WINSTON & STRAWN LLP

Life Sciences

Winston has been a major player in the life sciences industry for decades. We represent market-leading clients across this broad sector, including companies involved in pharmaceuticals, biologics, biosimilars, biotechnology, and medical devices. Our attorneys are seasoned practitioners—many of whom have technical degrees in areas key to the life sciences sector, including biology, chemistry, pharmacy, and biomedical engineering—and bring a unique understanding of the industry and perspective to our representations.

We understand the complexities inherent to the life sciences sector, which enables us to provide comprehensive counsel on the legal and business challenges in this highly regulated environment. The life sciences sector has faced unprecedented challenges throughout the last few years, and our team has been among the most active in helping clients respond to the evolving regulatory landscape. Our experience includes matters related to intellectual property, product liability and mass torts, consumer class actions, antitrust, international trade, privacy and data security, labor and employment, mergers and acquisitions, private equity, and commercial transactions. We also advise clients regarding regulatory and compliance matters— including government drug pricing and voluntary disclosures related to the Medicaid Drug Rebate Program, the VA's Federal Supply Schedule Program, and the 340B Program—and defend them in government investigations brought by federal and state agencies.

Key Contacts

T. Reed Stephens

Justin Levy

Nimalka Wickramasekera

Areas of Focus

Pharmaceuticals

We are unquestionably one of the premier law firms representing companies in the pharmaceutical sector. Our practice has been known as a leading player in the IP arena for decades and is "hands down the best generic-side ANDA/Hatch-Waxman patent litigation group" (*U.S. News*—Best Lawyers® "Best Law Firms"). Since 2020, we have appeared in 60 pharmaceutical patent cases and, over the years, we have obtained wins in matters involving blockbuster drugs such as Zubsolv®, Prozac®, Yasmin®, Baraclude®, Razadyne ER/Razadyne IR®, Temodar®, Amrix®, Amprya®, Sensipar®, and Testim®, among others.

In addition to fiercely protecting our clients' intellectual property and freedom to innovate, we are often tasked with defending clients' products and reputations. Leading pharmaceutical companies repeatedly turn to us to serve in key roles—lead trial counsel, multidistrict litigation counsel, state-wide coordinating counsel, appellate counsel—to resolve their most critical product liability issues. Our lawyers have been involved in some of the most-watched, "bet-the-company" product liability and mass tort cases in recent history, such as serving as defense counsel for Pfizer Inc. in the wave of product liability cases regarding its two prescription non-steroidal anti-inflammatory medications, Celebrex® and Bextra®; trial counsel for Wyeth Pharmaceuticals in the *Fen-Phen* product liability litigation; co-lead counsel for Otsuka in the *In re: Abilify (Aripiprazole)* Products Liability Litigation MDL, various state-court actions brought by more than 4,000 plaintiffs, and the Abilify® and Rexulti® failure-to-warn and design defect cases; and national counsel for Hikma Pharmaceuticals in the national opiate litigation.

Furthermore, our attorneys have extensive experience in matters involving state and federal government law enforcement and investigations. With former U.S. Department of Justice attorneys and in-house attorneys embedded in our Health Care and Life Sciences Industry Group, we can leverage our practitioners' experience to provide efficient and creative representation of our clients in a broad array of important False Claims Act (FCA) matters, including those covering such issues as drug price reporting of Average Wholesale Price and Medicaid Drug Rebate Best Price and sales to government purchasers on the Federal Supply Schedule. We also routinely guide clients through many of the industry's most-litigated FCA issues in the current environment. These include dealing directly with regulators on litigated, non-intervened FCA *qui tam* matters involving complex Stark and anti-kickback issues, violation of drug-pricing allegations, and others.

Biotechnology

Our life sciences attorneys have deep experience with product development and commercialization across the leading sectors of the life sciences industry, including biotechnology. Our team recognizes that biotechnology is a highly diversified, complex, and regulated industry, and we partner with our clients to help them navigate the research, financing, and commercialization stages of product development. Our team is fully integrated with all the firm's substantive practices, and we draw upon decades of experience to help bring important biotech products to market successfully.

