



## Don J. Mizerk

**PARTNER**

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### OVERVIEW

An experienced litigator of patent infringement and other intellectual property and commercial cases, Don helps clients navigate the rules of a complex regulatory environment in order to reach their business goals.

Don has extensive experience at the trial and appellate level litigating Hatch-Waxman statutory patent infringement and other actions involving prescription pharmaceutical drugs. These include Wellbutrin XL (bupropion), Intuniv (guanfacine), Megace ES (megestrol acetate), Dexilant (dexlansoprazole), Oxtellar XR (oxcarbazepine), Lidoderm (lidocaine), Ambien CR (zolpidem), Letairis (ambrisentan), Intermezzo (zolpidem), Livalo (pitavastatin), Strattera (atomoxetine), Androgel (testosterone), Axiron (testosterone), Restasis (cyclosporine), Adderall XR (mixed amphetamine salts), Clarinex (desloratadine), Amrix (cyclobenzaprine), Enablex (darifenacin), Cymbalta (duloxetine), Eliquis (apixaban), Luvox CR (fluvoxamine), Ryzolt (tramadol), Keppra XR (levetiracetam), Mirapex ER (pramipexole), Requip XL (ropinirole), and Wellbutrin SR/Zyban (bupropion). Among Don's considerable patent litigation forums are injunction hearings, Markman proceedings, trials, and appeals. He has represented clients in patent cases involving a wide range of technologies, including pharmaceuticals, aluminum alloys, silicon on insulator manufacturing, computer software and ergonomic computer accessories.

### Industry

Life Sciences

### Services

Antitrust & Competition

Antitrust Litigation

Appellate

Chemistry & Biotech

Clinical Research & Trials

Generic Drug / ANDA Litigation

Intellectual Property

Intellectual Property Litigation

Litigation & Alternative Dispute Resolution

Pharmaceutical Manufacturers

Post-Issuance Proceedings

Product Liability

Section 337

Before joining the firm, Don was Chief Assistant State's Attorney in the Cook County State's Attorney's Office.

## Experience

- Aided client FlatWing Pharmaceuticals in demonstrating that 39 claims in 4 patents filed by competitor were unpatentable.
- Represented TWi Pharmaceuticals, Inc. in a patent infringement case alleging its generic version of Par Pharmaceutical's Megace ES infringed Alkermes' (formerly Élan) patent for nanocrystal megestrol acetate. After a seven day bench trial, the court entered judgment for TWi in February 2014 finding Alkermes' patent invalid as obvious. *Par, Alkermes v. TWi*, 2014 WL 694976 (D. Md.)
- Represented Amerigen Pharmaceuticals, Ltd. in a patent infringement case alleging its generic version of Shire LLC's Adderall XR infringed several patents. The case was favorably settled after three days of trial. *Shire v. Amerigen* (D.N.J.)
- Represented TWi Pharmaceuticals Inc. in a patent infringement case alleging its generic version of Cephalon's Amrix infringed several patents. After conducting a seven day bench trial, the court issued an opinion in May 2011 finding that TWi's product did not infringe any claims of the '793 and '372 patents and entered judgment in its favor. Following the decision, TWi filed a motion to deem the case exceptional and for fees. The court granted TWi's motion and awarded TWi attorneys' fees. *In re Cyclobenzaprine Hydrochloride Extended Release Patent Litigation* (D.Del. 2012)
- Represented Virtus Pharmaceuticals, Inc. in litigation at the International Trade Commission (ITC) alleging Virtus' potassium chloride products unfairly competed against similar products marketed by Par Pharmaceuticals. The case settled favorably after Virtus filed suit against FDA challenging the agency's enforcement policies applicable to potassium chloride products. In Matter of: *Certain Potassium Chloride Products (ITC); Virtus v. FDA* (M.D. Fla)

