>Novartis Reports One Year Results of Phase III MERLIN Study Evaluating Beovu® Every Four Week Dosing and Provides Update on Beovu Clinical Program</i> , Novartis Media Releases (May 28, 2021) https://www.novartis.com/news/media-releases/novartis-reports-one-year-results-phase-iii-merlin-study-evaluating-beovu-every-four-week-dosing-and-provides-update-beovu-clinical-program (“Novartis Press Release”)	X
2033	U.S. Patent Application Publication No. 2023/0416353	X
2034	WO 2014/009465	X
2035	U.S. Food & Drug Admin., Eylea HD Approval Letter (Aug. 18, 2018) (“Eylea HD FDA Approval Letter”)	X

2036	Gerard A. Rodrigues, <i>Functional Characterization of Abicipar-Pegol, an Anti-VEGF DARPIn Therapeutic That Potently Inhibits Angiogenesis and Vascular Permeability</i> , 59 <i>Investigative Ophthalmology & Visual Science</i> 5836 (2018) (“Rodrigues 2018”)	X
2037	Declaration of Kathryn S. Kayali in Support of Motion for <i>Pro Hac Vice</i> Admission	

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

The undersigned hereby certifies that on May 21, 2026, I caused true and correct copies of:

- Regeneron Pharmaceuticals, Inc.’s Motion for *Pro Hac Vice*
Admission of Kathryn S. Kayali Pursuant to 37 C.F.R. § 42.10(c)
- Exhibit 2037: Declaration of Kathryn S. Kayali in Support of Motion
for *Pro Hac Vice* Admission

to be served via e-mail on the following:

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