# Life Sciences

## Where Science Meets Strategy

**In today's evolving life sciences industry, Katten guides and defends medical pioneers where they meet regulatory oversight and commercial disputes, helping pharmaceutical, biotechnology and medical device companies transform scientific breakthroughs into lasting market value.**

### Commercially Sound Counsel, Backed by Science

Katten's robust practice brings together more than 120 attorneys across intellectual property, regulatory, transactions and healthcare, including litigators focused on high-stakes Abbreviated New Drug Application (ANDA) disputes, former Assistant US Attorneys and professionals with advanced degrees in chemistry, microbiology and pharmaceutical engineering. We pair that scientific fluency with commercial and industry insights to align sophisticated legal strategy with our clients' business goals. Many of the world's largest generic and branded pharmaceutical companies trust Katten, as do emerging innovators and their investors, health systems, physicians, multi-provider networks, disease state management companies, trade associations, insurance companies and other managed care organizations. Katten confidently steers clients through every stage of the company and product life cycle.

**Regulatory and compliance:** Guidance across the full Food and Drug Administration (FDA)-regulated product life cycle, and on Medicare and Medicaid reimbursement, fraud and abuse, Hatch-Waxman strategy and biosimilars pathways, the use of artificial intelligence (AI) and compliance under the False Claims Act, Anti-Kickback Statute, Physician Payments Sunshine Act, Stark Law and the Health Insurance Portability and Accountability Act (HIPAA).

**Our regulatory team also advises digital health and AI-enabled diagnostic and clinical decision support companies on Software as a Medical Device (SaMD) classification and FDA clearance strategy. In addition, we counsel life sciences companies on structuring commercial and collaboration arrangements with health systems, physician groups and multi-provider networks under the Anti-Kickback Statute and Stark Law, as well as the fast-developing patchwork of state laws governing AI-enabled clinical tools.**

**Intellectual property (IP)**: Building, protecting, licensing and defending IP portfolios across pharmaceuticals, biotechnology, medical devices, diagnostics, digital health and technologies enabled by AI, including IP strategies for NewCos formed to develop out-licensed pharmaceutical

# Key Contacts




**Deepro R. Mukerjee**
**Partner and Chair, Intellectual Property Department**
New York
+1.212.940.8552
deepro.mukerjee@katten.com





**Brian Sodikoff**
**Partner and Co-Chair, Patent Litigation**
Chicago
+1.312.902.5462
brian.sodikoff@katten.com





**Lance A. Soderstrom**
**Partner and Co-Chair, Patent Litigation**
New York
+1.212.940.6330
lance.soderstrom@katten.com

candidates outside their home jurisdiction, spanning the full spectrum of patent, trademark, copyright and brand-related work.

On the patent side, this includes freedom-to-operate analysis and Hatch-Waxman, Biologics Price Competition and Innovation Act (BPCIA) and Patent Trial and Appeal Board (PTAB) disputes.

On the trademark and branding side, this includes clearance and prosecution of product, corporate and pipeline brand names; global trademark portfolio management; opposition and cancellation proceedings before the Trademark Trial and Appeal Board (TTAB); brand enforcement and anti-counterfeiting strategies; and advising on naming conventions for pharmaceutical products, including compliance with FDA and International Nonproprietary Name (INN) naming requirements.

On the copyright side, this includes protection of proprietary software, algorithms, clinical trial materials, medical device documentation, marketing and promotional content, and training data and outputs associated with AI-enabled technologies.

**White collar and investigations:** Representation of public and private companies and individuals in government and internal investigations and at trial. Our matters have involved the False Claims Act, the Anti-Kickback Statute, misbranding, FDA compliance issues, the Foreign Corrupt Practices Act, and other federal and state investigations, including serving as monitor of a multinational pharmaceutical company's compliance program following one of the largest penalties of its kind, and obtaining jury-trial acquittals on the most serious charges brought against a pharmaceutical company president, whom the government had indicted for illegally importing non-FDA-approved pharmaceuticals.

