

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALVOTECH USA INC. AND ALVOTECH HF,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

PGR2025-00085
Patent 12,168,036

**PETITIONER'S NOTICE OF INTENT TO DESIGNATE DEANNA
REICHEL, A PROVISIONALLY RECOGNIZED PTAB ATTORNEY, AS
BACK-UP COUNSEL 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. J. Pharmacol. 4205 (2017).

- 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).
- 1020 Arup Das, Paul G. McGuire & Sampathkumar Rangasamy, Diabetic Macular Edema: Pathophysiology and Novel Therapeutic Targets, Ophthalmology (2015)
- 1021 Barton J. Dear et al., Contrasting the Influence of Cationic Amino Acids on the Viscosity and Stability of a Highly Concentrated Monoclonal Antibody, 34 Pharm. Res. 193 (2017)
- 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)
- 1024 K Ghasemi Falavarjani & QD Nguyen, Adverse Events and Complications Associated with Intravitreal Injection of Anti-VEGFagents: a Review of Literature, Eye (2013)
- 1025 Feng He et al., Effect of Sugar Molecules on the Viscosity of High Concentration Monoclonal Antibody Solutions, 28 Pharm. Res. 1552 (2011)

- 1026 Allen C. Ho et al. Twenty-four-Month Efficacy and Safety of 0.5 mg or 2.0 mg Ranibizumab in Patients with Subfoveal Neovascular AgeRelated Macular Degeneration, 121 Ophthalmology 2181 (2014)
- 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).
- 1029 Su-Eon Jin & Sung-Joo Hwang, Ocular Delivery Systems for the Administration of Antibody Therapeutics, J. Pharm. 47 Investig. 373 (2017)
- 1030 Lehman Brothers Presentation, 9th Annual Global Healthcare Conference, Mar. 2006
- 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)
- 1032 Chakravarthy Narasimhan, Henryk Mach & Mohammed Shameem, High-Dose Monoclonal Antibodies Via the Subcutaneous Route: Challenges and Technical Solutions, an Industry Perspective, 3 Therapeutic Delivery 889 (2012).
- 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 Endothelial Growth Factor Trap-Eye in Patients with Neovascular Age-Related Macular Degeneration, 116 Ophthalmology 2141 (2009)
- 1035 Quan Dong Nguyen, et al., Evaluation of Very High- and Very Low

Dose Intravitreal Aflibercept in Patients with Neovascular Age Related Macular Degeneration, 28 J. Ocular Pharmacology and Therapeutics 581 (2012)

- 1036 RESERVED
- 1037 Lorena Perez-Gutierrez & Napoleone Ferrara, Biology and therapeutic targeting of vascular endothelial growth factor A, Nature Reviews Molecular Cell Biology (2023)
- 1038 Branden A. Salinas et al., Understanding and Modulating Opalescence and Viscosity in a Monoclonal Antibody Formulation, 99 J. Pharm. Sci. 82 (2010)
- 1039 Michael W. Stewart, Clinical and Differential Utility of VEGF Inhibitors in Wet Age-Related Macular Degeneration: Focus on Aflibercept, 6 Clin. Ophthalmol. 1175 (2012)
- 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)
- 1043 Dabir S. Viswanath et al., Correlations and Estimation of Pure Liquid Viscosity, Viscosity of Liquids: Theory, Estimation, Experiment, and Data (2007)
- 1044 Shujing Wang et al., Viscosity-Lowering Effect of Amino Acids and Salts on Highly Concentrated Solutions of Two IgG1 Monoclonal Antibodies, 12 Mol. Pharmaceutics 4478 (2015).
- 1045 Shawn Shouye Wang, Yifei (Susie) Yan, and Kin Ho, US FDA

Approved Therapeutic Antibodies with High-Concentration
Formulation: Summaries and Perspectives, 4 Antibody Therapeutics
262 (2021)

- 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
- 1051 Eylea® 2012 Label
- 1052 Eylea® 2014 Label
- 1053 Eylea® 2016 Label
- 1054 Eylea® HD 2024 Label
- 1055 Lucentis® 2017 Label
- 1056 RESERVED
- 1057 Vabysmo® 2022 Label
- 1058 Assessment Report, Eylea aflibercept, Committee for Medicinal
Products for Human Use (CHMP), European Medicines Agency
Science Medicines Health, Sept. 2012
- 1059 Center for Drug Evaluation and Research, “Pharmacology Review(s)”
App. No. 125387Orig1s000 (2011) (“Eylea Pharmacology Review”)

- 1060 EMA Annex
- 1061 Loureiro et al., Intravitreal Injections of Bevacizumab: The Impact of Needle Size in Intraocular Pressure and Pain, 11 J. Curr. Glaucoma Pract. 38 (2017)
- 1062 Napoleone Ferrara, Vascular endothelial growth factor and age related macular degeneration: from basic science to therapy, Nature Medicine (2010)
- 1063 Roomasa Channa, Michael Smith & Peter A Campochiaro, Treatment of macular edema due to retinal vein occlusions, Clinical Ophthalmology (2011)
- 1064 William Rhoades et al., Management of macular edema due to central retinal vein occlusion – The role of aflibercept, Taiwan J. Ophthalmol (2017)
- 1065 Declaration of June Ann Munford
- 1066 Clinical Study Protocol, A Randomized, Single-Masked, Active Controlled Phase 2 Study of the Safety, Tolerability, and Efficacy of Repeated Doses of High-Dose Aflibercept in Patients with Neovascular Age-Related Macular Degeneration, NCT04126317
- 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
- 1075 Declaration of Nitika Gupta Fiorella
- 1076 Declaration of Deanna Reichel

Pursuant to 37 C.F.R. § 42.10(c), the Petitioner, Alvotech USA Inc. and Alvotech HF (“Alvotech”), respectfully notifies the Board of its intent to designate Deanna Reichel, a provisionally recognized PTAB attorney, as back-up counsel in this proceeding. Petitioner seeks the counsel of Deanna Reichel due to her experience in representing Petitioner in other patent-related matters and particularly due to her familiarity with the substantive and technical issues involved in this proceeding. The Board previously granted *pro hac vice* admission of Deanna Reichel in PGR2023-00020 and IPR2024-00580, and Patent Owner does not oppose.

1. Lead Counsel

Martina Hufnal, Reg. No. 58,916 serves as lead counsel in this proceeding.

2. Accompanying Certification

Deanna Reichel satisfies 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 §§ 37 C.F.R. § 11.101 *et seq.* and disciplinary jurisdiction under § 11.19(a). This Notice of Intent To Designate a Provisionally Recognized PTAB Attorney as Back-Up Counsel is accompanied by a Declaration of Deanna Reichel.

Petitioner submits that Deanna Reichel has satisfied all requirements to be deemed admitted *pro hac vice* in this proceeding.

Respectfully submitted,

Dated: May 27, 2026

/Kristi L. R. Sawert/
Kristi L. R. Sawert, Reg. No. 45,702
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
T: 202-783-5070
F: 877-769-7945
PGR2025-00085@fr.com

Attorney for Petitioner

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 Notice of Intent to Designate Deanna Reichel were provided via email to the Patent Owner by serving the correspondence email addresses of record as follows:

David I. Berl, dberl@wc.com
Andrew V. Trask, atrask@wc.com
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
Eylea@wc.com

/Anastasia Renard/
Anastasia Renard
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
renard@fr.com