

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAREPTA THERAPEUTICS, INC.,
Petitioner,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,
Patent Owner
and REGENXBIO INC.,
Exclusive Licensee

Case IPR2024-00580
Patent 11,680,274

**DECLARATION OF DR. CASEY M. KRANING IN SUPPORT OF
PATENT OWNER'S UNOPPOSED MOTION FOR *PRO HAC VICE*
ADMISSION**

I, Dr. Casey M. Kraning, hereby declare to the following:

1. I am a member in good standing of the State Bars of Delaware and Pennsylvania, United States, the United States District Court for the District of Delaware, the United States Court for the Eastern District of Pennsylvania, and the U.S. Court of Appeals for the Federal Circuit.

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 the 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 applied for admission *pro hac vice* in IPR2021-00451, IPR2022-00381, IPR2022-00617, IPR2022-00682, IPR2023-

00589, IPR2023-00695, IPR2023-00726, IPR2023-01167, IPR2023-01342, IPR2023-01349, IPR2024-00070, and IPR2024-00240.

8. I have a Bachelor of Science in Chemistry, a Master of Science in Biomedical Engineering, and a Ph.D. in Biomedical Engineering, and I have personally reviewed and analyzed the patent-at-issue in this proceeding, the Petition, the Preliminary Response and the accompanying exhibits to each. I am also familiar with the prior art and have experience working with a technical expert on the subject matter of the patent-at-issue. Through my experience and analysis of the aforementioned documents, I have acquired substantial understanding of the underlying technological issues at stake in these proceedings.

9. I am a litigation attorney with 8 years of experience representing clients in patent cases in the pharmaceutical, life sciences, consumer products, and oil and gas industries. I regularly litigate patent cases before federal district courts. Through my experience in patent litigation matters, I have represented clients in many phases of litigation including in drafting and responding to discovery, working with technical experts, taking depositions, drafting motions and summary judgment briefs, conducting pre-suit diligence, and working on all stages of IPRs. I have also been substantively involved in developing technical and legal arguments. My biography is attached hereto as Appendix A.

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

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: 10/29/2024

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Appendix A



Casey M. Kraning, Ph.D.

Principal
Delaware
302-778-8422
cmk@fr.com

Overview

With a Ph.D. in biomedical engineering and extensive research experience in cellular and molecular medicine, Casey Kraning brings deep scientific knowledge to her litigation work with clients in the life sciences, pharmaceutical, and biotechnology industries.

Casey partners with clients to protect their innovations across a diverse range of industries, including pharmaceuticals, life sciences, household products, agriculture, and oil and gas. Known for her creative litigation strategies and direct communication style, Casey thinks outside of the box to best attain her clients' business goals inside and outside the courtroom. She has significant trial experience and excels at working with experts to dive deep into the intricacies of her clients' technology, and then crafting accessible applications of complex scientific concepts for a lay audience.

On the post-grant side of her practice, Casey has advocated for clients in all stages of *inter partes* review, having successfully worked on more than 30 IPRs and a dozen patent infringement cases on behalf of both plaintiff/patent owners and defendant/petitioners. Her notable matters include assisting the legal team for Coherus BioSciences, which successfully invalidated three patents in the AbbVie blockbuster drug Humira® patent family. In addition to arguing on behalf of her clients at Markman and Daubert hearings in U.S. District Courts, Casey helped an independent inventor defeat two IPR petitions at the institution stage and eventually secure a favorable settlement of the District Court litigation.

As a graduate student at Cornell University, Casey earned her Ph.D. in biomedical engineering. Her research involved measuring contractile forces of cancer cells as an indicator of metastatic potential and designing and fabricating novel collagen and PDMS microchannels to study cancer cell invasion. An excellent writer and articulate speaker, she published five peer-reviewed papers, a peer-reviewed book chapter, a review article, and 20 conference proceedings, as well as presented oral presentations at five national conferences while obtaining her Ph.D. She also initiated and maintained productive collaborations with five labs, both internal and external to Cornell.

Casey serves as co-chair of the Patent Trial and Appeal Board Bar Association Young Lawyers & Agents Committee. She maintains an active pro bono practice and regularly writes on timely topics in the intellectual property realm.

Outside of work, Casey enjoys attending concerts across a variety of genres and exploring the many state parks in her area.

Experience

Represented Coherus BioSciences in successfully invalidated three patents

Represented Magellan Midstream Partners

Professional associations

Delaware Bar Association

PTAB Bar Association

- Co-Chair, Young Lawyers and Agents Committee (2024-present)
- Vice Chair, Young Lawyers and Agents Committee (2022-2024)

Pro bono activities

Casey's pro bono work spans reproductive rights, LGBTQ, and disability issues, including securing a favorable result for an inmate who filed a lawsuit under the Americans with Disabilities Act for failure to provide accommodations for his disability while in prison. She also tried an Eighth Amendment challenge in Arkansas District Court brought by inmates on death row, performing multiple direct and cross-examinations, and has represented clients before the U.S. Citizenship and Immigration Services agency.

