

# Katten

Katten Muchin Rosenman LLP



## PHARMACEUTICAL AND LIFE SCIENCES

### Our Clients

Katten provides multidisciplinary services to a range of biotechnology and pharmaceutical companies. We represent companies with pharmaceutical products—both generic and brand-name—as well as companies with biologics, biosimilars, nutritional supplements and cosmetics.

### Our Services

Katten's Pharmaceutical team has a deep understanding of the myriad of legal and business issues that pharma/biotech companies face. Our attorneys provide counsel on a variety of areas, including:

- intellectual property litigation;
- antitrust;
- federal and state investigations;
- commercial litigation; and
- corporate and transactional issues.

### Intellectual Property Litigation

We regularly represent companies defending allegations of patent infringement as well as those asserting patents. We have handled several multi-million dollar "at-risk" launch cases and have worked on matters involving more than 45 different drugs. Our team has particular experience in litigating pharmaceutical patent damages cases. We also counsel companies regarding Hatch-Waxman Act-related patent litigation, as well as US Patent & Trademark Office (PTO) trial proceedings,

### RECOGNIZED BY

- *Chambers USA*
  - Intellectual Property (Illinois) 2016, 2015
- *Managing Intellectual Property IP Handbook*
  - "Highly Recommended" firm for intellectual property (Illinois) 2014, 2013
- *U.S. News – Best Lawyers®* "Best Law Firms"
  - Litigation – Intellectual Property (National, Chicago) 2017, 2016
  - Litigation – Patent (National, Chicago, Los Angeles) 2017, 2016
  - Patent Law (Chicago) 2016



such as *inter partes* reviews. If necessary, we will argue related appeals to the Federal Circuit.

Our team includes several members with advanced degrees, which provides us with the insight necessary to handle complex scientific and medical issues related to pharmaceutical litigation. We understand the Food and Drug Administration's (FDA's) policies and procedures and have the resources to assist with regulatory issues and provide counsel on FDA exclusivities that can affect launch decisions. Whether by means of beneficial settlement terms or trial and appellate-level advocacy in court or the PTO, we seek to maximize the value of our clients' intellectual property assets while supporting their business development efforts and financial goals.

## **Antitrust**

Our attorneys are highly experienced in handling a multitude of antitrust matters particular to the pharmaceutical industry. We advise 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. We have a proven track record of negotiating successful settlements with the FTC and managing drug divestitures when necessary.

In addition, our attorneys litigate "pay for delay" matters between brands, generics and pharmacies; handle reimbursement-related disputes involving pharmacy benefit managers (PBMs); and advise on violations regarding "reverse payments," fraud on the PTO and price-fixing allegations.

## **Federal and State Investigations**

With more than a dozen former Assistant US attorneys on our team, we provide comprehensive support for the broad range of investigative issues facing pharmaceutical companies, 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; and
- various accounting-related matters.

In addition, our attorneys have represented corporations or served as pool counsel for government investigations.

## **Commercial Litigation**

Katten regularly handles breach of contract cases resulting from pharma patent infringement cases, as well as matters involving vendor and supplier contracts. Our attorneys focus on the strategy that provides the best outcome for each individual client, whether it is a "bet the company" case or opting out of a class action case.

## **Corporate and Transactional**

We advise on a variety of corporate transactions for pharma companies, including mergers, acquisitions, joint ventures, divestitures and the issuance of stock. We frequently draft development and licensing agreements, which include setting benchmarks throughout the trial and approval phases. We also coordinate the acquisition of rights to market and sell individual drugs on behalf of developers and distributors.

In addition, we have represented investment management companies and hedge funds in transactions involving pharma-related entities. We also handle 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**

### ***Intellectual Property Litigation***

- Representation of one of the largest Canadian-owned pharmaceutical companies in a patent dispute concerning an ANDA for a generic version of a narcolepsy drug; the court ruled that the ANDA did not infringe the competitor's patent covering the brand-name version, finding that our client's proposed generic differs in claimed pharmaceutical composition.
- Representation of a global pharmaceutical company in a patent dispute in a Hatch-Waxman litigation over an antibiotic drug; Katten sought and received an expedited proceeding that led to an optimal settlement structure after our summary judgment briefing was filed.
- Representation of a cosmetics company in an action brought by a pharmaceutical corporation regarding an eyelash conditioner alleging patent infringement and unfair competition by selling its product as a cosmetic instead of obtaining FDA approval to sell the product as a prescription drug; Katten secured summary judgment of non-infringement for one of the three asserted patents, obtained a covenant not to sue on a second patent, and negotiated a dismissal without prejudice of the infringement claims on the third.