**Commercial litigation:** Pragmatic, litigation-tested counsel in contract, class action, Racketeer Influenced and Corrupt Organizations Act (RICO), consumer protection, product liability and reimbursement disputes.

**Corporate and transactional:** Mergers, acquisitions, joint ventures and divestitures, in addition to development, licensing, collaboration and manufacturing agreements and clearances such as Hart-Scott-Rodino (HSR) filings and Committee on Foreign Investment in the United States (CFIUS) review.

**Securities litigation and enforcement:** Defense of securities class actions arising from clinical or regulatory setbacks, stockholder derivative litigation, and US Securities and Exchange Commission (SEC), Financial Industry Regulatory Authority (FINRA) and other regulatory proceedings.

**Antitrust and competition:** Antitrust risk assessments of potential transactions, HSR compliance, Federal Trade Commission (FTC) and Department of Justice (DOJ) merger investigations, private antitrust litigation, Hatch-Waxman settlement counseling and business practices counseling.



**Anthony M. Del Rio**

**Partner and National Chair, Healthcare Practice**

Chicago
+1.312.902.5533
anthony.delrio@katten.com

**Data privacy and cybersecurity:** Data governance and regulatory compliance for protected health information, clinical research data and other sensitive data under HIPAA, US state privacy laws and the General Data Protection Regulation (GDPR).

**Private credit:** Representation of lenders and borrowers in debt financings for life sciences companies, including acquisition financings, senior secured, first/second lien and mezzanine debt, convertible debt, venture debt, royalty financings, refinancings and distressed workouts.

**Capital markets:** Initial public offerings (IPOs), alternative public offerings (APOs), including reverse mergers and de-SPACs follow-on and at-the-market programs, equity lines of credit (ELOCs), private investments in public equity (PIPEs), private placements and convertible debt offerings, with particular experience in the financing and commercialization of biosimilars.

## Our Experience

- Selected for monitorship of one of the world's largest manufacturers of generic medicines as part of FCPA settlement. Includes creation and implementation of multi-jurisdictional DOJ compliance program.
- Represent several pharmaceutical company officers in a large, multi-jurisdictional DOJ investigation involving FDA issues and anti-kickback statutes related to nationwide sales practices of opioid painkiller products.
- Represent pharmaceutical company and its affiliate in five new Hatch-Waxman patent litigations seeking to introduce generic pharmaceuticals into the market.
- Represent pharmaceutical client in defense of trademark infringement complaint filed in US District Court for District of Massachusetts, obtaining full dismissal of claims.
- Represent Sagent Pharmaceuticals, a leading provider of affordable pharmaceuticals to hospital market, in its $40 million acquisition of a portfolio of five ANDAs in the United States from Teva Pharmaceutical Industries and Actavis (Allergan Generics) as a result of the largest merger of generic pharmaceutical companies in history.
- Represent biopharmaceutical company with a focus on the treatment of patients with rare and debilitating dermatologic and head and neck conditions in its receipt of a $48 million investment from affiliates of Fidelity Investments.
- Defended nutritional ingredients and medical foods developer and manufacturer, and its directors and officers, in securities class action over alleged failure to disclose that sales of a product would be

greatly affected by changes in the Chinese regulations of infant formula manufacturers in its IPO and secondary offering documents.