Insights

Blog | April 5, 2024

Biologics and Biosimilars Landscape: IP, Policy, and Market Developments

Article | March 28, 2024

When Does IPR Estoppel Apply to Product or System Art in District Court?

Post-Grant Report | January 17, 2024

2023 Post-Grant Annual Report

Blog | October 17, 2023

USPTO Issues Proposed Rules on Pre-Issuance Internal Circulation and Review of PTAB Decisions

Blog | April 26, 2023

Legal Alert: USPTO Issues Advance Notice of Proposed Rulemaking for PTAB Proceedings

Post-Grant Report | February 28, 2023

2022 Post-Grant Annual Report

Webinar | January 31, 2023

Post-Grant for Practitioners | 2022 Year in Review

Blog | January 17, 2023

Biosimilars 2022 Year in Review

Article | December 22, 2022

Attorneys Dorothy Whelan, Karl Renner, and Casey Kraning, Ph.D., Author *National Law Journal* Article "A Look Back on a Decade of Practice at the PTAB"

Article | September 29, 2022

Associate Casey Kraning Authors Article for *The National Law Journal* "Congress and the America Invents Act — An Update on Recent Developments in the..."

News

January 2, 2024

Fish & Richardson Elevates 20 Attorneys to Principal

April 27, 2017

Fish & Richardson Announces 15 Recent Associates

Events

October 10, 2024

PTAB Bar Association Thought Leader Summit 2024

August 29, 2023

PTAB Bar Association Young Lawyers & Agents Committee Nuts & Bolts Series: "A Guide to the Patent Owner Response"

Additional insights

Publications

- ["Prior art stipulations, a petitioner's tool for addressing Fintiv Denials,"](#) *Westlaw Journal IP* (June 13, 2022)
- ["Stays Pending IPR In Del. District Courts Are Here To Stay,"](#) *Law360* (March 12, 2022)
- ["PTAB Splits on Instituting Challenges to Herceptin® Patents,"](#) *Fish Post-Grant Alerts* (August 2, 2017)
- ["Pfizer Takes Aim at Herceptin® Patent at the PTAB,"](#) *Fish Post-Grant Alerts* (July 12, 2017)
- ["Rituxan® Patents Resurface at the PTA,"](#) *Fish Post-Grant Alerts* (March 10, 2017)
- ["Biogen Dodges IPR Bullet on Key Tysabri® Patents,"](#) *Fish Litigation Blog* (October 20, 2016)
- "Microfabricated Collagen Tracks Facilitate Single Cell Metastatic Invasion in 3D," *Integrative Biology* 2013:5 606-16
- "Controlling Matrix Stiffness and Topography for the Study of Tumor Cell Migration," *Cell Adhesion & Migration*, 2012:6 274-9
- "Methods in Cell Biology (Chapter: Quantifying Traction Stresses in Adherent Cells) Elsevier," New York, 2012:110 139-78
- "Cellular Traction Stresses Increase with Increasing Metastatic Potential," *PLoS One*, 2012:7(2) e32572
- "The Role of the Cytoskeleton in Cellular Force Generation in 2D and 3D Environments," *Physical Biology*, 2011:8 015009 (selected as one of Physical Biology's "Highlights of 2011")
- "Microfabrication of an Asymmetric, Multi-layered Microdevice for Controlled Release of Orally Delivered Therapeutics," *Lab on a Chip*, 2008:8 1042-47
- "Determination of Surface Coverage and Orientation of Reduced Cytochrome c on a Silica Surface with Polarized ATR Spectroscopy," *Phys. Chem. C*, 2007:11(35) 13062-67

Media mentions

["New Patent Tribunal Rule Marks Push to Curb Political Influence,"](#) *Bloomberg Law* (October 16, 2023)

Services

Litigation

Patent Litigation

Post-Grant

Inter Partes Review

Post-Grant Review

Industries

Energy & Chemicals

Cleantech

Life Sciences

Biotech & Diagnostics

Pharmaceuticals

Admissions

Delaware (2016)

Pennsylvania (2017)

U.S. District Court for the District of Delaware

U.S. District Court for the Eastern District of Pennsylvania

U.S. Court of Appeals for the Federal Circuit

Education

J.D., University of Pennsylvania Law School (2016) Managing Editor, *Penn Intellectual Property Group Online*, awarded “Best Advocate” and “Best Appellee Brief” at the Western Regional of the AIPLA Giles Rich Moot Court

Ph.D., Biomedical Engineering, Cornell University (2013) Thesis: “The Role of Force Generation in Metastatic Cancer Progression”

M.S., Biomedical Engineering, Cornell University (2012)

B.S. *summa cum laude*, Chemistry, Butler University (2008)