

---

## *Life Sciences*

Advising life sciences innovators, investors and industry leaders on complex transactions, legal issues and business challenges.

Recognized for its knowledge in the life sciences, WilmerHale has represented life sciences clients across the United States and internationally for more than four decades. We understand the business of our life sciences clients and the unique regulatory and competitive demands they face. Our clients include biotechnology, pharmaceutical, diagnostic and medical device companies at all stages of growth and other key players in the space, including venture capitalists, investment banks, universities and research institutions.

WilmerHale's Life Sciences Practice has extraordinary breadth and depth, with a multidisciplinary team with experience and skills to address a broad range of matters for clients, including corporate finance, corporate governance and disclosure, licensing and strategic alliances, mergers and acquisitions, executive compensation and tax, patent litigation and licensing disputes, patent drafting and prosecution, strategic IP counseling, Food and Drug Administration (FDA) matters, competition and other regulatory matters, government investigations and litigation, real estate transactions and securities litigation and enforcement. Drawing upon deep industry knowledge as well as technical proficiency, our lawyers advise on legal strategy and complex transactions; protect clients' intellectual property through patent prosecution and portfolio development; and defend their interests in enterprise-critical patent litigation and licensing disputes in jurisdictions across the United States and internationally. Our team also has a track record of representing life sciences companies in securities litigation and government investigations.

We have served as trial and appellate counsel in multi-jurisdictional life science matters before the International Trade Commission, district courts throughout the US, the Federal Circuit and the US Supreme Court. Our lawyers also have an outstanding track record in *inter partes* review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB), ensuring a comprehensive approach to any litigation strategy. In addition, we represent life sciences clients in dealings with the United States and other governments on regulatory matters, including issues before the FDA and other agencies, merger clearance and enforcement actions and public policy and strategy.

---

## Key Contacts

---



### Stuart M. Falber

PARTNER

✉ [stuart.falber@wilmerhale.com](mailto:stuart.falber@wilmerhale.com)

📍 BOSTON

☎ + 1 617 526 6663



### Bruce S. Manheim Jr.

PARTNER

✉ [bruce.manheim@wilmerhale.com](mailto:bruce.manheim@wilmerhale.com)

📍 NEW YORK ☎ + 1 212 230 8817

📍 WASHINGTON DC



### Lisa J. Pirozzolo

PARTNER

✉ [lisa.pirozzolo@wilmerhale.com](mailto:lisa.pirozzolo@wilmerhale.com)

📍 BOSTON

☎ + 1 617 526 6388

---

## Related Solutions

Administrative Law

China Transactions

Cybersecurity and Privacy

Executive Compensation and  
Employee Benefits

Healthcare

International Trade, Investment  
and Market Access

Public Policy and Legislative  
Affairs

Technology Transactions and  
Licensing

Antitrust and Competition

Corporate Governance and  
Disclosure

Debt Finance

False Claims Act

Intellectual Property  
Counseling and Prosecution

Mergers and Acquisitions

Securities Litigation

White Collar Defense and  
Investigations

Capital Markets

Crisis Management and  
Strategic Response

Emerging Company and  
Venture Capital

Foreign Corrupt Practices Act  
and Anti-Corruption

Intellectual Property Litigation

Private Equity

Tax

---

## *Areas of Focus*

Life Sciences Transactions

Life Sciences Corporate  
Governance and Disclosure

Life Sciences Patent  
Litigation and Licensing  
Disputes

Life Sciences Patents and  
Other Intellectual Property -  
Technical Experience

Life Sciences Regulatory

Life Sciences Securities  
Litigation and Enforcement

Life Sciences Litigation

Life Sciences Real Estate  
Transactions

---

## *Experience*

### **CAPITAL MARKETS TRANSACTIONS**

Represented Arvinas, Constellation Pharmaceuticals, Stealth Biotherapeutics, Translate Bio and Trevi Therapeutics in recent IPOs, and the underwriters in the IPOs of Entasis Therapeutics, Rhythm Pharmaceuticals, TCR2 Therapeutics and Xeris Pharmaceuticals as well as clients in a broader selection of capital markets transactions including follow-on offerings and Rule 144A placements of convertible notes.

### **LICENSING AND STRATEGIC ALLIANCES**

Represented Apellis Pharmaceuticals in a development funding agreement with SFI Pharmaceuticals; Decibel Therapeutics in a strategic collaboration with Regeneron; MacroGenics in collaboration and licensing agreements with Incyte Corporation and Roche; Spark Therapeutics in a licensing and supply agreement with Novartis Pharmaceuticals; and Vividion Therapeutics in a strategic research collaboration with Celgene.

