




Geoffrey D. Biegler

Principal

 San Diego, CA

 858-678-4357

 biegler@fr.com

Overview

About Geoff

Geoff Biegler is a principal in the Southern California office of Fish & Richardson P.C. with an expansive litigation practice that spans all areas of intellectual property and complex commercial litigation, with a particular focus on pharmaceutical and life sciences litigation. He has extensive experience litigating both Hatch-Waxman cases and competitor pharmaceutical and biotechnology cases for products including ODEFSEY®, DESCOVY®, VEMLIDY®, SOVALDI®, HARVONI®, and EPCLUSA® (Gilead), YESCARTA® (Kite), XELODA® (Genentech/Roche), AMRIX® (Cephalon), BRCA1/BRCA2 genetic testing (Myriad Genetics), and CRISPR-Cas9 technology.

Mr. Biegler has successfully managed and tried matters through all phases of litigation, mediation, and arbitration in a variety of forums, spanning from the U.S. District Court for the District of Delaware to the Southern District of California, including the U.S. International Trade Commission. In addition to his experience in U.S. jurisdictions, Mr. Biegler also has significant experience managing and harmonizing patent disputes that include fronts on multiple, international jurisdictions.

In the courtroom, Mr. Biegler has conducted numerous witness examinations at trial and argued a variety of dispositive and non-dispositive motions, including *Markman* hearings and preliminary injunctions. Mr. Biegler has also handled due diligence efforts, pre-suit investigations, managed complex discovery, and assisted his clients in managing post-grant proceedings before the Patent Trial and Appeal Board.

Mr. Biegler teaches life sciences trial and patent practice courses and speaks on patent litigation topics around the country. As a result of his teaching and litigation experience, he is very knowledgeable regarding the Hatch-Waxman regulatory framework and the Biologics Price Competition and Innovation Act.

Focus Areas

Services

- Litigation
- Post-Grant
- Appellate
- Hatch-Waxman
- ITC Litigation
- Patent Litigation

Industries

- Chemicals
- Life Sciences
- Medical Devices

Education

J.D. *magna cum laude*, University of Minnesota Law School (2006)

B.S., Biology and Chemistry, University of Wisconsin, La Crosse (2000)

Experience

Gilead Sciences v. Apotex, et al. (D. Del.): representing plaintiff in pending Hatch-Waxman litigation against multiple generic companies concerning abbreviated new drug applications for Gilead's HIV treatments ODEFSEY®, DESCOVY®, and VEMLIDY®

Juno v. Kite (C.D. Cal.): representing Kite in pending litigation against Juno concerning Kite's CAR-T product YESCARTA® for the treatment of certain cancers

Multiple confidential matters involving CRISPR Cas-9 technology

Gilead Sciences, et al v. Teva USA, Inc., v. Natco Pharam, et al (D.N.J.): managed Hatch-Waxman litigation against multiple generic companies related to abbreviated new drug applications for Gilead's hepatitis C treatment SOVALDI® (sofosbuvir). Case settled prior to trial.

ResMed v. Fisher & Paykel: counsel for ResMed in patent dispute over CPAP flow generator and mask products spanning district court litigation, the International Trade Commission, multiple worldwide litigations, and over ten IPR proceedings. Case settled prior to trial.

Gilead Sciences, Inc. v. AbbVie, Inc. (D. Del.): managed litigation for Gilead in competitor pharmaceutical litigation involving Gilead's Hepatitis C treatment, HARVONI®. The litigation was resolved shortly before trial.

Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof (ITC) – trial counsel for complainant ResMed through Commission decision in case involving patent infringement by CPAP flow generator and mask products. Following the hearing, the Commission found a violation of Section 337.

In re: BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litigation (D. Utah): counsel for plaintiff Myriad Genetics in multi-district litigation involving patents related to the BRCA1 and BRCA2 genes.

