Pharmaceutical and Life Sciences

From pricing to patents, pharma and biotech companies face a myriad of legal and business issues. Katten's multidisciplinary team brings a deep understanding of those complexities with a proven track record of results.

Strategy based in science, validated by experience

In the high-stakes business of pharmaceutical products, your legal counsel needs to be agile and speak your language. Our team includes several members with advanced degrees, providing us with the insight necessary to handle complex scientific and medical issues.

Our litigators have handled several multi-million dollar "at-risk" launch cases and have worked on matters involving more than 45 different drugs. Katten also was selected as the monitor of a multinational pharmaceutical company's implementation of a compliance program subject to a deferred prosecution agreement and parallel civil settlement. This case includes one of the largest penalties imposed on a company of its kind in a Foreign Corrupt Practices Act (FCPA) enforcement.

Some of our key services include:

Intellectual property litigation

- Defends allegations of patent infringement as well as those asserting patents
- Litigates pharmaceutical patent damages cases
- Counsels companies regarding Hatch-Waxman Act-related patent litigation, as well as USPTO trial proceedings, such as inter partes reviews
- Argues related appeals to the Federal Circuit
- Leverages knowledge of FDA's policies and procedures to assist with regulatory issues and provide counsel on FDA exclusivities that can affect launch decisions
- Maximizes the value of intellectual property assets and supports business development efforts through beneficial settlement terms or trial, and appellate-level advocacy in court or the USPTO

Key Contacts

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Antitrust

- Advises on antitrust investigations, which often result from Hart-Scott-Rodino Act-related filings, by the Federal Trade Commission (FTC) and complaints filed by the plaintiffs' bar in relation to pharma mergers and acquisitions
- Negotiates settlements with the FTC and manages drug divestitures when necessary
- Litigates "pay for delay" matters between brands, generics and pharmacies
- Handles reimbursement-related disputes involving pharmacy benefit managers (PBMs)
- Provides guidance on violations regarding "reverse payments," fraud on the USPTO and price-fixing allegations

Federal and state investigations

- Provides comprehensive support for the broad range of investigative issues, including:
- Foreign Corrupt Practices Act (FCPA) matters
- False Claims Act litigation
- Shareholder demand letters
- Securities class action lawsuits
- Off-label promotion allegations
- Disclosure-related complaints
- Average wholesale price (AWP) issues
- Stark Law and federal Anti-Kickback Statute investigations
- Accounting-related matters
- Represents corporations or serves as pool counsel for government investigations

Commercial litigation

- Handles breach of contract cases resulting from pharma patent infringement cases, as well as matters involving vendor and supplier contracts
- Strategizes the how to achieve the best outcome, whether it is a "bet the company" case or opting out of a class action case

Corporate and transactional

- Advises on a variety of corporate transactions for pharma companies, including mergers, acquisitions, joint ventures, divestitures and the issuance of stock
- Drafts development and licensing agreements, which include setting benchmarks throughout the trial and approval phases
- Coordinates the acquisition of rights to market and sell individual drugs on behalf of developers and distributors
- Represented investment management companies and hedge funds in transactions involving pharma-related entities
- Handles senior secured credit facilities, acquisition of securities (e.g., common stock, convertible preferred stock, common stock warrants), and private investment in public equities (PIPEs)

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