

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

**DECLARATION OF MEGAN CHACON IN SUPPORT OF PETITIONER'S
MOTION FOR *PRO HAC VICE* ADMISSION**

I, Megan Chacon, hereby declare to the following:

1. I am a member in good standing of the State Bar of New York and California, U.S. District Court for the Southern District of New York, U.S. District Court for the Eastern District of Texas, U.S. District Court for the Southern District of California, U.S. Court of Appeals for the Federal Circuit and U.S. District Court for the Central District of California.

2. I have not been suspended or disbarred from practice before any court or administrative body.

3. I have never had an application for admission to practice before any court or administrative body denied.

4. No sanction or contempt citation has been imposed against me by any court or administrative body.

5. I have read and will comply with the Office Patent Trial Practice Guide and the Board's Rules of Practice for Trials set forth in part 42 of Title 37 Code of Federal Regulations.

6. I 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).

7. In the past three years, I have not applied for or received admission *pro hac vice*.

8. I am an experienced patent litigation attorney with fifteen years of experience of representing clients involved in life sciences, including eight years of experience representing clients in cases involving biologics. I regularly litigate patent cases before the U.S. District Courts across the country and at the U.S. International Trade Commission.

9. I am intimately familiar with the issues and subject matter presented in this above-captioned *post grant* review proceeding. For example, I have extensively reviewed the above identified patent, its prosecution history, the Petition for PGR (including the invalidity grounds therein, and the cited references), and all exhibits filed in this case.

10. My biography is attached hereto as Appendix A.

11. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: May 27, 2026

/ *Megan A Chacon* /
MEGAN CHACON
Fish & Richardson P.C.
Email: chacon@fr.com

APPENDIX A



Megan A. Chacon

Principal
San Diego, New York
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212 765 5070
chacon@fr.com

Overview

Megan Chacon's practice emphasizes complex patent litigation across a wide range of technologies. She has extensive experience in the life sciences and pharmaceutical fields, including Hatch-Waxman litigation.

Megan has worked on matters involving a wide variety of pharmaceutical compounds, formulations, and treatment methods for conditions such as schizophrenia, bipolar depression, pain management, hepatitis C virus, oral testosterone therapy, and osteoporosis. Megan also has experience with biotechnology, chemicals, medical devices, and consumer products.

Megan's experience covers all aspects of pre-litigation due diligence and litigation, including case assessment, domestic and international document collection and production, managing fact and expert discovery teams and strategy, depositions, dispositive motions, *Markman* hearings, settlement strategy, and pre-trial and trial work. While Megan focuses her practice in the U.S. district courts and has appeared in many across the country, she also has experience with the U.S. International Trade Commission.

Prior to joining the firm, Megan practiced as a patent litigator at a leading intellectual property law firm in New York focusing on Hatch-Waxman litigation. She also served as a student judicial extern to the Honorable Clark Waddoups of the U.S. district court for the District of Utah (2009).

Experience

Juno Therapeutics Inc. et al. v. Kite Pharma Inc. (C.D. Cal.): Counsel for Kite in ongoing litigation against Juno concerning Kite's CAR-T cancer therapy YESCARTA®.

Sumitomo Dainippon Pharma Co., Ltd. v. Emcure Pharma Ltd. et al. (D. NJ): Representing Plaintiffs in Hatch-Waxman litigation over schizophrenia and bipolar depression medication LATUDA®.

In the Matter of Certain Sleep-Disordered Breathing Treatment Mask Systems and Components Thereof — Int'l Trade Comm'n Investigation No. 337-TA-1022 (I.T.C.): Counsel for complainant ResMed in the investigation against New Zealand manufacturer Fisher & Paykel Healthcare involving two ResMed patents on CPAP masks to treat sleep apnea.

iCeutica Inc. et al v Lupin, Ltd., et al. (D. Md.): Representing Plaintiffs in Hatch-Waxman litigation over pain medication VIVLODEX®.

Gilead Sciences, Inc. v. AbbVie (D. Del.): Represented Plaintiff in litigation over its hepatitis C treatment HARVONI®.

Represented Plaintiff in Hatch-Waxman litigation over ocular pain drug.

Represented a biopharmaceutical company in litigation related to the company's oral testosterone therapy formulation.

iCeutica Inc. et al v Lupin, Ltd., et al. (D. Del): Represented Plaintiffs in Hatch-Waxman litigation over pain medication ZORVOLEX®.

Warner Chilcott Co., LLC v. Teva Pharmaceuticals USA, Inc. (D. NJ): Represented Plaintiff in Hatch-Waxman litigation over osteoporosis treatment ATELVIA® (prior to joining Fish & Richardson).

