



Michael J. Freno

Partner

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OVERVIEW

Michael Freno is a partner and counsels clients on intellectual property matters and focuses on intellectual property litigation and opinions relating to validity and infringement. Based on 15 years of litigation experience, Michael advises pharmaceutical companies on federal Hatch-Waxman litigations and Patent Office proceedings, including *Inter Partes* Review and Post-Grant Review. His litigations have involved all kinds of small molecule pharmaceuticals, dosage forms, and methods of use, including anti-HIV agents, beta-blockers, atypical anti-psychotics, chemotherapeutic agents, oral contraceptives, antidepressants, calcium-channel blockers, nitrogen scavenging drugs, hypothyroidism treatments, ADHD and ADD drugs.

Michael also counsels clients on all aspects of the regulatory and litigation strategy for successfully launching pharmaceutical products. Starting with product selection, Michael advises clients on design-around opportunities, performs patent landscape analyses, provides non-infringement and invalidity opinions, and counsels clients on FDA regulatory hurdles.

In addition to his pharmaceutical practice, Michael has successfully litigated IP cases across the United States, including patent cases of various technologies, including biologics (antibodies against the DR5 death receptor), polymers (fluoroelastomers), mechanical products (fiberglass reinforced doors) and electrical engineering technology (organic light emitting diodes and LCDs). Michael also has extensive experience in unfair competition, false advertising, and trademark infringement.

PROFESSIONAL BACKGROUND

Prior to joining K&L Gates, Michael was partner at another Seattle law firm, and before that, he worked in New York for 11 years, specializing in complex patent litigation matters.

Before law school, Michael taught logic as a graduate student at both The Ohio State University and the University of Wisconsin-Milwaukee. He also developed methods to test the stability of novel drug formulations for two years as an analytical chemist at G.D. Searle in the 1990s.

ACHIEVEMENTS

- Listed in *The Best Lawyers in America*® for Biotechnology and Life Sciences Practice (2024)
- Listed in *The Best Lawyers in America*® for Patent Law (2024)

PROFESSIONAL / CIVIC ACTIVITIES

- American Intellectual Property Law Association
- Washington Biotechnology & Biomedical Association

EDUCATION

- J.D., Cornell Law School, 2001
- M.A., University of Wisconsin, Milwaukee, 1997
- B.A., Kenyon College, 1993 (*magna cum laude*)

ADMISSIONS

- Bar of New York
- Bar of Washington
- United States Patent and Trademark Office
- United States Court of Appeals for the Federal Circuit
- United States Court of Federal Claims
- United States District Court for the District of Colorado
- United States District Court for the Southern District of New York
- United States District Court for the Western District of Washington

AREAS OF FOCUS

- IP Litigation
- Antitrust, Competition, and Trade Regulation
- Commercial Disputes
- E-Discovery Analysis and Technology (e-DAT)
- Food, Drugs, Medical Devices, and Cosmetics (FDA)

