

Stephanie L. Schonewald, PhD

Partner



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Practice Areas

Intellectual Property Protection

Education

University of Denver Sturm College of Law
JD (2009) Torts and Administrative Law, with
honors

University of Colorado at Denver Health
Sciences Center
PhD (2006) Biochemistry,
Molecular Genetics

University of Northern Iowa
BS (2000) Chemistry, *summa
cum laude*

Admissions

Massachusetts

Maryland

District of Columbia

U.S. District Court, Eastern District of Texas

U.S. Patent & Trademark Office

Dr. Stephanie Schonewald counsels biotech and pharmaceutical companies on the strategic development of patent portfolios, patent prosecution, and post-grant patent challenges. She advises clients on a broad range of patent matters, including patent portfolio management and counseling, with particular experience in cell therapies, microbiome therapeutics, gene therapies, antibodies and other related immunotherapies, vaccines, antisense oligonucleotides and siRNAs, and diagnostic methods for various diseases.

Advising clients who are involved in contentious patent scenarios, Stephanie has handled a variety of third party submissions, protests, and post-grant proceedings before the United States Patent and Trademark Office (USPTO). She has worked on over 55 *inter partes review*, post grant review, and covered business method review proceedings before the Patent Trial and Appeal Board (PTAB).

In addition, Stephanie also advises clients on the management of their US patent office activity alongside other global patent activity. For example, she routinely consults with clients on European third party observations and oppositions, and has consulted with clients on post-grant challenges in other key jurisdictions, including Australia, China, and Japan.

Her clients include Regeneron Pharmaceuticals, Inc., Foundation Medicine, Inc., BioNTech SE, Akouos, Inc., Biogen, Helix Nanotechnologies, Sana Biotechnology, and Viridian Therapeutics.

Representative Engagements

Patent Trial and Appeal Board

- ***Sandoz Inc. v. Biogen MA Inc., PTAB:*** Counsel for Biogen in defending patent directed to novel methods of treating inflammatory and autoimmune diseases using TYSABRI® (natalizumab).
- ***Triplet Therapeutics, Inc. v. Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, PTAB:*** Counsel for Patent Owner Louisiana State University and interested party Takeda Pharmaceuticals U.S.A., Inc. in defense of Louisiana State University's patent directed to oligonucleotide compositions targeting the DNA mismatch repair system for the treatment of associated DNA repeat expansion diseases.
- ***Valo Early Discovery, Inc. v. Hybrigenics SA., Fed. Circ.:*** Counsel for Valo Early Discovery, Inc. (f/k/a Integral Early Discovery, Inc.) in an appeal of a PTAB post-grant review decision involving a patent protecting novel inhibitors of ubiquitin-specific protease 7 (USP7).
- ***Guardant Health, Inc. v. Foundation Medicine, Inc., PTAB:*** Counsel for Foundation Medicine in IPR proceedings defending patents protecting innovative comprehensive genomic cancer assays using next generation sequencing.

- ***Foundation Medicine, Inc. v. Guardant Health, Inc., PTAB:*** Counsel for Foundation Medicine in IPR proceedings challenging patents directed to methods for detecting genetic mutations.
- ***Regeneron Pharm., Inc. v. Kymab Ltd., PTAB:*** Counsel for Regeneron in multiple IPR proceedings challenging patents directed to transgenic mice and methods of using transgenic mice.
- ***Daiichi Sankyo Co., Ltd. v. Alethia Biotherapeutics, Inc., PTAB:*** Counsel for Alethia in defense of its patent directed to antibodies for inhibiting bone resorption.
- ***Progenics Pharmaceuticals, Inc. v. Max-Planck-Gesellschaft zur Förderung der Wissenschaften e. V., PTAB:*** Counsel for Progenics Pharmaceuticals, Inc. in a PGR proceeding challenging a patent directed to compounds for preparing 18F-radiolabeled Prostate-Specific Membrane Antigen (PSMA)-targeting conjugates.
- ***Hybrigenics SA v. FORMA Therapeutics, Inc., PTAB:*** Counsel for FORMA Therapeutics, Inc. in a PGR proceeding defending a patent protecting novel inhibitors of ubiquitin-specific protease 7 (USP7).
- ***Saudi Arabian Oil Co. v. SK Innovation Co. Ltd., PTAB:*** Counsel for Saudi Arabian Oil Co. in an IPR proceeding challenging a patent directed to polycarbonates.
- ***ADT LLC, et al. v. Script Security Solutions LLC, PTAB:*** Counsel for Alarm.com, Inc. in proceedings challenging patents directed to a portable security alarm system.
- ***Alarm.com, Inc. v. Rothschild Broadcast Distribution Sys., LLC, PTAB:*** Counsel for Alarm.com, Inc. in an IPR proceeding challenging a patent directed to systems and methods for media content storage and delivery.
- ***Central Security Group - Nationwide, Inc. et al. v. Ubiquitous Connectivity, LP, PTAB:*** Counsel for Central Security Group in challenging patents related to the use of SMS (short message service) messages and cellular networks to control and monitor environmental devices.
- ***Akamai Technologies, Inc. v. Limelight Networks, Inc., PTAB:*** Counsel for Akamai Technologies, Inc. in challenging a patent related to retrieving content objects in a content delivery network.
- ***Oil States Energy Services, LLC v. Greene's Energy Group, LLC, et al., Supreme Court:*** Counsel for the Boston Patent Law Association in filing *amicus* brief in support of neither party on the merits.

