

Geoffrey Biegler

Partner



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San Diego

Intellectual Property
Intellectual Property Litigation
Life Sciences IP Litigation
Patent Office Litigation
Hatch-Waxman Litigation
Life Sciences

Geoff is a seasoned life sciences litigator with a particular focus on pharmaceuticals and biotechnology, including Hatch-Waxman cases, Biologics Price Competition and Innovation Act (BPCIA) cases, competitor pharmaceutical and biotechnology cases, and life sciences-related post-grant proceedings at the Patent Trial and Appeal Board (PTAB).

Geoff has extensive experience litigating cases for products including Gilead's Odefsey, Descovy, Vemlidy, Sovaldi, Harvoni and Epclusa; Kite's Yescarta; Alovtech's adalimumab biosimilar; Genentech/Roche's Xeloda; Cephalon's Amrix; Myriad Genetics' BRCA1/BRCA2 genetic testing; and CRISPR-Cas9 technology, among others.

In the context of those disputes, Geoff has successfully managed and tried matters through all phases of litigation, mediation, and arbitration in a variety of forums, spanning from the US District Court for the District of Delaware to the Central District of California, including the US International Trade Commission (ITC) and the PTAB. He also has handled due diligence efforts and pre-suit investigations and assisted his clients in managing post-grant proceedings before PTAB. In addition to his experience in US jurisdictions, Geoff has significant experience managing and harmonizing patent disputes that include multiple, international jurisdictions.

In the courtroom, Geoff has conducted numerous witness examinations at trials and hearings and argued a variety of dispositive and non-dispositive motions, including Markman hearings and preliminary injunctions. He also has extensive experience managing complex discovery and directing case strategy.

Geoff frequently teaches and speaks on life sciences litigation topics, including the regulatory framework of the Hatch-Waxman Act and the BPCIA.

Geoff's recent representative experience

- Defending Moderna in litigation brought by Alnylam over Moderna's COVID- 19 vaccine, SPIKEVAX®.
 First of two cases dismissed after favorable Markman ruling, in Moderna v. Alnylam (D. Del.)
- Represented Gilead in a post grant review proceeding filed by Atea Pharmaceuticals alleging that a Gilead
 patent covering novel nucleoside phosphoramidate prodrugs was unpatentable. After a preliminary
 response, the Board denied institution of Atea's request for post-grant review in Atea Pharmaceuticals v.
 Gilead Sciences (PTAB)
- Lead counsel for NeuroDerm and Mitsubishi Tanabe Pharma Corp. in post-grant review challenging an AbbVie patent related to treatments for Parkinson's disease. The Board found all claims of AbbVie's patent unpatentable in a Final Written Decision in NeuroDerm Ltd. v AbbVie (PTAB)