Recognitions & awards

Leader of Influence in Law

San Diego Business Journal 2024

San Diego's Top Attorneys

San Diego Metro Magazine (SD Metro) 2022

Women of Influence

San Diego Business Journal 2021

Fellow

Leadership Council on Legal Diversity 2019

Top 40 Under 40

San Diego Daily Transcript 2019

Women Worth Watching

Profiles in Diversity Journal 2019

Professional associations

Law360 Life Sciences Editorial Advisory Board, 2020

Insights

Blog | October 27, 2025

Lessons for Biopharma From the Battle of Entresto®

Blog | April 18, 2025

Trump's Drug Price Executive Order: What Drugmakers Should Know

Webinar | January 22, 2025

Hatch-Waxman 2024 Year in Review

Blog | January 8, 2025

Hatch-Waxman 201

Article | November 20, 2024

How a Second Trump Presidency Could Shape IP

Webinar | September 12, 2024

Hatch-Waxman 201

Article | February 5, 2024

Hatch-Waxman 2023 Year in Review

Blog | December 18, 2023

The Federal Circuit Weighs in On Hatch-Waxman "Skinny" Label Infringement Dispute

Webinar | December 7, 2023

Hatch-Waxman 2023 Year in Review

Blog | November 9, 2023

FTC Challenges More Than 100 Patents as Improperly Listed in Orange Book

Blog | September 25, 2023

Federal Circuit Evaluates Enablement for Antibody Claims for the First Time Since *Amgen v. Sanofi* *Baxalta Inc. et al. v. Genentech, Inc.*

Webinar | January 4, 2023

Hatch-Waxman 2022 Year in Review

Blog | October 11, 2022

Federal Circuit Affirms PTAB's Final Written Decision that Merck's Claimed Inventions Were Not "At Once Envisaged" From the Prior Art

Webinar | April 14, 2022

Viewing the Orange Book Under a Microscope: The Regulatory Framework & its Implications for Branded Drug Makers

Webinar | December 9, 2021

Hatch-Waxman 2021 Year in Review

News

Media Coverage | April 14, 2025

Fish & Richardson's San Diego Office Celebrates 30 Years of IP Leadership

San Diego Business Journal

Media Coverage | December 6, 2024

Principal Megan Chacon on the Future of Biopharma Patents Under Second Term of the Trump Administration

Life Sciences Intellectual Property Review

Media Coverage | November 27, 2024

Principal Megan Chacon Highlights Gratitude-Worthy Patent Litigation Trends in 2024

IAM

Media Coverage | November 21, 2024

Principal Megan Chacon Explores Changes to Biopharma Patent Landscape During Second Trump Administration

Life Science Leader

News | October 30, 2024

Principals Megan Chacon and Alex Gelberg Recognized as Leaders of Influence in Law by the *San Diego Business Journal*

News | March 14, 2024

Fish & Richardson and ACLU of San Diego Secure Settlement in Class Action Lawsuit Regarding Processing Delays for People in Immigration Custody

News | May 20, 2022

San Diego Metro Magazine Names Principal Megan Chacon to its 2022 Top Attorney List

News | August 27, 2021

Fish & Richardson Part of Gilead Legal Team That Secures Reversal of \$1.2 Billion Judgment Against Kite Pharma for Cancer Therapy

News | July 9, 2021

Fish & Richardson Attorneys Megan Chacon and Crystal Culhane Named 2021 Women of Influence in Law by the *San Diego Business Journal*

News | June 25, 2019

Fish & Richardson Principals Named 2019 "Women Worth Watching" by *Profiles in Diversity Journal*

News | March 13, 2019

Fish & Richardson Principal Megan Chacon Selected for Leadership Council on Legal Diversity's 2019 Fellows Program

News | February 4, 2019

Fish & Richardson Elevates 11 Attorneys to Principal

Events

October 29, 2024

Kisaco Pharma & Biotech Patent Litigation North America 2024

April 7, 2019

Patent Resources Group (PRG) Spring 2019 Advanced Courses Program

March 21, 2019

USD's Annual Patent Law Conference

September 28, 2017

Benchmark Litigation Women in Business Law Forum LA

Additional insights

Publications

- Life Sciences Patent Eligibility "101": Mayo at Five, co-authored with Geoff Biegler and Dalia Kothari.

Speaking engagements

- Patent Resources Group Advanced Patent Law Course, Hatch-Waxman and Biosimilars: *A Hatch-Waxman and BPCIA (Biosimilars) Immersion Course*, Lecturer (April 10-12, 2019)
 - "Patentable Subject Matter in the Life Sciences," *University of San Diego School of Law Intellectual Property Law Conference* (March 22, 2019)
 - "Biosimilar and Hatch-Waxman Litigation," *San Diego Office CLE Event* (January 24, 2018)
 - "Fishbowl Session," Facilitator, *Benchmark Litigation Women In Business Law Forum Los Angeles* (September 28, 2017)
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Services

Litigation

Patent Litigation

Industries

Energy & Chemicals

Life Sciences

Medical Devices

Admissions

New York (2012)

U.S. District Court for the Southern District of New York (2014)

California (2015)

U.S. District Court for the Eastern District of Texas (2015)

U.S. District Court for the Southern District of California (2015)

U.S. Court of Appeals for the Federal Circuit (2018)

U.S. District Court for the Central District of California (2019)

Education

J.D., Boston University School of Law (2011) Articles Editor, *Journal of Science and Technology Law*

B.S., Chemical Engineering, University of Utah (2008)

