



CHARLES M. LIZZA

PARTNER

Newark
One Riverfront Plaza
1037 Raymond Blvd., Suite 1520
Newark, NJ 07102-5426

New York
1270 Avenue of the Americas
Suite 2005
New York, NY 10020

Phone number: (973) 286-6715
Fax number: (973) 286-6815
clizza@saul.com

SERVICES

Life Sciences and IP Litigation
Appellate
Class and Collective Actions
Litigation

INDUSTRIES

Pharmaceutical
Life Sciences

Charlie Lizza brings more than 35 years of litigation experience to his representation of pharmaceutical companies in high stakes patent litigation. Mr. Lizza concentrates his practice in Hatch-Waxman ANDA litigation and protecting the intellectual property of branded pharmaceutical and medical device companies. He currently serves as New Jersey litigation counsel in more than three dozen patent cases for approximately 20 major pharmaceutical companies. Under Mr. Lizza's leadership, Saul Ewing Arnstein & Lehr's patent litigation team was ranked fourth, nationally, for the number of cases involving patentee representation between 2015 and the first quarter of 2017, and fourth, nationally, for the number of cases involving ANDA plaintiff representation between 2009 and the first quarter of 2017.

Mr. Lizza is Chair of Saul Ewing Arnstein & Lehr's Intellectual Property Litigation Practice, Vice Chair of the Litigation Department and Co-Chair of the firm's Life Sciences Practice. Over the years, Mr. Lizza has represented a major tobacco manufacturer in all of its product liability cases in New Jersey, including class action litigation, and has handled a wide range of complex, bet-the-company commercial litigation cases in the U.S. Federal Courts from California to Puerto Rico. Mr. Lizza has also served as a court-appointed mediator in the U.S. District Court for the Southern District of New York and has mediated approximately 10 cases in that court.

Mr. Lizza serves as a member of the Local Patent Rules Committee for the U.S. District Court for the District of New Jersey, Chairman of the New Jersey Supreme Court's Committee on the Unauthorized Practice of Law and as a member of the Supreme Court's Professional Responsibility Rules Committee. He also serves as a Trustee of the Association of the Federal Bar of New Jersey and Co-Chair of its Judicial Conference. Mr. Lizza has taught at seminars for Federal Judges in the District of New Jersey and reviewed and edited materials presented to newly appointed Judges and Magistrate Judges.

In public service, Mr. Lizza currently serves on the Board of Trustees of Saint Peter's

University. He has served as Chairman of the Board of Directors of Covenant House New York and as Chairman of the Board of Trustees of Saint Peter's Prep in Jersey City, NJ. In 2014, he was inducted into the Eagle Scout Hall of Fame of the Patriots' Path Council where he currently serves as a member of its Executive Board.

Prior to joining Saul Ewing in 2007, Mr. Lizza was a partner for more than 15 years with the New York-based firm LeBoeuf, Lamb, Greene & MacRae LLP. Prior to that, he was an associate at Shearman & Sterling and a Law Clerk to Chief Judge David N. Edelstein of the U.S. District Court for the Southern District of New York.

Mr. Lizza is admitted to practice in the U.S. Supreme Court, the Court of Appeals for the Federal, Third and Ninth Circuits, the New Jersey Federal and State Courts and the New York Federal and State Courts.

CHAMBERS USA TESTIMONIALS

Since 2011, Mr. Lizza has been named one of "America's Leading Lawyers in Intellectual Property Law" by *Chambers USA*. In 2016, he was named to *The Best Lawyers in America* list, Commercial Litigation, and since 2014, he has been named an "IP Star" by *Managing Intellectual Property* magazine.

- "Charles Lizza is an experienced litigator, noted for his expertise in patent and product liability disputes, particularly in the pharmaceutical and medical device arenas. 'The experience and results have been outstanding. He's very knowledgeable regarding the judges and court procedures,' reports one impressed client, who also singles out Lizza's 'excellent writing skills and great judgment.'" (*Chambers USA*, 2017)
- "Charles Lizza mainly represents clients in complex pharmaceutical and medical device patent litigation. Clients appreciate his 'very sound and useful strategic advice' and 'deep knowledge and great experience,' while peers say they '*have been very impressed with him - he is a talented lawyer with excellent judgment.*'" (*Chambers USA*, 2016)
- "Charles Lizza is a widely respected IP practitioner with a great deal of experience handling complex litigation. Market commentators say: '*He has extraordinary judgment, he's quick on his feet and has great confidence.*'" (*Chambers USA*, 2015)
- "Charles Lizza is praised by sources for his '*good judgment*' and '*sage advice.*' His clients include Celgene, Sunovion Pharmaceuticals and Prometheus Laboratories." (*Chambers USA*, 2014)
- "Charles Lizza is commended by sources for his '*attention to detail*' and ability to '*understand how judges think.*' He has a strong following among pharmaceutical companies, his clients, including the likes of Procter & Gamble, Merck and GlaxoSmithKline." (*Chambers USA*, 2013)
- "Charles Lizza is an expert in pharmaceutical-related patent litigation. He is lauded as a '*very good sounding board for decision making, provides valuable guidance on strategy in the federal court, and is very easy to work with.*'" (*Chambers USA*, 2012)
- "Charlie exercises both '*fantastic judgment and a superb understanding of each case.*' ... Recent highlights include assisting both Celgene and King Pharmaceuticals in patent-related disputes." (*Chambers USA*, 2011)