Hoffman-La Roche and Genentech v. Teva (D.N.J.): counsel for Roche and Genentech in Hatch-Waxman litigation involving XELODA® oral chemotherapy treatment. The litigation settled shortly before trial.

NUTech Ventures v. Syngenta Seeds (D. Neb.): counsel for NUTech Ventures (associated with the University of Nebraska-Lincoln) in patent case related to genetically modified corn. Argued and obtained successful Markman ruling on behalf of NUTech. Case settled in 2014.

3M Innovative Properties Co. v. Avery Dennison (D. Minn.): counsel for 3M in patent and antitrust cases related to retroreflective sheeting used on highway road signs. Obtained successful *Markman* and summary judgment rulings on behalf of 3M. Cases settled in 2013.

3M Innovative Properties Co. v. DuPont (D. Minn.): counsel for 3M in patent infringement case

related to ion-exchange based emulsifier technology for removing APFO during manufacturing process for Teflon®. Case settled after claim construction.

In re: Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation (D. Del.): represented Plaintiff Cephalon in multi-district Hatch-Waxman litigation involving Cephalon's skeletal muscle relaxant drug product, AMRIX®. Following a bench trial, obtained a Federal Circuit decision finding that claims covering AMRIX® were not obvious.

Maquet v. Terumo (N.D. Cal.) and *In the Matter of Certain Vein Harvesting Surgical Systems and Components Thereof* (ITC): counsel for defendant Terumo in district court and ITC cases involving Terumo's VirtuoSaph Endoscopic Vein Harvesting System. Both cases settled favorably.

Sciele Pharma, Inc., et al v. Mylan Labs., et al (D. Del.): counsel for plaintiffs in Hatch-Waxman action over blood-pressure drug, SULAR®. Case successfully resolved upon patent expiration.

MIT & Repligen v. ImClone Corp. (D.Mass.): counsel for plaintiffs in patent litigation over cell lines used to manufacture the late-stage colon cancer drug ERBITUX®. Case settled on morning of opening statements for \$65 million.

Insights

Publications

- "An Update On 2020 U.S. Biosimilars Regulation & Litigation," *Biosimilar Development* (September 2020)
- "Hatch-Waxman Success: Start the Invention Story at the Beginning," *The Recorder* (August 2020)
- "FDA Seeks to Modernize the Orange Book," *Fish Litigation Blog* (June 2020)
- "Generic Drug Labeling and Induced Patent Infringement," *Fish Litigation Blog* (June 2020)
- "How Pandemic-Related Delays Affect Hatch-Waxman Litigants," *Law360* (May 2020)
- "Mayo at Five: Are Traditional Method of Treatment Claims in Danger Under Section 101?," *Fish Litigation Blog* (October 2017)
- "Mayo at Five: Eligibility of Diagnostic Method Claims," *Fish Litigation Blog* (September 2017)
- Life Sciences Patent Eligibility "101": Mayo at Five, *Fish Litigation Blog* (2017)

Presentations

- "Hatch-Waxman: How to Prepare for the Paragraph IV Letter," *Fish & Richardson Webinar* (June 3, 2021)
- "Biosimilars – 2020 Year in Review," *Fish & Richardson Webinar* (January 28, 2021)

- “Biosimilars: A 2020 Mid-Year Review,” *Fish & Richardson Webinar* (July 2020)
- “Hatch-Waxman: Positioning Your Company For Success Against Generic Challenges,” *Fish & Richardson Webinar* (June 2020)
- “Hatch-Waxman and Biosimilars: A Hatch-Waxman and BPCIA (Biosimilars) Immersion Course,” *Patent Resources Group Advanced Patent Law Course* (April 2018)
- “Venue in Hatch-Waxman Cases,” *PatCon 8: The Annual Patent Conference* (March 2018)

Recognition

- Named to “Best Lawyers” by *Best Lawyers in America* (2022)

Memberships & Affiliations

Member, American Intellectual Property Law Association, Federal Circuit Bar Association, and Federal Bar Association.