- IP Procurement and Portfolio Management
- Pharma and BioPharma Litigation

REPRESENTATIVE EXPERIENCE

- Represented Par Pharmaceuticals, Inc. in a Hatch-Waxman patent lawsuit filed by Alza Corp. involving Par's application to market an extended release methylphenidate hydrochloride product. The parties settled. Par's Alza Corp. v. Par Pharm., Inc., No. 13-1104 (D. Del.).
- Represented third-party intervenor Par Sterile Products, LLC in a lawsuit filed by Hospira, Inc. against FDA for approving Par's generic version of Precedex. Par successfully obtained a summary judgment within four weeks, and defeated a preliminary injunction. Hospira Inc. v. Sylvia Mathews Burwell, No. 14-2662 (D. Md.).
- Represented Cipla Limited and Cipla USA, Inc. in a patent infringement lawsuit filed against Sunovion Pharmaceuticals, Inc. involving Sunovion's levalbuterol product. The parties settled before trial. Cipla Ltd. v. Sunovion Pharmaceuticals Inc., No. 15-cv-00424-LPS (D.Del.)
- Represented Cipla Limited and Cipla USA, Inc.. in a Hatch-Waxman patent infringement lawsuit filed by Abraxis Bioscience, LLC involving Cipla's paclitaxel product. Abraxis dismissed the action pursuant to a settlement. Abraxis Bioscience, LLC and Celgene Corp. v. Cipla Limited, No. 16-9074-JMV (D.N.J.).
- Represented Cipla Limited and Cipla USA, Inc. in a Hatch-Waxman patent infringement lawsuit filed by Amgen involving Cipla's cinacalcet product. Amgen dismissed the action pursuant to a settlement. Amgen Inc. v. Aurobindo et al., No. 16-cv-00880 and 16-853-GMS consolidated
- Representing Genus Lifesciences, Inc. in a trade secret misappropriation lawsuit filed against Mallinckrodt LLC involving Mallinckrodt's use of Genus's trade secrets to increase the value of Mallinckrodt's drug master file for cocaine. The case is pending. enus Lifesciences, Inc. v. Mallinckrodt LLC and SpecGX, LLC, No. xx-cv-xxx (E.D. Pa.)
- Representing a generic pharmaceutical company in a Lanham Act false advertising lawsuit against Lannett Corporation, Inc. involving Lannett's alleged false advertising of its C-Topical product (cocaine hydrochloride 4% solution). The case is pending. Genus Lifesciences, Inc. v. Lannett Company, Inc., No. 18-cv-07603-WHO (N.D. Cal.)
- Represented Lehigh Valley Technologies, Inc., Endo Global Ventures, Endo Ventures Limited, and Generics Bidco I, LLC in a Lanham Act false advertising lawsuit at the ITC against Virtus Pharmaceuticals, LLC involving Virtus alleged false advertising of its potassium chloride product. The case settled. Lehigh Valley Techs., Inc. v. Virtus Pharm., Inc., Inv. No. 337-TA-1013 (U.S.I.T.C.).
- Represented Lehigh Valley Technologies, Inc., Endo Global Ventures, Endo Ventures Limited, and Generics Bidco I, LLC in a Lanham Act false advertising lawsuit against Virtus Pharmaceuticals, LLC involving Virtus alleged false advertising of its potassium chloride product. The case settled. Lehigh Valley Techs., Inc. v. Virtus Pharm., Inc., Inv. No. 16-cv-00435 (D.Del.).

- Represented defendant Par Pharmaceuticals, Inc. in this Hatch-Waxman patent infringement lawsuit filed by Merck Sharp & Dohme Corp. involving Par's posaconazole product. Merck Sharp & Dohme Corp. v. Par Sterile Prods., LLC, No. 16-948 (D.N.J.).
- Represented defendant Par Pharmaceuticals, Inc. and Anchen Pharmaceuticals, Inc. in this Hatch-Waxman patent infringement lawsuit filed by Forest Laboratories, LLC involving Par's generic version of Namzaric. Forest Laboratories LLC et al v. Amneal Pharmaceuticals LLC et al., No. 15-cv-00756-LPS (D.Del.)
- Represented Par Sterile Products, LLC, Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. in a patent infringement lawsuit filed by Fresenius Kabi involving Par's levothyroxine product. Fresenius Kabi USA, LLC v. Innopharma Licensing, LLC et al., 15-cv-03655-KM (D.N.J.)
- Represented Par Sterile Products, LLC in a patent infringement lawsuit filed by Novartis Pharmaceuticals Corp. involving Par's launch of a zoledronic acid product. Novartis dismissed the case pursuant to a settlement. In re: Certain Consolidated Zoledronic Acid Cases, No. 12-3967 (D.N.J.)
- Represented defendant Par Pharmaceuticals, Inc. in this Hatch-Waxman patent infringement lawsuit filed by AstraZeneca, A.B. involving Par's saxagliptin product. AstraZeneca stipulated to the dismissal of all claims. AstraZeneca AB v. Aurobindo Pharma Ltd. et al., No. 14-cv-00664-GMS (D.Del.)
- Represented Par Sterile Products, LLC in a Lanham Act false advertising lawsuit against Fresenius Kabi USA, LLC involving Fresenius's alleged false advertising of its vasopressin product. The case settled. Par Sterile Products, LLC v. Fresenius Kabi USA, LLC, No. 14-cv-03349 (N.D.Ill.)
- Represented defendant Adamis Pharmaceuticals Corp. in this Hatch-Waxman patent infringement lawsuit filed by kaleo, Inc. Involving Adamis's naloxone hydrochloride injection product. After two months, kaleo voluntarily dismissed the action. kaleo, Inc. v. Adamis Pharmaceuticals Corp., No. 19-cv-00917-RGA (D.Del.)