- Represented biopharmaceutical company Amarin in a securities class action over an alleged misrepresentation to investors regarding the likelihood of FDA approval for a broader indication.
- Represented pharmaceutical company in antitrust and breach of contract suit against a multinational consumer goods company over the right to sell a generic decongestant. The consumer goods company agreed to sell the plaintiffs a generic form of the anti-congestion drug if they failed to obtain FDA approval for their own generic before a third party launched a similar version.
- Represented Apotex in antitrust and patent claims—including *Walker Process* fraud, the *Therasense* standard for inequitable conduct and reverse-payment liability theories—in relation to being illegally excluded from the billion-dollar-a-year market for a narcolepsy drug.
- Represented privately held China-based company provider of pharmaceutical products in its sale to a US-based, China-focused specialty pharmaceutical company valued at more than $100 million.
- Represent Hospira, a leading company in generic injectable pharmaceuticals, in a joint venture with a private equity fund for development, regulatory approval, commercialization and distribution of three biosimilar products.
- Outside compliance counsel to an innovator of medical devices and solutions in orthopedics, spinal care and neuroscience. We provide regulatory compliance advice related to sales practices and physician relationships, conduct multiple internal investigations, and interface with the DHHS Office of Inspector General.
- Represent former member of the board of directors of a pharmaceutical corporation in an SEC and DOJ investigation of the company involving possible violations of the FCPA concerning drug approval and price reimbursement in China as well as various restatements of the company's financials unrelated to any alleged FCPA violations.
- Represented investment firm and its related funds in purchasing up to $36 million of convertible notes issued by a publicly held pharmaceuticals developer. Involved restructuring our client's prior loan to the developer.
- Defended biotechnology company in putative class action brought in the US District Court for the District of New Jersey under Section 10(b) of the Securities Exchange Act of 1934. Plaintiffs also alleged violations of Section 11 of the Securities Act of 1933 based on purportedly misleading statements made during a secondary stock offering. We obtained dismissal based on failure by plaintiffs to state

legally sufficient claims under the Exchange Act and Securities Act and *scienter*.

- Represented president of a pharmaceutical company in a seven-week federal criminal jury trial in the US District Court for the Eastern District of New York. The case concerned the alleged importation of pharmaceuticals that were not approved by the FDA. We obtained acquittals on the most serious counts in the indictment, The US Court of Appeals for the Second Circuit erased all convictions and ordered a new trial.
- Represented global pharmaceutical company in patent dispute in a Hatch-Waxman litigation over an antibiotic drug. We sought and received an expedited proceeding that led to an optimal settlement structure after our summary judgment briefing was filed.
- Represent one of the largest Japanese generic pharmaceutical companies based in two Hatch-Waxman patent litigations seeking to introduce generic pharmaceuticals into the market.

## Recognitions

*Recognized or listed in the following:*

- *ANDA Litigation Intelligence Report*
  - Best Performing Law Firms Overall (Representing Defendants or Plaintiffs), 2020-2022, 2024-2025
  - Best Performing Law Firms Representing Defendants, 2020-2022, 2024-2025
  - Best Performing Law Firms Representing Plaintiffs, 2023
  - Top 100 Most Active Law Firms Overall (Representing Defendants or Plaintiffs), 2020–2025
  - Top 100 Most Active Law Firms Representing Defendants, 2020–2025
  - Top 100 Most Active Law Firms Representing Plaintiffs, 2023, 2025
- *Best Law Firms*
  - Litigation – Intellectual Property
    - National, 2012–2026
    - Chicago, 2012–2026
    - Los Angeles, 2025–2026
  - Litigation – Patent
    - National, 2012–2018
    - Charlotte, 2026

        - Chicago, 2012–2018
        - Los Angeles, 2014–2018
- *BTI Litigation Outlook*
    - IP Litigation Honor Roll, 2018
- *Chambers USA*
    - Intellectual Property
        - Illinois, 2006–2022
    - Intellectual Property: Patent
        - New York, 2026
    - Intellectual Property: Trademark & Copyright
        - Nationwide, 2025-2026
    - Intellectual Property: Trademark, Copyright & Trade Secrets
        - Illinois, 2021–2026
    - Intellectual Property: Litigation
        - District of Columbia, 2021–2024
- *IAM Patent 1000*
    - Patent Litigation, 2017
    - Patent Litigation, Charlotte, 2022–2023
    - Patent Litigation, New York, 2022–2026
    - Patent Litigation, Illinois, 2022–2023
- IPR Intelligence Report
    - Top 100 Most Active Law Firms representing Petitioners, 2022
- *Managing Intellectual Property* IP Stars
    - Patent Contentious
        - United States, 2017, 2020–2021
    - Ranked Firm
        - United States (National), 2023
    - Top Tier Firm
        - New York, 2023–2025
        - Illinois, 2023–2025
- *The Legal 500 United States*
        - Patents: Litigation, 2025-2026