## **Antitrust**

- Representation of a leading specialty pharmaceutical company in an antitrust and breach of contract suit against a multinational consumer goods company over the right to sell a generic decongestant in which 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.
- Representation of 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.
- Representation of an oncology-focused biopharmaceutical company in an FTC antitrust investigation of its acquisition by one of the largest brand pharmaceutical companies for \$6.5 billion, which was successfully concluded and deal closed.

## **Federal and State Investigations**

- Outside compliance counsel to an innovator of medical devices and solutions in orthopedics, spinal care and neuroscience; Katten provides regulatory compliance advice related to sales practices and physician relationships, conducts multiple internal investigations, and interfaces with the DHHS Office of Inspector General.
- Representation of a clinical-stage biopharmaceutical company that develops and markets omega-3 treatments for heart disease in litigation over an alleged failure to disclose an FDA "warning" about the importance of outcome studies for other drugs when deciding whether to grant expanded approval for the company's lead drug; Katten twice procured dismissal of the complaints.
- Representation of a former member of the board of directors of a pharmaceutical corporation in connection with an SEC and DOJ investigation of the company involving possible violations of the FCPA in connection with drug approval and price reimbursement in China as well as various restatements of the company's financials unrelated to any alleged FCPA violations.

- Representation of a British company that markets and develops cannabis-based pharmaceuticals in a securities class action lawsuit brought based on the company's alleged failure to disclose internal control deficiencies; Katten procured voluntary dismissal through our negotiation with plaintiffs' attorneys.
- Representation of a genetic testing and diagnostics company and its officers and directors in four putative class actions alleging that the defendants failed to disclose the company's gross margins were purportedly trending downward in connection with its IPO.
- Representation of a biopharmaceutical company in a securities class action over an alleged misrepresentation to investors regarding the likelihood of FDA approval for a broader indication.
- Representation of a nutritional ingredients and medical foods developer and manufacturer, and its directors and officers, in a securities class action over an alleged failure to disclose that sales of one of its products would be greatly affected by changes in the Chinese regulations of infant formula manufacturers in its IPO and secondary offering documents.

## **Commercial Litigation**

- Representation of one of the world's largest specialty generic pharmaceutical companies in its defense against claims that the client's and a co-defendant's at-risk launches of generic versions of a proton pump inhibitor caused the brand manufacturer \$3 billion in damage, which ultimately resulted in a favorable settlement.
- Representation of a pharmaceutical corporation in a breach of contract case regarding a generic blood thinner product that the corporation launched at risk; the litigation ultimately settled on appeal.
- Representation of a developer of stem cell therapy in an alleged breach of contract regarding technology licensed to a Texas company for extraction, banking and reinjection of stem cells in the United States.

## **Corporate and Transactional**

- Representation of a developer and commercializer of innovative cancer drugs in the issuance of

common stock and warrants in a deal with a leading biotechnology investment firm.

- Representation of a leading health care investment organization in a series of transactions with public biotechnology companies, including:
  - the acquisition of \$33 million of common stock and convertible preferred stock from a Switzerland- and California-based biopharmaceutical company and a modification of the terms of existing warrants the client held in said company.
  - the provision of a \$15 million senior secured credit facility to a leading provider of advanced image analysis and obtaining 500,000 common stock warrants.
  - provision of a \$20 million senior secured credit facility to a specialty pharmaceutical company that develops drugs for chronic diseases and obtaining 6 million common stock warrants.
  - the purchase of \$30 million of convertible preferred stock of a clinical-stage publicly traded pharmaceutical company focused on cancer and modification of the terms of an existing \$120 million credit facility with the company, in addition to the purchase of \$3 million of common stock and warrants of another biopharmaceutical company focused on peptide drugs.
- the purchase of \$20.1 million of common stock and convertible preferred stock of pharmaceutical company focused on muscular diseases and obtaining 6.7 million common stock warrants.
- Representation of 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.
- Representation of an oncology-focused biopharmaceutical company in its defense of an unsolicited takeover proposal.
- Representation of an investment firm and its related funds in the purchasing of up to \$36 million of convertible notes issued by a publicly held pharmaceuticals developer, involving the restructuring of our client's prior loan to the developer.
- Representation of a privately held China-based provider of pharmaceutical products in its sale to a US-based, China-focused specialty pharmaceutical company valued at more than \$100 million.
- Representation of a pharmaceutical manufacturer in the acquisition of North American rights to an anticonvulsant and an anxiety drug.