

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ALVOTECH USA INC. AND ALVOTECH HF,  
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner.

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PGR2025-00085  
Patent 12,168,036

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**PETITIONER'S UNOPPOSED MOTION FOR *PRO HAC VICE*  
ADMISSION OF MEGAN CHACON UNDER 37 C.F.R. § 42.10(c)**

**EXHIBIT LIST**

- 1001 U.S. Patent No. 12,168,036 (Graham et al.)
- 1002 File History for U.S. Patent No. 12,168,036
- 1003 Declaration of Dr. Donald Joseph D’Amico
- 1004 Declaration of Dr. Robert J. Falconer
- 1005 U.S. Patent No. 7,608,261 (Furfine)
- 1006 U.S. Patent No. 8,921,316 (Dix)
- 1007 U.S. Publication No. 2016/0144025 A1 (Vitti)
- 1008 Center for Drug Evaluation and Research, “Clinical Pharmacology and Biopharmaceutics Review(s)” App. No. 125387Orig1s000 (2011) (“2011 Eylea® Clinical Review”)
- 1009 Product Information EYLEA® aflibercept (rch), (“AU Eylea® Label”)
- 1010 U.S. Publication No. 2015/0071920 A1 (Larson)
- 1011 U.S. Publication No. 2017/0232199 A1 (Fiedler)
- 1012 WO 2016/154288 (Ingber)
- 1013 PTE Application U.S. Patent No. 7,374,758, (App. No. 11/016,503)
- 1014 Robert L. Avery, MD et al., INTRAVITREAL INJECTION TECHNIQUE AND MONITORING Updated Guidelines of an Expert Panel, Retina, J. Retinal and Vitreous Diseases, 34, S1-S18 (2014)
- 1015 Sahar Awwad et al., Principles of Pharmacology in the Eye, 174 Brit.

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- 1016 David M. Brown et al., Intravitreal Aflibercept for Diabetic Macular Edema, 122 American Acad. of Ophthalmology 2044 (2015)
- 1017 CATT Research Group, Ranibizumab and bevacizumab for Neovascular Age-Related Macular Degeneration, 364 NEJM 1897 (2011)
- 1018 Nil Celik et al., Intraocular Pharmacokinetics of Aflibercept and Ophthalmology & Visual Science 5574 (2015)
- 1019 Steven R. Cohen & Thomas W. Gardner, Diabetic Retinopathy and Diabetic Macular Edema, 55 Dev. Ophthalmol. 137 (2016).
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- 1022 Elia J. Duh, Jennifer K. Sun & Alan W. Stitt, Diabetic retinopathy: current understanding, mechanisms, and treatment strategies, JCI Insight (2017)
- 1023 Elwes et al., Clinical Outcomes of Switching to Aflibercept Using a pro re nata Treatment Regimen in Patients with Neovascular AgeRelated Macular Degeneration Who Incompletely Responded to Ranibizumab, 18 BMC Ophthalmology (2018)
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- 1027 Taehun Hong, Kazuki Iwashita & Kentaro Shiraki, Viscosity Control of Protein Solution by Small Solutes: A Review, 19 Current Protein and Peptide Science 746 (2018).
- 1028 Naoto Inoue et al., Arginine and Lysine Reduce the High Viscosity of Serum Albumin Solutions for Pharmaceutical Injection, 117 J. Bioscience & Bioengineering 539 (2014).
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- 1031 Joan W. Miller, Saghar Bagheri & Demetrios GF Vavvas, Advances in Age-related Macular Degeneration Understanding and Therapy, 10 U.S. Ophthalmic Rev. 119 (2017)
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- 1033 Martin S. Neergaard et al., Viscosity of High Concentration Protein Formulations of Monoclonal Antibodies of the IgG1 and IgG4 Subclass – Prediction of Viscosity Through Protein-Protein Interaction Measurements, 49 European J. Pharm. Sci. 400 (2013)
- 1034 Quan Dong Nguyen, et al., A Phase I Study of Intravitreal Vascular