Biosimilars

Since the Biologics Price Competition and Innovation Act (BPCIA), or Biosimilars Act, was enacted in March 2010, our attorneys have played a pivotal role in some of the first cases in district courts and in proceedings before the U.S. Patent and Trademark Office. We are one of the few firms with hands-on experience litigating these cases and regularly present on BPCIA issues at conferences and other industry events. Currently, we advise a number of clients on potential biosimilar applications under the BPCIA, analyzing and preparing patent opinions regarding validity, infringement, freedom to operate, and related issues, including determining how best to proceed under the particular client's circumstances.

> "Winston & Strawn has an impressive ability to handle complicated pharmaceutical patent litigation."

Chambers USA, IP Client

Related Capabilities

Patent Litigation | Government Program Fraud, False Claims Act & Qui Tam Litigation | Intellectual Property | Product Liability & Mass Torts | Commercial Litigation & Disputes | Employee Benefits & Executive Compensation | Labor & Employment | Litigation/Trials | Environmental | Mergers & Acquisitions | Private Equity | Privacy & Data Security | Trade Secrets, Non Competes & Restrictive Covenants | Health Care | Medical Devices

Recent Experience

- Docter Inc. and Aimfinity Investment Corp. I Announce Definitive Merger Agreement
- Winston Serves as Trial Counsel in Monsanto Roundup Litigation
- GIO World Health Business Combination with Apeiron Capital Investment Corp.
- Torreya Partners's Sale to Stifel Financial Corp.
- ProKidney Business Combination with Social Capital Suvretta Holdings Corp. III
- BMO Harris Bank N.A's US$100M Credit Facility for Q Biopharma Holdco, LLC
- Gelesis, Inc.'s Business Combination with Capstar Special Purpose Acquisition Corp.
- Alpha Tau Medical Ltd. and Healthcare Capital Corp. Announce Business Combination
- Benson Hill Announces Business Combination with Star Peak Corp. II
- Grundfos Holding A/S's Acquisition of MECO

Resources

Product Liability & Mass Torts Digest

PTAB Perspectives

Related Insights & News

SPEAKING ENGAGEMENT

Kurt Mathas to Discuss Reference Drug Patent Challenges at 15th Annual Summit on Biosimilars & Innovator Biologics

JUNE 20, 2024

SEMINAR/CLE

2024 Health Care & Life Sciences Summit

JUNE 4, 2024

SEMINAR/CLE

Winston's Product & Mass Torts Summit Series 2024

MAY 9, 2024

BLOG

A Potential Shield: FDCA Preemption in Product Liability and Mass Torts Litigation

MAY 6, 2024

ARTICLE

Tylenol MDL Highlights Expert Admissibility Headaches

MAY 3, 2024

SPEAKING ENGAGEMENT

Ivan Poullaos Discusses Jury Trial Preparedness in ANDA Cases at Paragraph IV Disputes Conference

APRIL 25, 2024

RECOGNITIONS

Winston Paris Teams Win Palmarès du Droit 2024 International Law Firm of the Year Award

MARCH 26, 2024

RECOGNITIONS

Winston & Strawn Partners Recognized in *Chambers Europe* 2024

MARCH 14, 2024

BLOG

Sixth Circuit Confirms Experts Cannot Infer Causation from Association Based on Single Study to Exclusion of Contrary Studies Without Explanation

MARCH 4, 2024

CLIENT ALERT

Updates on Drug Regulations in Japan – Reducing Barriers to Entry for Drug Companies Entering the Japanese Market

MARCH 4, 2024

BLOG

In re Acetaminophen MDL Court Highlights the Significance of Regulator and Medical Organization Conclusions on Causation in Assessing Expert Methodologies

FEBRUARY 23, 2024

BLOG

In re Acetaminophen MDL Reiterates That Cherry-Picking Data And Exceeding Study Limitations Are Unreliable Expert Methodologies

FEBRUARY 2, 2024