### **IP COUNSELING AND POST-GRANT PROCEEDINGS**

Secured a significant victory for **Bristol-Myers Squibb** when the PTAB rejected an IPR filed by the adverse party challenging their anticoagulant drug product Eliquis®; secured a total victory, along with co-counsel, for **Gilead Sciences** when the PTAB denied institution of the tenth straight petition for IPR of patents directed to Gilead's Hepatitis C products, including the blockbuster drugs Sovaldi®, Harvoni® and Epclusa®; represented **Smith & Nephew** in IPRs challenging six patents relating to knee implants and suture anchors; represented Genentech in biosimilar patent litigation and related IPRs involving its \$7 billion-a-year drug, Herceptin®; obtained a favorable decision for **Genentech** and **City of Hope**, denying institution of an IPR petition filed by Genzyme challenging the validity of the Cabilly monoclonal antibody patents; obtained a successful result for **Becton Dickinson** when the PTAB invalidated all challenged claims in two IPRs against an Enzo patent directed to nucleic acid hybridization assays, and the Federal Circuit affirmed the PTAB's decisions on appeal.

### **PATENT LITIGATION AND LICENSING DISPUTES**

Won a major, complete victory for **Bristol-Myers Squibb** and **Pfizer** in one of the largest Hatch-Waxman cases ever filed, covering 25 generic companies' attempt to challenge Eliquis®; earned a milestone victory for **Becton Dickinson**, ending an eight-year multinational patent infringement dispute with Braun Melsungen in US district

court, the Federal Circuit, the PTAB and numerous jurisdictions across the globe; successfully represented **Millennium Pharmaceuticals** at the Federal Circuit involving a patent covering its parent company, Takeda's blockbuster oncology drug Velcade®; successfully defended Astellas Pharmaceuticals' subsidiary **OSI Pharmaceuticals** and **Genentech** against a patent infringement suit in relation to the oncology drug Tarceva® when the PTAB invalidated all asserted claims, and the Federal Circuit affirmed; represented **AbbVie** in some of the first litigations arising under the Biologics Price Competition and Innovation Act (BPCIA) related to proposed sales of biosimilar products; prevailed on behalf of **Ancestry** in a lawsuit brought by 23andMe when all asserted patent claims were ruled to be invalid because they were directed to patent ineligible subject matter.

## **VENTURE CAPITAL FINANCINGS**

Represented Carisma Therapeutics in its \$53 million Series A financing, Decibel Therapeutics in its \$55 million Series C financing, Generation Bio in its \$100 million Series B financing, Pandion Therapeutics in its \$58 million Series A financing, Ribometrix in its \$30 million Series A financing, Ribon Therapeutics in its \$65 million Series B financing, Schrödinger in its \$85 million late stage financing, and numerous others. Also represent leading life sciences venture funds and other strategic investors, such as Atlas Venture, Flagship Pioneering, MPM Capital, Sofinnova Ventures and many others, in financings.

## **M&A**

Represented Arsanis in its sale to X4 Pharmaceuticals for \$165 million, Exonics Therapeutics in its sale to Vertex Pharmaceuticals for \$245 million (not including contingent payments), Potenza Therapeutics in its sale to Astellas Pharma for \$405 million (including contingent payments), PTC Therapeutics in its acquisition of Agilis Biotherapeutics for \$200 million and Thermo Fisher Scientific in the sale of its anatomical pathology business to PHC Holdings for \$1.14 billion.

## **SECURITIES FRAUD LITIGATION AND SEC INVESTIGATIONS**

Defend clients in federal securities fraud class action suits, derivative suits, and US Securities and Exchange Commission investigations related to disclosures surrounding the progress of clinical trials, the FDA approval process, and product safety and efficacy. Successful representations include recent wins on behalf of Tetrphase Pharmaceuticals, ConforMIS, InVivo Therapeutics, AVEO Pharmaceuticals, Medtronic, and many others.

## **REAL ESTATE TRANSACTIONS**

Represented a New York Stock Exchange publicly traded real estate investment trust in multiple transactions, including leasing matters, joint ventures, acquisitions, financings and development projects for office, lab and retail complexes in key life sciences cluster locations; represented a real estate developer that specializes in healthcare facilities in the acquisition, leasing and development of the first-ever proton therapy center in New York City; and counseled a global pharmaceutical company in the development of its more than a million-and-a-half square-foot campus in Cambridge, Massachusetts, from the time it chose to shift its major research headquarters from Europe to Cambridge through the present.