## Experience

- Represented Teh Seng Pharmaceutical Mfg. Co. Ltd. and TWi Pharmaceuticals Inc. in a patent infringement case alleging their generic version of Endo's Lidoderm transdermal patch infringed several patents. The case was favorably settled on the eve of trial. *Endo, Teikoku v. TWi, Teh Seng* (D. Del. 2014)
- Represented TWi Pharmaceuticals, Inc. in a patent infringement case alleging its generic version of Purdue's Intermezzo infringed several patents. After trial appeal, the patents were found invalid as obvious. *Purdue Pharmaceuticals v. TWi* (D. N.J. 2015)
- Represented TWi Pharmaceuticals Inc. (and its predecessor Anchen Pharmaceuticals Inc.) in a patent infringement case alleging its generic version of Shire's Intuniv infringed several patents. The case was favorably settled after the filing of a motion for summary judgment. *Shire v. Anchen, TWi* (D.Del. 2012)
- Represented MedPharmex in a patent infringement case regarding its generic version of Merck's animal drug Mometamax. After initial proceedings, the Court entered a judgment of noninfringement in favor of our client.
- Represented Anchen Pharmaceuticals Inc. (now Par Pharmaceutical) in a patent infringement case involving its generic version of Jazz's Luvox CR. The case was favorably settled after filing a motion for summary judgment. *Elan, Jazz v. Anchen* (C.D. Cal. and D. Del. 2010)
- Represented Anchen Pharmaceuticals (now Par Pharmaceutical) in a patent infringement case alleging its generic version of Biovail's Wellbutrin XL infringed several patents. The court granted Anchen's motion for summary judgment finding that Anchen's product did not infringe any Biovail patent. Biovail also made two attempts to seek an injunction against the Food and Drug Administration (FDA) to prevent approval of Anchen's Abbreviated New Drug Application (ANDA) product, both of which were denied. Anchen launched its generic product in December 2006. *Biovail Labs v. Anchen* (C.D. Cal. 2006)
- Successfully defended pharmaceutical manufacturer in U.S. International Trade Commission (ITC) against competitor's claim that generic drug was marketed unfairly.

## Experience

- Aided Sigmapharm Laboratories in arguing for claim construction. Court adopted proposed construction verbatim.
- Secured victory for TruPharma, LLC in federal court litigation brought by a competitor alleging false advertising and unjust enrichment, among other counts, in connection with the manufacture and sale of a medical cream. Complaint dismissed with prejudice.

## Recognition

- Crain's *Chicago Business*, Notable Litigators and Trial Attorneys, 2023
- *The Best Lawyers in America*®, Litigation - Intellectual Property, 2023
- *Benchmark Litigation*, Local Litigation Star, 2022-2025
- *Managing Intellectual Property* IP STARS, Patent star, 2022-2024
- Martindale-Hubbell AV Preeminent, 2001-present
- *Leading Lawyers*, Intellectual Property Law, 2012-present

## Education

- J.D., Vanderbilt University Law School
  - Order of the Coif
  - *Vanderbilt Law Review*, senior articles editor, 1987-1988
- B.A., Illinois Wesleyan University
  - Political Science
  - *magna cum laude*, highest research honors

## Admissions

- Illinois
- U.S. District Court, Central District of California
- California
- U.S. District Court, Northern District of California
- U.S. District Court, Northern District of Illinois
- U.S. District Court, Northern District of Illinois (Trial Bar)
- U.S. Court of Appeals, Federal Circuit
- U.S. Court of Appeals, Sixth Circuit
- U.S. Court of Appeals, Seventh Circuit
- U.S. Supreme Court

## Clerkship

The Hon. Harry W. Wellford, U.S. Court of Appeals, Sixth Circuit, 1988-1989

## Community Leadership

- The Night Ministry, Board of Directors, 2016-present
- Illinois Wesleyan University, Chicago Leadership Council, 1991-1996, 2005-present
- Catherine Cook School, Annual Fund Campaign Board, 2014-present
- Near North Montessori School, Board of Directors, 2012-2013
- Illinois Motor Vehicle Theft Prevention Council, Grant Review Committee, 1993-1996



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