

Peter L. Giunta

Partner

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OVERVIEW

Pete Giunta advises clients on intellectual property issues and litigates patent and technology disputes. His experience spans a wide array of technologies, including pharmaceuticals, biopharmaceuticals, biotechnology, medical devices, diagnostics, and electronics. Before studying law, Pete worked in several pharmaceutical and chemical companies, which helps him understand the issues companies face, and practice with a business-minded approach.

Pharmaceuticals and biologics are a major part of Pete's practice. He helps clients navigate the interface between patent and food and drug law. Generic, brand, biosimilar, and over-the-counter drug companies rely on his input in developing strategies for FDA filings, product launches, and post-marketing protection. His experience spans many therapeutic areas, including cancer, diabetes, HIV/AIDS, central nervous system, asthma, and microbial diseases. It also spans many dosage forms, including solid oral formulations, sterile injectables, inhaled dosage forms, topical agents, and ophthalmic solutions.

Pete has litigated numerous Hatch-Waxman cases through trial and appeal. He has had cases in federal district courts, the US Court of Appeals for the Federal Circuit, and the International Trade Commission (ITC). Pete is registered to practice before the US Patent & Trademark Office and counsels clients on Patent Trial and Appeal Board proceedings such as *inter partes* reviews (IPRs). In addition to litigation, Pete has represented clients in negotiations, mediations, and AAA and LCIA arbitrations in patent, trademark, and commercial disputes.

He likewise provides patent infringement, validity, and freedom-to-operate opinions, and advises on prosecution and licensing.

PROFESSIONAL BACKGROUND

- Clerkship, Honorable Lawrence M. McKenna, US District Court Judge in the Southern District of New York, 2004-2005
- Practiced at a well-regarded New York intellectual property law firm, 2005-2014

PROFESSIONAL / CIVIC ACTIVITIES

- Hon. William C. Conner Inn of Court

EDUCATION

- J.D., Benjamin N. Cardozo School of Law, *(cum laude; Order of the Coif; Editor, Cardozo Law Review)*
- B.S., Seton Hall University, *(Chemistry, magna cum laude)*

ADMISSIONS

- Bar of New Jersey
- Bar of New York
- United States Patent and Trademark Office
- United States Court of Appeals for the Federal Circuit
- United States District Court for the District of New Jersey
- United States District Court for the Eastern District of New York
- United States District Court for the Southern District of New York

THOUGHT LEADERSHIP *POWERED BY HUB*

- 1 August 2025, Optional Refrigeration Freezes Induced Patent Infringement Claim
- 30 January 2023, Are Medical Diagnostic Methods Patent Ineligible by Convention?: CareDx, Inc. v. Natera, Inc. and Eurofins Viracor, Inc.
- 30 July 2019, When Saying More Gets You Less: The Federal Circuit Affirms That Superfluous Prosecution Arguments Can Limit Doctrine of Equivalents Infringement
- 13 July 2017, Federal Circuit Instructs the PTAB on Written Description in University Interference Proceeding
- 6 July 2017, Sandoz v. Amgen – Biosimilars at the U.S. Supreme Court
- 9 June 2017, Where Can Hatch-Waxman and BPCIA Cases Stick After *TC Heartland LLC v. Kraft Foods Group Brands LLC*?
- 8 June 2017, Remicade® Update: Passing Up Your Chance to Dance Can Increase Damages
- 28 April 2017, *Sandoz v. Amgen*—Biosimilars at the Supreme Court—Oral Argument
- 4 April 2017, Markush Madness: Watson Avoids Infringement by Adding an Element to a Formulation
- 27 January 2017, To the Federal Circuit, Some PTAB Petitioners Have No Appeal Whatsoever

- 3 October 2016, Fall Brings a Flurry of Biosimilar Approvals: FDA Approves Biosimilars of Enbrel® and Humira®
- 20 September 2016, Remicade® Update: Double Patenting Redoubles in Post-Gilead Biosimilar Case
- 19 August 2016, Humira® Update: Big Guns Take Aim at Top-Selling Biologic
- 21 July 2016, Federal Circuit Confirms Post-Licensure Notice of Commercial Marketing Is Mandatory in Biosimilar Litigation
- 6 June 2016, ANDA Filing May Subject a Pharmaceutical Company to Personal Jurisdiction in Patent Infringement Suits Anywhere in the U.S.
- 1 June 2016, Federal Circuit Holds That an Offer to Sell a Drug Product Was a Patent-Invalidating Offer for Sale under Pre-AIA § 102(b) Even Though the Offer Lacked “Safety and Liability Terms”
- 13 April 2016, The Next Move in the Name Game: FDA Provides Long-Awaited Draft Guidance on Biosimilar Labeling

OTHER MEDIA MENTIONS

- Mentioned, "Gilead, Cipla Ink Deal To End HIV Drug Buyers' Antitrust Suit," *Law360*, 1 March 2024

AREAS OF FOCUS

- IP Litigation
- Antitrust and Competition
- Food, Drugs, Medical Devices, and Cosmetics (FDA)
- International Arbitration
- IP Procurement and Portfolio Management
- Pharma and BioPharma Litigation
- Post-Grant Patents
- Technology Transactions and Sourcing

INDUSTRIES

- Healthcare
- Life Sciences

REPRESENTATIVE EXPERIENCE

- 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.
- Represent MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. in a Hatch-Waxman patent infringement lawsuit filed by Boehringer involving MSN's afatinib product. This case is still pending.
- 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.
- 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.
- Represented Lehigh Valley Technologies, Inc., Endo Global Ventures, Endo Ventures Limited, and Generics Bidco I, LLC in a Lanham Act false advertising lawsuit against Sandoz and Upsher-Smith involving defendants alleged false advertising of its potassium chloride product. The case settled.
- 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.
- Represented Par Sterile Products, LLC, Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. in a patent infringement lawsuit filed against Luitpold Pharm., Inc. involving Luitpold's epinephrine product. The case was dismissed.
- Represented defendant Par Pharmaceuticals, Inc. in this Hatch-Waxman patent infringement lawsuit filed by Merck Sharp & Dohme Corp. involving Par's posaconazole product.
- 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 Namenda.
- 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.
- 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.
- 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.
- 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.