Patent Prosecution and Counseling

- Preparation and global prosecution of patent applications directed to diagnostic and therapeutic products including antibodies, gene therapies, vaccines, stem cells, pharmaceutical formulations, nanotechnology, nucleic acid molecules, biologics, medical devices, mouse platforms for antibody development, and methods of treating diseases.
- Develops life-cycle management strategies for various clients, large and small, to protect assets whose base composition of matter protection may be expiring before products can be commercialized.
- Coordinates worldwide protection and dispute strategy on behalf of clients with ongoing matters, both offensive and defensive, in multiple jurisdictions.
- Counsels various clients developing biologic therapeutics with respect to freedom to operate issues.
- Counsels a large immunology company in defending its patents and challenging its competitors' patents involved in European Oppositions.
- Defended two patents through Supplemental Examination.

Publications and Presentations

- “Post-grant proceedings and their impact on life science patents,” moderator, Life Sciences Patent Network, May 2024
- “Notice of Proposed Rulemaking – Motions to Amend,” speaker, PTAB Bar Association Program Committee Webinar, April 2024
- “The Art of Successful Portfolio Management,” moderator, Consero IP Life Sciences Executive Roundtable, March 2024
- “Effectively Using and Dealing with Experts at the PTAB,” speaker, IPWatchdog PTAB Masters, January 2024
- “Best Practices and Tips for Winning at the PTAB,” moderator, IPWatchdog Life Sciences Masters, October 2023
- “Impact on PTAB Discretion - PTAB Proposed Rule Changes: Changes to Fintiv and Compelling Merits,” panelist, PTAB Bar Association webinar, June 2023
- “Bootcamp: Nuts and Bolts of Proceedings Before the PTAB,” panelist, 2023 PTAB Bar Association Annual Conference, March 2023
- “The Secrets to PTAB Success: Advanced IPR Strategies,” moderator, IPWatchdog: PTAB Masters, February 2023
- “The Future of the Written Description Requirement,” moderator, IPWatchdog: Life Sciences Masters, October 2022
- “Enhancing Your Research & Development Pipeline,” moderator, Consero IP Life Sciences Executive Roundtable, March 2022
- “Patent Specification Concerns Make IPRs Tricky For Drug Cos.,” quoted, *Law360*, January 2022
- “Life Sciences and IPR: Orange Book & Biologic Patents at the PTAB,” panelist, IP Watchdog PTAB Masters, January 2022
- “Section 112 Enablement: What to Watch Out For,” panelist, BIO IP Counsels Committee Webinar, September 2021
- “Patent Challengers Reassess Strategies After Ruling Bars Tactic,” quoted, *Bloomberg Law*, June 2020
- “Boston’s Top Women at the PTAB,” moderator, Boston Patent Law Association, February 2020
- “Patent Office Guidance at Odds With Court Strategy, Attorneys Say,” quoted, *Bloomberg Law*, February 2020
- “In the Hot Seat - Case Law Update and Trends,” panelist, BIO IPCC Fall Conference, November 2019
- “Mission Incomprehensible – Indefiniteness and Support in Post-Grant Trials,” webinar panelist, American Intellectual Property Law Association (AIPLA), October 2019
- “Precluding the Problem: Tips and Pitfalls for Prosecutors,” panelist, American Intellectual Property Law Association (AIPLA) Spring Meeting, May 2019
- “Patent Cases Round-Up,” panelist, 2019 American Bar Association-Intellectual Property Law (ABA-IPL) Annual Meeting and 34th Intellectual Property Law Conference, April 2019
- “How to Make ‘Connections’ and ‘Friends’ in 140 Characters or Less: Social Networking for Lawyers,” webinar panelist, the Federal Circuit Bar Association, March 2019
- “Networking for Young Lawyers,” webinar panelist, the Federal Circuit Bar Association, January 2019

- “PTAB Practice Post-SAS: What You Need To Know,” moderator, Boston Bar Association, December 2018
- “Post-Grant Amendments at the USPTO,” panelist, Boston Patent Law Association
- “Practical Tips For Tackling Your First Couple of Years As An Associate,” panelist, Federal Circuit Bar Association
- “Will The Pendulum Swing Back In IPR Proceedings?,” co-author, *IP Law360*
- “AIA Post-Grant Proceedings: Multiple Petitioners Filing a Single Petition Must Present their Case with a ‘Single Voice,’” co-author
- “AIA Post-Grant Proceedings: Rejection of Invalidity Defenses at District Court did not Prohibit PTAB’s Later Finding of Unpatentability,” co-author
- “Diverse Career Paths,” panelist, Federal Circuit Bar Association
- “Mock Appellate Argument,” co-presenter, AUTM-LES Joint Meeting
- “The Mouse TrkB mRNA Contains Two IRESes that are Differentially Regulated,” co-author, *PLoS ONE*
- “Identification of Intrinsic and Extrinsic Determinants that Regulate Internal Initiation of Translation Mediated by the FMRI 5’ Leader,” co-author, *BMC Molecular Biology*

Professional and Community Involvement

- Boston Patent Law Association (Co-Chair of the Contested Matters Committee)
- Boston Intellectual Property American Inn of Court
- PTAB Bar Association
- American Intellectual Property Law Association
- American Bar Association
- Federal Circuit Bar Association

Recognition

- A World’s Leading Patent Practitioner by *IAM Patent 1000* (2022-2024)
- Top IPR Attorney by *Patexia Insights* (2022)
- *Best Lawyers in America*: “Ones to Watch” (2021-2024)
- A “Top 50 Women in PTAB Trials” by the PTAB Bar Association
- *Legal 500* (2022-2024)
- *LMG Life Sciences*: “Life Sciences Star”
- *Massachusetts Super Lawyers*