

Robert Cerwinski

Managing Partner, Gemini Law LLP







LANGUAGE

- English
- · Beginner Japanese

BAR ADMISSIONS

New York

Rob Cerwinski, managing partner, is a seasoned patent litigator and IP strategist with 20+ years of experience at premier U.S. law firms helping international clients launch biopharma products into the highly-competitive U.S. market.

Mr. Cerwinski specializes in helping companies devise cost-effective strategies to navigate the complex and intertwined legal, regulatory and financial hurdles that can delay or prevent product launch. His successes in pre-litigation strategy and in the courtroom have driven the launch of 20+ biopharma products in the U.S. and Europe.

Mr. Cerwinski holds a Master of Science Degree in molecular biology and has a deep understanding of the science, business and regulation of biopharma product development, manufacture and marketing. Mr. Cerwinski co-founded the industry-leading biosimilars practice at Goodwin Procter LLP and is a recognized global authority on biosimilars. He is Senior Editor of the leading legal treatise in the field, Guide to Guide to Biosimilars Litigation and Regulation in the U.S. (published by Thomson-Reuters) and founded Goodwin's award-winning biosimilars blog, Big Molecule Watch and its companion blog, Big Molecule Watch China.

Mr. Cerwinski was named an IAM Global Leader in Intellectual Property Law in 2021 and is ranked in the Gold Tier of the IAM Patent 1000.

EXPERIENCE

- Celltrion in BPCIA litigation concerning Celltrion's biosimilar to Herceptin. Genentech v Celltrion (D. Del.)
- Celltrion in BPCIA litigation concerning Celltrion's biosimilar to Rituxan. Genentech v Celltrion (D.N.J.)
- Celltrion in Inter Partes Review proceedings in the USPTO concerning patents relating to trastuzumab and rituximab.
- Fresenius in Inter Partes Review proceedings in the USPTO concerning patents relating to filgrastim and pegfilgrastim.

- Fresenius in Post Grant Review proceedings in the USPTO concerning a patent relating to adalimumab.
- Actavis in Hatch-Waxman patent infringement litigation concerning Actavis's generic equivalent to Noxafil®, an antibiotic. A favorable settlement was obtained after trial. Merck v. Fresenius (D. Del.)
- Dr. Reddy's in Hatch-Waxman patent infringement litigation concerning DRL's generic equivalent to Suboxone®, an anti-addiction product. A judgment of non-infringement was obtained after trial. *Indivior v.* DRL (D. Del.)



EXPERIENCE - Continued

- Fresenius in Hatch-Waxman patent infringement litigation concerning Fresenius's generic equivalent to Cubicin®, an antibiotic. A favorable settlement was obtained before trial. Cubist v. Fresenius (D. Del.)
- Actavis in Hatch-Waxman patent infringement litigation concerning Actavis's generic equivalent to Staxyn®, an ED medication. A judgment of patent invalidity was obtained after an appeal to the Federal Circuit. Bayer v. Actavis (D. Del.)
- Teva in Hatch-Waxman patent infringement litigation concerning Teva's generic equivalent to Pfizer's Atelvia®, an osteoporosis medication. Warner Chilcott v. Teva Pharmaceuticals (D.N.J.)
- Teva in Hatch-Waxman patent infringement litigation concerning Teva's generic equivalent to Pfizer's Neurontin®, an epilepsy medication. A favorable settlement was obtained during jury trial. Warner-Lambert v. Teva Pharmaceuticals (D.N.J.)
- Teva in Hatch-Waxman litigation concerning Teva's generic equivalent to OxyContin®, an opioid pain medication. A judgment of patent invalidity was obtained after trial. A favorable settlement was obtained prior to trial. Purdue Pharma v. Teva Pharmaceuticals (S.D.N.Y.)
- Teva in a patent infringement action concerning Teva's generic equivalent to Biaxin®, an antibiotic. A favorable settlement was obtained while summary judgment motion was pending. Abbott Laboratories v. Teva Pharmaceuticals (N.D. III.)
- Teva in patent infringement action concerning Teva's generic equivalent to Biaxin XL®, an antibiotic. A favorable settlement was obtained after the Federal Circuit vacated a preliminary injunction. Abbott Laboratories v. Teva Pharmaceuticals (N.D. III.)
- Teva in a patent infringement action concerning Teva's generic equivalent to Augmentin®, an antibiotic. Seven patents were invalidated in two summary judgment motions and a bench trial. i(E.D. Va.)
- Teva in a patent infringement action involving Teva's equivalent to Wellbutrin®, an antidepressant. A favorable settlement was obtained. Glaxo Wellcome v. Teva Pharmaceuticals (D. Del.)
- Teva in Hatch-Waxman litigation concerning Teva's equivalent to Zithromax®, an antibiotic. A favorable settlement was obtained while summary judgment motions were pending. Teva Pharmaceuticals v. Pfizer (S.D.N.Y.)