## **TRADE INDUSTRY REPRESENTATION**

Represented Pharmaceutical Research and Manufacturers of America (PhRMA) as *amicus* before the Second and Third Circuit Courts of Appeals addressing two antitrust issues of significance to the industry: Hatch-Waxman reverse payment settlements, and so-called “product hopping” claims. On behalf of PhRMA, we submitted antitrust briefs addressing product hopping to the Second Circuit in the *Namenda* case, and to the

Third Circuit in the *Doryx* case. We also submitted an amicus brief addressing reverse payments to the Third Circuit in *Wellbutrin*.

---

## Recognition



***Recognized as a Top Law Firm for  
Life Sciences***

*Chambers USA*

2007–2023



***Biotechnology Law Firm of the Year***

*U.S. News – Best Lawyers®*

2024



***Ranked WilmerHale Among the Top  
Law Firms for Life Sciences***

*The Legal 500 US*

2013–2023

- *Chambers USA: America's Leading Lawyers for Business* – Named a top law firm for life sciences (2007–2023) in which sources say our attorneys are “great at teamwork,” “responsive, efficient and very technically sophisticated,” “best in class” and “highly professional with a broad range of experience.”
- *The Legal 500 United States* – Consistently recognizes WilmerHale among top law firms for our work in the area of Life Sciences (2013–2023 editions); sources said the firm “assembles a knowledgeable team” who employ “a diversity of thought to make sure that a dispute is considered from all angles.”
- *U.S. News - Best Lawyers®* – Named Biotechnology Law Firm of the Year (2020, 2024), Patent Firm of the Year (2021) and IP Litigation Law Firm of the Year (2018). Recognized in first-tier Best Law Firms lists in for biotechnology, healthcare, FDA, corporate, intellectual property litigation, M&A, patent, securities/capital markets, securities litigation and venture capital (2014–2024); received first-tier metropolitan rankings in Boston, Colorado, New York, San Jose and Washington DC for several of these and other practice areas relevant to the life sciences industry (2019–2024).

- *LMG Life Sciences* – Named the US Life Cycle Firm of the Year in 2017 and 2021, and shortlisted for the recognition on ten occasions (2012–2020, 2022 and 2023); 20 WilmerHale lawyers were recognized as “life sciences stars” in the 2021 edition, 22 were recognized in the 2022 edition and 21 were recognized in the 2023 edition. Highly recommended as a leading life sciences law firm with rankings in the areas of: patent prosecution, patent strategy and management, general patent litigation, Hatch-Waxman patent litigation, corporate, licensing and collaboration, M&A, venture capital and white collar/government investigations (2012–2023).
- *Chambers Global* – Recognized as a leader in life sciences (2013–2024); acknowledged for global work in the sector including cross-border IP disputes, patent litigation, investigations, regulatory matters and transactions with sources praising the firm’s “capacity to navigate the complexities of the regulatory environment in the global life sciences industry” and “strong offering across both sides of the Atlantic” (2020).
- *The Legal 500 EMEA* – Recognized as a “Top Tier Firm” in 1 practice area and recommended in 9 other practice areas, including Life Sciences, in 2023.
- *LMG Life Sciences Awards* – Named Venture Capital Firm of the Year and shortlisted for the Life Cycle, Corporate, IP and Litigation Firm of the Year (2023); named the Hatch-Waxman Litigation Firm of the Year and shortlisted for the Life Cycle, Corporate, Venture Capital, Inter-Partes Review, IP and Government Investigations Firm of the Year (2022); received the Impact Case of the Year Award for our work on *Enzo Life Sciences v. Roche Molecular Systems* and shortlisted for Firm of the Year in the Licensing & Collaboration, General Patent Litigation, IP, *Inter Partes* Review, and Government Investigations categories (2020); named as the General Patent Litigation Firm of the Year and Intellectual Property Firm of the Year and shortlisted for the Hatch-Waxman Litigation (Branded) Firm of the Year, *Inter Partes* Review Firm of the Year (2019); and winner of the Hatch-Waxman Impact Case of the Year Award for our role in *Millennium Pharmaceuticals v. Sandoz* (2018).
- *Managing IP* – Consistently recognized as one of the best firms in the United States for life sciences (2013–2020); honored as the US Patent Contentious Firm of the Year seven times since 2011.
- *FierceBiotech* – Named Voyager Therapeutics' strategic collaboration—led by WilmerHale—with Neurocrine Biosciences as one of the top 15 biopharma licensing deals of 2019.
- *BTI Power Rankings Report* – Named among the top 10 law firms for having strong and lasting client relationships with the pharmaceutical industry (2017).