



David H. Silverstein

Partner

New York

TEL 212.261.5651

dsilverstein@axinn.com

PRACTICE AREAS

Biotechnology
FDA
Intellectual Property
Patents
Pharmaceuticals
Trade Secret, Trademark & Copyright

EDUCATION

JD – Duke University (2003)
MS, Chemistry – Cornell University (1999)
BS, Chemistry, magna cum laude – University of Georgia (1997)

ADMISSIONS

New York
New Jersey
US Court of Appeals for the Federal Circuit
US District Court Northern District of New York
US District Court Southern District of New York
US District Court Western District of New York

PROFILE

David Silverstein is a registered patent attorney with twenty years of experience handling legal and regulatory matters, on the generic and the branded side, relating to pharmaceutical and biotech products. David has served as lead counsel in matters before the U.S. district courts, Patent Trial and Appeal Board, and U.S. Court of Appeals for the Federal Circuit. In addition, David's practice includes performing due diligence, license negotiation, and counseling in connection with complex commercial transactions involving pharmaceutical and biotech products. David is frequently involved in FDA strategy and counseling, including filing or responding to citizen petitions, and coordinating FDA strategy with patent litigation strategy.

David previously practiced in-house at Par Pharmaceutical and, prior to that, at major New York firms. While in-house, David oversaw and managed all aspects of patent, antitrust, unfair competition and trade secret litigation. David also served as Par's in-house regulatory counsel, advising on regulatory strategies and frequently representing Par before FDA's Office of Chief Counsel and other regulators.

Together with his graduate training in protein crystallography and structure-based drug design, David combines his courtroom and industry experience to develop strategies that enable his clients to achieve their technical, legal, and commercial objectives simultaneously.

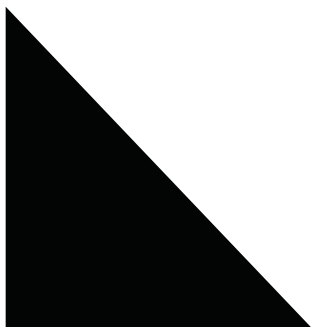
EXPERIENCE

Representative matters:

US District Court District of New Jersey

US Patent and Trademark Office

- *AstraZeneca Pharm., LP v. Sylvia Burwell*, 16-cv-01336-RDM (D.D.C.). Represented intervenors Apotex and Par to successfully oppose AstraZeneca's motion for a temporary restraining order allowing generic versions of blockbuster Crestor® to immediately enter the market.
- *Insys Therapeutics, Inc. v. Par Pharm., Inc.*, 17-cv-01078-LPS (D. Del.). Represented generic drug manufacturer, Par, in Hatch-Waxman litigation involving multiple patents directed to FDA-approved cannabinoid (Syndros®). Secured dismissal of case based on non-infringement position resulting in Par having the ability to launch upon approval of its ANDA product.
- *Noden Pharma DAC v. Anchen Pharm., Inc.*, 17-cv-00728-MPT (D. Del.). Represented generic drug manufacturer, Anchen, in Hatch-Waxman litigation involving multiple patents directed to aliskiren (Tekturna®). Litigation defenses helped Anchen secure, during early discovery, a favorable license to manufacture and commercialize its ANDA product.
- *Par Pharm., Inc. v. Horizon Therapeutics, LLC*, IPR2015-01127 (P.T. A.B.). Represented Petitioner in review of U.S. Patent No. 8,404,215 directed to nitrogen scavenging drug (Ravicti®) resulting in invalidity of all challenged claims.
- *Horizon Therapeutics v. Par Pharm., Inc.*, 14-cv-384 (E.D. Tex.); *Horizon Therapeutics v. Par Pharm., Inc.*, 18-cv-01224-RGA (D. Del.); *Horizon Therapeutics v. Par Pharm., Inc.*, 17-cv-05901-KM (D.N.J.); *Horizon Therapeutics v. Par Pharm., Inc.*, 16-cv-03910 (D.N.J.); *Par Pharm., Inc. v. Horizon Therapeutics, LLC*, IPR2018-01550 (P.T.A.B.); *Par Pharm., Inc. v. Horizon Therapeutics, LLC*, IPR2017-01768 (P.T.A.B.); *Par Pharm., Inc. v. Horizon Therapeutics, LLC*, IPR2017-01767 (P.T.A.B.); and *Par Pharm., Inc. v. Horizon Therapeutics, LLC*, IPR2017-01769 (P.T. A.B.). Represented generic drug manufacturer, Par, as the defendant in multiple, simultaneous Hatch-Waxman litigations and as the petitioner in multiple *inter partes* reviews involving patents directed to nitrogen scavenging drug (Ravicti®). Secured favorable settlement for Par and dismissal of each litigation and IPR.
- *Omeros Corp. v. Par Sterile Products, LLC*, 15-cv-773-RGA (D. Del.). Represented generic drug manufacturer, Par, in Hatch-Waxman litigation involving multiple patents directed to ketorolac tromethamine/phenylephrine HCl (Omidria®). Secured favorable settlement for Par after three-day bench trial.
- *Alcon Pharms. Ltd. et al. v. Par Pharm. Inc.*, 15-cv-7240 (D.N.J.). Represented generic drug manufacturer, Par, in Hatch-Waxman



litigation involving multiple patents directed to ciprofloxacin/dexamethasone (Ciprodex®). Secured dismissal of case based on non-infringement position resulting in favorable settlement for Par.

HONORS

- World's Leading Patent Professionals (2020-2022), *IAM Patent 1000*

