



Michael K. Nutter

Partner

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PRACTICES

Healthcare

Intellectual Property

Intellectual Property Litigation

INDUSTRIES

Life Sciences

Mike is a first-chair trial lawyer and registered patent attorney. He leads McGuireWoods' pharmaceutical and life sciences patent litigation group, focusing primarily on small molecule pharmaceutical patent litigation within the framework of the Act, as well as biosimilar patent litigation within the Biologics Price Competition and Innovation Act (BPCIA). The depth of his experience in the space has been recognized by IAM Patent 1000, which notes that he is a "star of the pharmaceutical circuit."

Mike's clients are primarily generic drug companies facing patent infringement cases involving Abbreviated New Drug Applications (ANDAs) that include a Paragraph IV certification to one or more Orange Book listed patents. He works closely with clients in resolving ANDA-related issues before the FDA, including labeling issues, issues with API, patent listing disputes, and issues pertaining to new drug and marketing exclusivities. As a complement to his ANDA litigation practice, Mike provides clients with strategic counseling in developing long-term legal and business strategies for developing and launching generic pharmaceutical products.

Mike holds a Bachelor of Science degree in Chemical Engineering from the University of Illinois.

EXPERIENCE

- Mike represents leading pharmaceutical companies in patent infringement actions, including:
- A pending action in the District of New Jersey regarding client's ANDA to make a generic version of the oral solution Xywav® (calcium, magnesium, potassium, and sodium oxybates).
- Pending actions in the District of Delaware regarding client's ANDA to make a generic version of the type-2 diabetes drug Jardiance® (empagliflozin).
- Pending action in the District of New Jersey regarding client's ANDA to make a generic version of the vaginal insert Imvexxy® (estradiol). No trial date set.
- An action regarding client's ANDA to make a generic version of the Parkinson's disease drug Nuplazid® (pimevanserin). No trial date set.
- An action in the District of Delaware regarding client's ANDA to make a generic version of the overactive bladder drug Myrbetriq® (mirabegron). No trial date set.
- An action in the District of Delaware regarding client's 505(b)(2) application to make a generic version of the drug Elcys® (cysteine hydrochloride), which is indicated to meet the nutritional

requirements of newborn infants requiring total parenteral nutrition (TPN). Case settled on terms favorable to the client.

- An action in the Southern District of Indiana regarding client's ANDA to make a generic version of the low-testosterone drug Axiron® (testosterone topical solution). All patents found invalid and/or not infringed after multi-week trial.
- An action in the District of New Jersey regarding client's ANDA to make a generic version of the topical solution Jublia® (efinaconazole). Case settled on terms favorable to the client.
- An action in the District of New Jersey regarding client's ANDA to make a generic version of the bipolar depression drug Latuda® (lurasidone HCL). Case settled on the first day of trial.
- An action in the District of Delaware regarding client's ANDA to make a generic version of the severe acne drug Doryx® MPC (doxycycline hyclate). Case settled on terms favorable to the client.
- An action before the Texas Judicial Branch regarding client's ANDA to make a generic version of the eczema cream Locoid® (hydrocortisone butyrate). Case settled on terms favorable to the client.
- An action in the District of Delaware regarding client's ANDA to make a generic version of the opioid dependence buccal tablet Bunavail® (buprenorphine and naloxone). Case settled on terms favorable to the client.
- An action in the District of New Jersey regarding client's ANDA to make a generic version of the pulmonary arterial hypertension drug Orenitram® (treprostinil). Case settled on terms favorable to the client.
- An action in the District of New Jersey regarding client's ANDA to make a generic version of the drug Dificid® (fidaxomicin), indicated for the treatment of Clostridium difficile-associated diarrhea (CDAD). Case settled on terms favorable to the client.

EDUCATION

- Chicago-Kent College of Law, Illinois Institute of Technology, JD, with Honors, 1997
- University of Illinois at Chicago, BS, Chemical Engineering, cum laude, 1994

ADMISSIONS

- Illinois
- U.S. Patent and Trademark Office

- U.S. Court of Appeals for the Federal Circuit
- U.S. Court of Appeals for the 7th Circuit
- U.S. District Court for the Northern District of Illinois

HONORS

- Recognized for Hatch-Waxman patent litigation, *LMG Life Sciences*, 2012-2022
- Recognized as an IP Star, *Managing Intellectual Property*, 2013-2022
- Recognized by *IAM Patent 1000*, 2016-2022
- 40 Illinois Attorneys Under Forty to Watch, *Chicago Daily Law Bulletin*, 2010

EVENTS

- Speaker, "The Practice of Hatch-Waxman Litigation: Town Hall with the Magistrate Judges," 16th Annual Paragraph IV Disputes Conference, November 9, 2021

LANGUAGES

- Spanish