EXPERIENCE

Helsinn and Roche Palo Alto (Aloxi®)

Representation of Helsinn Healthcare S.A. and Roche Palo Alto LLC in two separate trial victories against Teva and Dr. Reddy's involving the Aloxi® brand drug product (market value of judgments \$3.2 billion). Aloxi® is an intravenous therapy for the prevention of chemotherapy-induced nausea and vomiting with annual sales totaling more than \$600 million. In the case against Teva, following a 12-day bench trial, U.S. District Judge Mary L. Cooper issued a 167-page opinion and judgment in favor of Helsinn on infringement and validity, upholding Helsinn's patents over multiple claims of obviousness and the on-sale bar provisions of the America Invents Act, which was an issue of first impression due to changes in the AIA. The case is now pending appeal in the Federal Circuit. In the "paper NDA" case against Dr. Reddy's, following a 6-day bench trial, Judge Cooper issued an opinion and judgment in favor of Helsinn on infringement and validity. (News Article 1 , News Article 2 , News Article 3)

Merck (Emend® IV)

Representation of Merck Sharp & Dohme Corp. in a trial victory against Sandoz Inc. in Hatch-Waxman patent litigation involving the Emend® IV brand drug product (market value of judgment in excess of \$1.5 billion). Emend® IV is an intravenous therapy for the prevention of chemotherapy-induced nausea and vomiting with annual sales totaling more than \$400 million. Following a bench trial that took place over the course of two weeks - and with just two days to spare before the 30-month stay expired - U.S. District Judge Peter G. Sheridan upheld the validity of Merck's compound patent, finding that its claims were valid and infringed. (News Article)

Sumitomo Dainippon Pharma and Sunovion (Latuda®)

Representation of Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. against Teva, Emcure, and InvaGen in ANDA patent litigation involving the Latuda® brand drug product. Latuda® is an anti-psychotic drug used to treat schizophrenia and depression in adults with bipolar disorder with annual sales totaling approximately \$1 billion. The case concluded after a favorable *Markman* ruling forced the defendants to concede infringement and validity of Sunovion's patent. The case is now on appeal to the Federal Circuit. (News Article) (News Article 2)

Celgene (Revlimid®)

Representation of Celgene Corporation against Natco, Arrow, Watson, and Dr. Reddy's involving Celgene's blockbuster Revlimid® brand drug product. Revlimid® is a more potent derivative of its predecessor Thalomid® and is used to treat multiple myeloma and certain blood disorders known as myelodysplastic syndromes. Revlimid® has annual sales totaling more than \$6 billion. This representation is ongoing with respect to the case against Dr. Reddy's. (News Article)

Sunovion Pharmaceuticals (Lunesta®)

Representation of Sunovion Pharmaceuticals (formerly Sepracor Inc.) against 10 generic pharmaceutical manufacturers (one of the largest Hatch-Waxman cases filed) in ANDA patent litigation concerning the blockbuster Lunesta® brand drug product. Lunesta® is a highly successful sleep aid with worldwide recognition of its butterfly/moth ads and annual sales totaling approximately \$1 billion. The case concluded at the Federal Circuit with a precedent-setting judgment of infringement

and dismissal of all inequitable-conduct defenses. U.S. District Judge Dennis M. Cavanaugh issued one of the first post-Exergen decisions dismissing a generic drug manufacturer's inequitable-conduct defense. (News Article)

Boehringer (Pradaxa®)

Representation of Boehringer Ingelheim against Teva, Alkem, Mylan, and Breckenridge in ANDA patent litigation involving the Pradaxa® brand drug product. Pradaxa® is an anticoagulant that prevents stroke and blood clots in patients who have atrial fibrillation. Annual sales of Pradaxa® total approximately \$800 million. Boehringer prevailed on a motion to dismiss for lack of personal jurisdiction brought by Mylan in the wake of the Supreme Court's Daimler decision, which was an emerging issue in Hatch-Waxman litigation across the country and an issue of first impression in the District of New Jersey. This representation is ongoing. (News Article)

University of Illinois (Prezista®)

Representation of the Board of Trustees of the University of Illinois against six generic pharmaceutical manufacturers in patent litigation involving the Prezista® brand drug product. Prezista® is an HIV treatment drug, and the University's patent covered a method of using Prezista® in combination with another drug to overcome patient resistance to HIV treatment. Prezista® has annual sales totaling approximately \$230 million. The case concluded with a favorable settlement for the University. (News Article)

Supernus (Oxtellar XR®)

Representation of Supernus Pharmaceuticals Inc. in a trial victory against Actavis and Watson in patent litigation involving the Oxtellar XR® brand drug product. Oxtellar XR® is a novel, once-daily antiepileptic drug indicated for adjunctive therapy for the treatment of seizures in adults and in children 6 to 17 years of age. Annual sales of Oxtellar XR® total approximately \$10 million. Following a seven-day bench trial, U.S. District Judge Renee M. Bumb issued a judgment in favor of Supernus on infringement and validity. A second case against TWI Pharmaceuticals was tried in 2017 and is pending a decision by Judge Bumb. (News Article)