- Represented Gilead in Hatch-Waxman litigation over Vemlidy, Descovy and Odefsey (its breakthrough treatments for HIV and hepatitis B virus) against nine different generics that filed 15 abbreviated new drug applications (ANDAs), winning on all terms at Markman and settling favorably the morning of trial in Gilead Sciences v. Apotex, et al. (D. Del.)*
- Represented Alvotech in its multi-jurisdiction biosimilar dispute with AbbVie over arthritis drug adalimumab, sold as Humira, the world's top-selling drug by revenue, in Alvotech USA Inc. et al. v. AbbVie Inc. et al., 1:21-cv-00589 (E.D. Va.) and AbbVie Inc. et al. v. Alvotech hf., 1-21-cv-02258 (N.D. III.)*
- Represented Kite in litigation over its CAR-T cancer product Yescarta, including putting on Kite's written description expert at jury trial; after trial, the US Court of Appeals for the Federal Circuit found Juno's patent invalid for lack of written description, clearing Kite of any liability in the matter in Juno Therapeutics, Inc. v. Kite Pharma, Inc. (C.D. Cal.)*
- Handled multiple confidential matters involving CRISPR Cas-9 technology*
- Managed Hatch-Waxman litigation against multiple generic companies related to ANDAs for Gilead's hepatitis C treatment Sovaldi (sofosbuvir), resulting in the case being settled prior to trial, in Gilead Sciences, Inc., et al. v. Teva USA, Inc., Gilead Sciences Inc. et al v. Natco Pharma, et al. (D.N.J.)*
- Represented ResMed in a patent dispute over CPAP flow generator and mask products spanning district court litigation, the ITC, multiple worldwide litigations and 10+ Inter Partes Review proceedings, with the case being settled prior to trial, in ResMed v. Fisher & Paykel (ITC)*
- Managed litigation for Gilead in competitor pharmaceutical litigation involving Gilead's hepatitis C treatment, Harvoni, with the litigation being resolved shortly before trial, in Gilead Sciences, Inc. v. AbbVie, Inc. (D. Del.)*
- Acted as trial counsel for ResMed through an ITC decision in a case involving patent infringement by CPAP flow generator and mask products; after the hearing, the ITC found a violation of Section 337 in Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof (ITC)*
- Served as trial counsel for Myriad Genetics in multidistrict litigation involving patents related to the BRCA1 and BRCA2 genes In re: BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litigation (D. Utah)*
- Represented Roche and Genentech in Hatch-Waxman litigation involving Xeloda oral chemotherapy treatment, with the litigation settled shortly before trial, in Hoffman-La Roche and Genentech v. Teva (D.N.J.)*
- Represented NUtech Ventures (associated with the University of Nebraska-Lincoln) in a patent case related to genetically modified corn, and argued and obtained a successful Markman ruling on behalf of NUtech, resulting in the case being settled, in NUtech Ventures v. Syngenta Seeds (D. Neb.)*
- Represented 3M in a patent infringement case related to ion-exchange based emulsifier technology used during manufacturing process for Teflon, with the case settled after claim construction, in 3M Innovative Properties Co. v. DuPont (D. Minn.)*
- Represented Cephalon in multidistrict Hatch-Waxman litigation involving its skeletal muscle relaxant drug
 product, Amrix, with the case resulting in a finding of infringement and validity for Cephalon, in *In re:*Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation (D. Del.)*
- Defended Terumo in district court and ITC cases involving its VirtuoSaph Endoscopic Vein Harvesting System, with both cases settled favorably, in Maquet v. Terumo (N.D. Cal.) and In the Matter of Certain Vein Harvesting Surgical Systems and Components Thereof (ITC)*
- Represented the plaintiffs in Hatch-Waxman action over blood pressure drug Sular, with the case being successfully resolved upon patent expiration, in Sciele Pharma, Inc., et al. v. Mylan Labs., et al. (D. Del.)*

Represented the plaintiffs in patent litigation over cell lines used to manufacture the late-stage colon
cancer drug Erbitux, with the case being settled on the morning of opening statements for \$65 million, in
MIT & Repligen v. ImClone Corp. (D.Mass.)*

Speaking engagements

- Co-presenter, "Regulatory Exclusivity Update in Europe and the USA and the Interplay With IP Strategy," Life Sciences Strategy Summit on IP & Exclusivity, October 2024
- Co-presenter, "Life Sciences Litigation: Preparing for Successful Hatch-Waxman Litigation," Cooley Rx series, May 2024
- Co-presenter, "<u>Life Sciences Litigation: Hatch-Waxman, 2023 Year in Review</u>," Cooley Rx series,
 January 2024
- Co-presenter, "Life Sciences Litigation: Biosimilars, 2023 Year in Review," Cooley Rx series,
 December 2023
- Co-presenter, "Life Sciences Litigation: Learnings from 40 Years of Litigation Under the Hatch-Waxman Act," Cooley Rx series, September 2023

Education

University of Minnesota Law School JD, 2006

University of Wisconsin, La Crosse BS, 2000

Admissions & Credentials

California

Court Admissions

US Supreme Court

US Court of Appeals for the Federal Circuit

Rankings & Accolades

Best Lawyers: Top IP Lawyer
Super Lawyers: Rising Star

Memberships & Affiliations

American Intellectual Property Law Association

Federal Circuit Bar Association

Federal Bar Association

^{*}Representation handled prior to joining Cooley