- Breckenridge in a patent infringement action involving Breckenridge's sulfatol acne medication. A favorable settlement was obtained. Bradley Pharmaceuticals v. Breckenridge Pharmaceutical (D.N.J.)
- Teva in Hatch-Waxman litigation concerning generic equivalents to Allegra® and Allegra-D 12 Hour® allergy medications. The case settled after a preliminary injunction was denied and summary judgments of noninfringement and invalidity were obtained. Aventis and AMR v. Teva Pharmaceuticals (D.N.J.)
- Estée Lauder in a patent infringement litigation concerning cosmetic emulsions. A favorable settlement was obtained. Revlon v. Estée Lauder (S.D.N.Y.)
- Faulding in patent infringement litigation concerning Cardizem CD®, a hypertension medication. A favorable settlement was obtained. Hoechst Marion Roussel v. Faulding (D.N.J.)
- American Home Products and Takeda Chemical Industries in a patent infringement litigation concerning acellular pertussis vaccines. Summary judgment of noninfringement was obtained. Evans Medical v. American Cyanamid (S.D.N.Y.)

Professional Experiences

Prior to forming Gemini, Mr. Cerwinski was a partner at Goodwin Procter LLP in New York City. Before joining Goodwin in 2014, Mr. Cerwinski was a partner at Kenyon & Kenyon LLP. Before pursuing a career in law, he worked for a major Japanese pharmaceutical company in Tokyo assisting with intellectual property matters concerning biotechnology products.

Professional Activities

Mr. Cerwinski is a member of the New York City Bar Association, the New York State Bar Association, the New York Intellectual Property Law Association, the American Intellectual Property Law Association and the American Bar Association.



PUBLICATIONS

Mr. Cerwinski has been interviewed extensively by Dow Jones, Forbes, the <u>Center for Biosimilars</u>, Bloomberg, SCRIPS, The Pink Sheet, and other publications. Thought leadership highlights include:

- Speaker, "<u>Top of Mind Issues for Global Life Sciences</u> <u>Companies in the Era of COVID-19</u>," Goodwin Webinar, April 2020
- Co-author, "INSIGHT: Why the Illegality Doctrine Shouldn't Apply to Cannabis Patents", Bloomberg Law, January 2020
- Speaker, "Goodwin Lawyers Give a Look at Biosimilar Litigation," Not So Different: A Podcast from the Center for Biosimilars, January 2020
- Senior Editor, <u>Guide to Biosimilars Litigation and</u>
 <u>Regulation in the U.S.</u>, published by Thomson Reuters,
 November 2019
- Co-author, "Protect At All Costs: How the Maker of the World's Bestselling Drug Keeps Prices Sky-High", Fortune, July 2019
- "The US's First All Biosimilar Patent Suit Shows New Pharma IP Landscape is Emerging," IAM Global, February 2019 [Subscription Required]
- Speaker, "<u>Current Infliximab Litig</u>ation," The Center for Biosimilars, September 2017
- Speaker, "<u>Recent Trends in PTAB Decisions on Biologics</u>, <u>Biosimilars</u>," The Center for Biosimilars, September 2017

- Speaker, "The Potential for an Executive Order on Drug Pricing," The Center for Biosimilars, September 2017
- Speaker, "Shall we Dance: Mastering the "Steps" of the BPCIA While Avoiding Common Pitfalls," American Conference Institute 8th Annual Biosimilars Summit, June 2017
- Speaker, "Biosimilar Investment Landscape in 2017," Goodwin Seminar, January 2017
- Speaker, "<u>Biosimilars: Annual Market Review</u>," Goodwin Seminar, January 2016
- Speaker, "Analysis of Amgen v. Sandoz Federal Circuit Decision," Goodwin Webinar, August 2015
- Speaker, "<u>Declining to Dance? Lessons Learned from Early BPCIA Cases on Whether the Pathway is Mandatory</u>" American Conference Institute 6th Annual Biosimilars Summit, June 2015
- Co-author, "Order in Amgen v. Sandoz Provides First Judicial Interpretations of the BPCIA Patent Dispute Resolution Provisions," Goodwin Alert, March 2015
- Speaker, "<u>Understanding Biosimilars: Intellectual Property</u> <u>Challenges</u>," Goodwin Seminar, January 2015

CREDENTIALS

Education

- · J.D., Boston University School of Law, 1997 (cum laude)
- M.S., Cellular and Molecular Biology, Roswell Park Cancer Institute, 1993
- B.S., Biology, Rensselaer Polytechnic Institute, 1991

Bar admissions and qualifications

- New York City Bar Association
- New York State Bar Association
- New York Intellectual Property Law Association
- American Intellectual Property Law Association
- · American Bar Association

Admissions

 Mr. Cerwinski is admitted to practice in New York, as well as before the U.S. District Court for the Southern District of New York and the U.S. Court of Appeals for the Federal Circuit.

Recognition

- Gold Tier of the IAM Patent 1000 The World's Leading Patent Professionals as one of the world's leading patent litigators (2017, 2019-2022) and as an IAM Global Leader in 2021, 2022 and 2023.
- Legal 500 USA IP Litigation (2018)