Jazz (Xyrem®)

Representation of Jazz Pharmaceuticals against Roxane, Amneal, Par, Ranbaxy, Watson, Sun, Wockhardt, and Lupin in patent litigation involving the Xyrem® brand drug product. Xyrem® is a drug used to treat cataplexy and daytime sleepiness in narcolepsy patients with annual sales totaling approximately \$130 million. This representation is ongoing and a trial is anticipated in 2018. (News Article)

Johnson & Johnson-DePuy Orthopaedics (Pinnacle® and Duraloc® Acetabular Cup Systems)

Representation of DePuy (a division of New Jersey-based Johnson & Johnson) in patent litigation against Stryker involving DePuy's Pinnacle® and Duraloc® Acetabular Cup Systems, which have annual sales totaling approximately \$200 million. Following a favorable *Markman* ruling for DePuy, Stryker conceded its infringement suit against DePuy and moved for a judgment pursuant to Fed. R. Civ. P. 54(b). DePuy successfully defeated that motion, which eventually led to Stryker withdrawing all of its infringement claims against DePuy. (News Article)

Gilead (Letairis®)

Representation of Gilead Sciences, Inc. and Royalty Pharma Collection Trust against Watson, Actavis, and Sigmapharm in patent litigation involving the Letairis® brand drug product. Letairis® is an oral drug used for the treatment of pulmonary arterial hypertension with annual sales totaling approximately \$595 million. The case was settled in 2017 on terms highly favorable to Gilead.

Celgene (Abraxane®)

Representation of Celgene Corporation and Abraxis Bioscience, LLC against Actavis and Cipla in ANDA litigation involving Celgene's Abraxane® brand drug product. Abraxane® is an injectable drug used to treat breast, lung, and pancreatic cancers, among others, with annual sales totaling approximately \$1 billion. This representation is ongoing.

BioMarin (Kuvan®)

Representation of BioMarin Pharmaceutical Inc. and Merck & Cie against Dr. Reddy's and Par in patent litigation involving the Kuvan® brand drug product. Kuvan® is a drug used to reduce blood Phe levels in patients with Phenylketonuria with annual sales totaling approximately \$60 million. The case was settled in 2017 on terms highly favorable to BioMarin.

Vivus (Qsymia®)

Representation of Vivus against Actavis and Dr. Reddy's in patent litigation involving the Qsymia® brand drug product. Qsymia® is a weight loss drug that uses a combination of phentermine and topiramate extended-release with annual sales totaling approximately \$20 million. This representation is ongoing. (News Article)

HONORS

Named a "Local Litigation Star" in New Jersey by *Benchmark Litigation*, 2020

Named one of "America's Leading Lawyers in Intellectual Property Law" by *Chambers USA*, 2011 to present

Named to the NJBiz Law Power Top 50 list, 2019

Named to *The Best Lawyers in America* list, Commercial Litigation, 2016 to present

Named an "IP Star" by *Managing Intellectual Property* magazine, 2014 to present

Eagle Scout Hall of Fame, 2014

Honored as "Legend" of Saint Peter's Prep, 2007

JUDICIAL APPOINTMENTS

Chairman, Supreme Court of New Jersey Committee on the Unauthorized Practice of Law, Member, 2002 to present

Supreme Court of New Jersey Professional Responsibility Rules Committee, 2008 to present

Supreme Court of New Jersey Committee on Model Civil Jury Charges, 2004-2006

U.S. District Court of New Jersey Local Patent Rules Committee, 2011 to present

Federal Mediator, U.S. District Court for the Southern District of New York, 1992 to present

MEMBERSHIPS AND AFFILIATIONS

Trustee, Association of the Federal Bar of New Jersey, 2014 to present

Trustee, Saint Peter's University, 2017 to present

Director, Covenant House New York, 1995 to 2016, Chairman, 1998-2003

Trustee, Saint Peter's Prep, 1994-2004, Chairman, 1999-2004, Governance Committee, 2010 to present

Trustee, Briant Park Olmstead Conservancy, 2009 to 2015

Executive Board, Patriots' Path Council, B.S.A., 2010 to present

Adjunct Professor of Law, Rutgers University School of Law, 1985-1986

EDUCATION

J.D., Georgetown University Law Center, 1980, *magna cum laude*

- Editor, *The Georgetown Law Journal*
- Fellowship-Instructor, Legal Writing and Oral Advocacy
- American Jurisprudence Award (Corporations)

B.A., St. Peter's College, 1977, *summa cum laude*

- Rhodes Scholar Nominee
- Graduate Prize-Journalism

BAR ADMISSION

New Jersey

New York

FIRM INVOLVEMENT

Chair, Intellectual Property Litigation

Vice Chair, Litigation Department

Chair, Life Sciences & IP Litigation Practice

CLERKSHIPS

Chief Judge David N. Edelstein, U.S. District Court for the Southern District of New York