

Pharmaceutical and Life Sciences Litigation

Overview

Patents and intellectual property rights protect deep investments in breakthrough therapeutics, diagnostics and medical devices. Challenges to patents and claims of anticompetitive practices expose companies to steep liabilities. Katten guides and defends medical pioneers where they converge with regulatory oversight and commercial disputes. Our attorneys have triumphed at trial and settled countless threats for some of the world's largest pharmaceutical and biotech companies.

Defending pharma investments and company growth

Competition places pressures on pharma's patent budgets, development timelines and corporate behavior. We protect top-10 generic, biosimilar and specialty brands, as well as drug and device makers, against harmful allegations and threats to intellectual property. Experienced in matters involving more than 45 drugs and dozens of trials, we reduce the uncertainty of litigation by targeting the issues that matter most in:

- Accounting investigations
- Abbreviated Biologic License Applications
- Abbreviated New Drug Applications
- Antitrust
- At-risk launches
- Breach of contract and commercial claims
- Fraud
- Hatch-Waxman Act, Paragraph IV litigation
- Monitorships
- Patent infringement and invalidity
- Securities claims

"Katten has helped us by providing excellent opinions for Hatch Waxman litigations in a very cost-effective manner."

- U.S. News – Best Lawyers® 2018 "Best Law Firms" (Litigation - Intellectual Property) survey response

Managing disputes and government oversight

Regulations create distinct obligations for life sciences companies and their executives. Understanding the nuances of patent, Food and Drug Administration, and antitrust regulations has allowed our trial attorneys and litigators to effectuate the law and prevail in novel arguments. Katten navigates drugmakers through the post-*FTC v. Actavis* landscape, counseling to prevent litigation from arising in patent agreements and avoid claims of uncompetitive behavior. We maintain productive relationships with the:

- Federal Trade Commission
- US Department of Justice
- US Food and Drug Administration
- US Patent and Trademark Office
- US Securities and Exchange Commission

High-stakes trial advocacy nationwide

Katten attorneys are a familiar and effective presence in high-profile patent jurisdictions, including Illinois, New Jersey and Delaware, and in state and federal trial and appellate courts, the International Trade Commission, and the Patent Trial and Appeal Board. In addition to our work with established medical and pharma companies, we advise emerging enterprises on intellectual property, disclosure, fundraising and other regulatory responsibilities.

Our Experience

- Represented global pharmaceutical company Apotex in US District Court for the District of New Jersey and Federal Circuit. Successfully challenged patent covering the use of ofloxacin for ear infections. Invalidated all asserted claims, then recovered several million dollars from a posted bond for an improvidently issued preliminary injunction.
- Represented pharmaceutical company Apotex in US District Court for the Northern District of Illinois and Federal Circuit regarding a patent covering a competitor's blockbuster blood pressure medication. Successfully allowed Apotex to enter the market without being blocked by the brand's PED period.
- Represented biopharmaceutical company Amarin in a 10b-5 securities class action in the US District Court for the District of New Jersey. The client's lipid-

lowering drug had been approved by the FDA for use in a small market of patients with extremely high cholesterol levels. When the FDA declined Amarin's application to approve the drug for patients with moderately elevated levels, the stock price declined. Plaintiffs alleged Amarin misrepresented to investors the likelihood that it would obtain FDA approval for the broader indication by not revealing certain information to shareholders about a prior meeting with the FDA. The court dismissed the case as the allegations in the complaint were not specific enough to meet the bar for securities class actions, and some of the claims did not allege misconduct. Plaintiffs filed a second consolidated amended class complaint that was also dismissed; the US Court of Appeals for the Third Circuit affirmed the dismissal and denied a petition for rehearing *en banc*.

