



Partner, Litigation

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Education

Yale Law School, J.D., 2003

- Thomas I. Emerson Prize (Best Paper on a Subject Related to Legislation)
- *Yale Law Journal*, Book Reviews Editor

Harvard University, A.B., Social Studies, 2000

- *magna cum laude*
- Phi Beta Kappa

Admissions & Qualifications

2005, District of Columbia

2004, Connecticut

Clerk & Government Experience

Law Clerk to the Honorable Diarmuid F. O'Scannlain, U.S. Court of Appeals for the Ninth Circuit

Michael D. Shumsky

Mike Shumsky is a partner in Kirkland & Ellis LLP's Washington, D.C. office. He represents pharmaceutical companies in high-stakes litigation, and offers strategic counseling regarding lifecycle management initiatives, regulatory affairs, and legislative concerns. He frequently appears before the FDA, and has argued both FDA-related and non-FDA cases throughout the country. Mike also maintains an active appellate practice and routinely appears in cases before the U.S. Supreme Court.

In 2013, *Law360* and *Super Lawyers* each named Mike a "Rising Star" — the former for his life sciences practice and the latter for his appellate work. Mike's writing and oral advocacy have garnered praise from courts and commentators. *See, e.g., Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1310 (D.C. Cir. 2010); ANDA Exclusivity Protected From Patent Delisting Under Appeals Court Ruling, *The Pink Sheet*, Mar. 8, 2010.

Mike also serves as a Lecturer in Law at Columbia Law School, where he co-teaches a seminar on Supreme Court advocacy.

Representative FDA-Related Litigation

- *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (U.S. 2013): secured U.S. Supreme Court decision holding that the Hatch-Waxman Act preempts state-law tort claims targeting the design/composition of generic drug products.
- *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (U.S. 2011): secured U.S. Supreme Court decision holding that the Hatch-Waxman Act preempts state-law tort claims challenging generic drug product labeling.
- *PLIVA, Inc. v. Drager*, 741 F.3d 470 (4th Cir. 2014): secured Fourth Circuit decision holding that the Hatch-Waxman Act preempts state-law negligence, strict liability, warranty-based, and fraud claims targeting generic drugs.
- *Mylan Pharms. Inc. v. Sebelius*, 856 F. Supp. 2d 196 (D.D.C. 2012): persuaded FDA to award client 180-day exclusivity for generic modafinil products, and successfully defended that award in subsequent litigation.
- *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010): obtained pre-enforcement review and secured injunctive relief precluding the FDA from denying client 180-day exclusivity for sales of generic losartan potassium.
- *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006) and *Sandoz, Inc. v. FDA*, 2006 WL 2591087 (D.C. Cir. 2006): secured reversal of FDA decision denying client 180-day exclusivity for sales of generic simvastatin.
- *Teva Pharms. USA, Inc. v. FDA*, 441 F.3d 1 (D.C. Cir. 2006) and *Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006): secured reversal and remand of FDA decision denying client 180-day exclusivity for sales of generic pravastatin, and successfully defended FDA's post-remand award of exclusivity to client.

Michael D. Shumsky

Courts

U.S. Supreme Court, 2008

U.S. Court of Appeals for the Sixth Circuit, 2013

U.S. Court of Appeals for the Fourth Circuit, 2009

U.S. Court of Appeals for the D.C. Circuit, 2006

U.S. District Court for the District of Columbia, 2006

U.S. Court of Appeals for the Federal Circuit, 2005

U.S. Court of Appeals for the Seventh Circuit, 2005

U.S. Court of Appeals for the Ninth Circuit, 2004

U.S. District Court for the District of Columbia, 2006

Other Representative Litigation

- *Buckeye Check Cashing, Inc. v. Cardegna*, 546 U.S. 440 (2006): secured U.S. Supreme Court reversal of Florida Supreme Court decision refusing to enforce an arbitration clause.
- *Dow AgroSciences LLC v. National Marine Fisheries Serv.*, 637 F.3d 259 (4th Cir. 2011): secured reversal and remand of district court decision declining to exercise jurisdiction over challenge to a federal agency's Biological Opinion.
- *Chartschlaa v. Nationwide Mut. Ins. Co.*, 538 F.3d 116 (2d Cir. 2008): secured reversal of judgment holding that independent insurance agent was a franchisee under state law.
- *In re Air Crash Near Peixoto De Azevado, Brazil, on September 29, 2006*, No. 07-md-1844 (E.D.N.Y. July 2, 2008), *aff'd* 354 Fed. Appx. 585 (2d Cir. Dec. 2, 2009): secured dismissal of mass litigation arising from one of the largest air disasters in Brazilian history.
- *United States v. W.R. Grace & Co.*, 526 F.3d 499 (9th Cir. 2007) (en banc): successfully defended district court decision that barred the government from calling undisclosed witnesses and using undisclosed documents in complex criminal litigation arising under the Clean Air Act.

Publications

- "Severability, Inseverability, and the Rule of Law," 41 HARV. J. ON LEGIS. 227 (2004).

Seminars, Lectures, and Appearances

- "Prescription for Litigation: Will An FDA Rule Change Drive Up Drug Costs?," U.S. Chamber Institute for Legal Reform (September 2013).
- "Making Sense of Federal Preemption," National Foundation For Judicial Excellence, *Ninth Annual Judicial Symposium: Emerging Issues In State and Federal Constitutional Law* (July 2013).
- "Litigation Strategies For Securing 180-Day Exclusivity," American Conference Institute, *Paragraph IV Disputes, Second West Coast Edition* (December 2011).
- "Developments in Products Liability: Pharmaceutical Litigation After *Mensing*," Law and Economics Center, George Mason University School of Law, *Sixth Annual Judicial Symposium on Civil Justice Issues* (November 2011).
- "Emerging Issues Regarding 180-Day Exclusivity," Food and Drug Law Institute, *Brands, Generics and Hatch-Waxman: New Challenges, Unabated Controversy* (June 2011).