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- 1038 Branden A. Salinas et al., Understanding and Modulating Opalescence and Viscosity in a Monoclonal Antibody Formulation, 99 J. Pharm. Sci. 82 (2010)
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- 1040 Lisa L. Sun, Todd Goodwin, and Joseph J. Park, Optical coherence tomography changes in macular CMV retinitis, 18 Dig. J. Ophthalmol. 1 (2012)
- 1041 George Trichonas & Peter K. Kaiser, Aflibercept for the Treatment of Age-Related Macular Degeneration, 2 Ophthalmol. Ther. 88 (2013)
- 1042 Rohit Varma, et al., Prevalence of and Risk Factors for Diabetic Macular Edema in the United States, 132 JAMA Ophthalmol. 1334 (2014)
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- 1046 RESERVED
- 1047 Wykoff et al., Optimizing Anti-VEGF Treatment Outcomes for Patients with Neovascular Age-Related Macular Degeneration, 24 J. Managed Care Specialty Pharm. S3 (2018)
- 1048 Macugen® 2011 Label
- 1049 Beovu® 2019 Label
- 1050 Eylea® 2011 Label
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- 1057 Vabysmo® 2022 Label
- 1058 Assessment Report, Eylea aflibercept, Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency

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- 1060 EMA Annex
- 1061 Loureiro et al., Intravitreal Injections of Bevacizumab: The Impact of  
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- 1064 William Rhoades et al., Management of macular edema due to central  
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- 1065 Declaration of June Ann Munford
- 1066 Clinical Study Protocol, A Randomized, Single-Masked, Active  
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Repeated Doses of High-Dose Aflibercept in Patients with  
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- 1067 U.S. Patent No. 11,103,552 (Graham et al.)
- 1068 “Lowering Drug Prices by Once Again Putting Americans First,”  
Executive Order issued April 15, 2025
- 1069 White House Fact Sheet on Drug Pricing, December 19, 2025

- 1070 Alvotech Press Release, December 19, 2025
- 1071 Teva/Alvotech Press Release, February 18, 2025
- 1072 FDA Press Release, October 29, 2025
- 1073 Declaration of Philip Chen
- 1074 Declaration of Megan Chacon

Pursuant to 37 C.F.R. § 42.10(c), the Petitioner, Alvotech USA Inc. and Alvotech HF (“Alvotech”), respectfully requests that the Board recognize Megan Chacon as counsel *pro hac vice* in this proceeding. Alvotech seeks the counsel of Megan Chacon due to her experience in representing Alvotech in other patent-related matters and particularly due to her familiarity with the substantive and technical issues involved in this proceeding. This motion is authorized by the Notice of Filing Date Accorded to Petition and Time for Filing Patent Owner Preliminary Response that was mailed on September 26, 2025.

#### **I. Statement of Facts**

Ms. Chacon is a patent litigation attorney with fifteen years of representing clients involved in life sciences, including eight years of experience representing clients in cases involving biologics. Ms. Chacon regularly litigates patent cases before the U.S. District Courts across the country and at the U.S. International Trade Commission. Through her practice in such cases, Ms. Chacon has gained substantial experience in all aspects of patent infringement litigation and other areas of intellectual property. Ms. Chacon’s biography is attached as Appendix A of Exhibit 1074.

Ms. Chacon also has particular experience and familiarity with the substantive and technical issues involved in this *post grant* review proceeding.

Alvotech has developed a particular relationship with Ms. Chacon such that Alvotech desires to continue the relationship with Ms. Chacon for the purpose of this proceeding.

## **II. Affidavit of Individual Seeking to Appear**

This Motion for *Pro Hac Vice* Admission is accompanied by an Affidavit of Megan Chacon. Accordingly, Alvotech submits that there is good cause under 37 C.F.R. § 42.10(c) for the Board to recognize Megan Chacon as counsel *pro hac vice* during this proceeding.

Respectfully submitted,

Dated: May 27, 2026

/Kristi L. R. Sawert/  
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**CERTIFICATE OF SERVICE**

Pursuant to 37 CFR § 42.8(b), the undersigned certifies that on May 27, 2026, a complete and entire copy of this Petitioner's Motion for *Pro Hac Vice* and Accompanying Exhibit were provided via email to the Patent Owner by serving the correspondence email addresses of record as follows:

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