- Represented pharmaceutical company in antitrust and contract breach suit against Reckitt Benckiser over the right to sell generic Mucinex.
- Lead counsel to Apotex, a global pharmaceutical drug company, regarding 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. We established that the relevant patent was invalid, not infringed and procured by fraud. The decision was affirmed on appeal. We then brought the antitrust claims through a 4-week jury trial before securing a favorable settlement with the last defendant just before jury deliberations.
- Represented pharmaceutical corporation and certain of its officers and directors in a securities class action brought by investors after the *London Times* published a story stating that our client was expected to restate its financial results; the company's stock price subsequently fell 5%. Following a meeting with Katten, lead counsel for the putative class agreed to voluntarily dismiss the case.
- 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 regarding drug approval and price reimbursement in China as well as various restatements of the company's financials unrelated to any alleged FCPA violations.
- Represented MedTorque in patent litigation surrounding a medical device. Secured dismissal of one of three asserted patents in a motion to dismiss. Convinced plaintiff to voluntarily drop a second patent. Secured a recommendation of summary judgment of non-infringement from magistrate before settling entire matter on favorable terms.

- Defended pharmaceutical company and certain of its officers against a putative securities class action lawsuit in the US District Court for the District of New Jersey. Plaintiff alleged that defendants previously misrepresented the likelihood that the FDA will approve the client's leading drug candidate for sale to the public, causing its stock price to be artificially inflated, but dropped the suit.
- Represented GW Pharmaceuticals in a US District Court for the Southern District of New York securities class action lawsuit alleging failure to disclose internal control deficiencies. After proactively contacting and managing potential confidential witnesses, and presenting the results of an initial investigation into the merits of the case to lead counsel for the putative class showing that plaintiffs would be unable to identify either a false statement (no restatement was expected and the company had not previously certified the adequacy of its internal controls) or *scienter* (since there were no publicly reported stock sales), we obtained voluntary dismissal.
- 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 pharmaceutical company in patent litigation regarding an over-the-counter versions of a GERD drug. We took the case over from another firm for trial. After our cross-examination of the inventor and primary expert witness, the brand consented to entry of a final judgment of non-infringement.
- Represented research-based pharmaceutical manufacturer in challenging a patent related to an anti-inflammatory medication that often treats acne. Obtained favorable pre-trial *Markman* decision and favorable settlement on the eve of trial.

- Litigation in the US District Court for the District of Delaware involving multiple patents associated with pre-colonoscopy cleansing using sodium picosulfate, magnesium oxide and anhydrous citric acid. Obtained judgment of non-infringement for both Orange Book patents.
- Litigation in US District Court for the Middle District of Florida involving a patent directed to a controlled release of mesalamine. Obtained Rule 36 affirmance from the US Court of Appeals for the Federal Circuit regarding original trial court victory. Affirmance was entered less than 24 hours after oral argument.
- Represented Mylan in infringement dispute regarding multiple patents for topical foam acne treatment Evoclin®. Defendant Glenmark Pharmaceuticals alleged the filings were "sham litigation" to delay approval of a generic. We persuaded the US District Court for the District of Delaware to dismiss the antitrust counterclaim.
- Co-counsel in US District Court for the District of New Jersey involving multiple patents associated with an adjunct to diet and exercise in type 2 diabetes mellitus. After multi-week trial, received decision in our client's favor invalidating all asserted claims of two separate patents.
- Represented pharmaceutical company in damages portion of a patent litigation. In district court, successfully held plaintiff to limited damages. Appellate court reversed award of pre-judgment interest.

Key Contacts



Brian Sodikoff

Partner and Co-Chair, Patent Litigation

Chicago
+1.312.902.5462
brian.sodikoff@katten.com



Deepto R. Mukerjee

Partner and Co-Chair, Patent Litigation

New York

+1.212.940.8552

deepto.mukerjee@katten.com

Recognitions

- *BTI Litigation Outlook*
 - IP Litigation Honor Roll, 2018
- *Chambers USA*
 - Intellectual Property
 - Illinois, 2006–2021
 - Intellectual Property: Trademark, Copyright & Trade Secrets
 - Illinois, 2021
 - Intellectual Property: Litigation
 - District of Columbia, 2021
- IAM Patent 1000
 - Patent Litigation
 - 2017
- *Managing Intellectual Property IP Stars*
 - Patent Contentious
 - United States, 2017
- *U.S. News Best Lawyers – "Best Law Firms"*
 - Litigation – Intellectual Property
 - National, 2012–2021
 - Chicago, 2012–2021
 - Litigation – Patent
 - National, 2012–2018

- Chicago, 2012–2018
- Los Angeles, 2014–2018