

# Life Sciences

Influenced by rapid technological change, evolving regulatory requirements, intellectual property and trade secret concerns and a consistently shifting business environment, life sciences companies face many challenges and opportunities unique to the industry. Our dedicated team of attorneys, patent agents, scientists and staff understand the complexities characteristic of life sciences companies and work efficiently and effectively to meet their business needs. Polsinelli delivers a coordinated and tailored approach for any client from incubators to mature businesses, research organizations to individual scientists.

Our multidisciplinary team provides clients with a full-service approach through every lifecycle stage and can serve as outside counsel for any legal need including those unique to the industry. We counsel clients in corporate governance and registration, licensing, mergers and acquisitions, venture capital financings and investment advice, Freedom to Operate opinions, patent strategy, FDA compliance, litigation, employment policies, government incentives and real estate transactions.

## Scientist/Research Entity

As a scientist or research entity, you want to protect your innovation. Whether you plan to keep your product, have plans to license it or develop a business around it, Polsinelli can help you protect your innovation and develop your next steps.

**Intellectual Property Strategy & Development:** The firm can also assist in developing a comprehensive IP strategy. This can include licensing agreements, if you plan to license your product, and ways to protect your innovation from infringement. The first step will be to have an initial discussion about your innovation and what kind of protection it might need. The firm can help you determine whether your innovation is eligible for a patent or another form of intellectual property protection.

If a patent seems suitable, the next step will usually be a thorough patent search to determine if your innovation or something similar has already been patented.

If your innovation is unique, the firm can help you draft and file a patent application with the relevant patent office (such as the United States Patent and Trademark Office, if you're in the US).

**Commercialization Assistance:** At Polsinelli, we can provide assistance in commercializing your innovation, such as helping you draft and negotiate licensing agreements, provide advice on how to market and sell your product, and advise you on potential business structures and fundraising opportunities.

Even after your patent is granted, you will need to monitor the market for any potential infringements and enforce your rights as needed.

## Emerging Growth Companies/Incubators

Starting out, you need funding as you establish a business. The process of establishing an emerging growth company and securing funding can be quite complex and involves various steps. A law firm can be invaluable during this process and at Polsinelli, we act on your behalf as your outside general counsel to manage all of your legal needs including:

**Funding:** Once your business plan is in place, you can start seeking funding. This can come from various sources, including angel investors, venture capitalists, loans, or grants. In some cases, you might start with personal savings or money from friends and family before seeking external funding. We can also help with the legal aspects of securing funding, such as negotiating with investors and drafting investment agreements.

**Intellectual Property and Trade Secrets:** Developing a business around your innovation accentuates the need to protect your idea and Polsinelli attorneys can assist with patent prosecution and trade secret policies.

**Employment Policies:** As you start to hire employees, you'll need to develop clear employment policies. This includes things like hiring practices, benefits, compensation, and procedures for handling grievances.

**Real Estate/Equipment/Facility Considerations:** Depending on the nature of your business, you might need to lease or purchase property. Special considerations will need to be taken if you require specialized facilities like clean rooms, lab space, or cold storage.

**Regulatory Compliance:** It's important to understand both federal and state regulations that apply to your business. This can include everything from employment laws to environmental regulations to industry-specific guidelines. In some cases, you may need to obtain certain licenses or permits before you can legally operate your business.

**Accounting and Financial Management:** You will need to set up systems for managing your business's finances. This can include setting up a business bank account, implementing accounting software, and hiring an accountant or bookkeeper.

## Expansion

As established companies continue to grow and expand their operations, their needs become increasingly complex.

**Going Public:** Taking a company public through an Initial Public Offering (IPO) involves many legal and financial considerations. Polsinelli assists clients with securities registration, SEC compliance, due diligence, and coordinating with underwriters and other stakeholders.

**Mergers and Acquisitions (M&A):** When purchasing or acquiring other companies, there are many antitrust regulations to consider. This can include ensuring the deal does not create a monopoly or restrict competition. We help guide you through the due diligence process, negotiate terms, and handle necessary regulatory filings.

**Patent and Trademark Protection:** Portfolio maintenance, brand protection, and enforcement of both are important for growing and established companies. Our attorneys have decades of experience preserving clients' rights in intellectual property, trade, advertising and publicity, including work on behalf of some of the world's most well-known brands.

**Talent Acquisition and Immigration:** Acquiring the best talent often involves navigating complex immigration laws if hiring from outside the country. Our labor and employment attorneys frequently assist companies with respect to immigration law and visa processes, ensuring the company can legally hire and retain foreign talent.

**Investments and Spin-Offs:** Whether investing in other companies or spinning off a portion of the business, there are various financial, tax, and legal considerations. We can help analyze potential deals, draft and review contracts, and ensure the business structure meets the company's needs.

**Corporate Governance:** Establishing a board and other governance structures involves a range of legal and regulatory requirements. This includes board member selection, defining executive compensation, taking minutes, and more. We ensure you are compliant and have an effective governance structure.

**Trade Secrets and Restrictive Covenant Laws:** Protecting trade secrets is essential for any company, but this must be balanced with complying with restrictive covenant laws. We can help with best practices for protecting intellectual property, drafting non-compete and non-disclosure agreements, and ensuring all measures comply with current laws.

## VCs/PEs investing in Biotech/Life Sciences

Venture Capital and Private Equity firms have a different perspective in evaluating where to invest their funds. They are evaluating the assets of the companies in which they invest (IP, real estate, etc.), developing funding rounds for their portfolio companies and deciding which companies to join their portfolio.

**IP Due Diligence:** Polsinelli is equipped to conduct thorough assessments of a target company's intellectual property assets, such as patents, trademarks and trade secrets. We help many Venture Capital firms understand the strength of a company's IP portfolio and its potential for competitive advantages.

**Fund Formation and Deployment:** Our attorneys advise every stage of the private investment life cycle from fund formation, investment and M&A activity, debt financings (including private credit and bank financings), equity financings, recapitalizations, special situations, and daily counsel to dispositions and exits on behalf of investment funds.

# Matters

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## Pharmaceuticals

- Sale of CyDex Pharmaceuticals, Inc. to Ligand Pharmaceuticals Incorporated
- Sale of Planet Biopharmaceuticals, Inc. to Ares Allergy Holdings Inc.
- Sale of Cedarburg Pharmaceuticals, Inc. to Albany Molecular Research, Inc. (\$40+ million)
- Represented an emerging anti-cancer company in a collaboration and license agreement with a major industry player followed by a restructure and sale of its assets
- Represented an emerging company developing novel COX-2 inhibitors for the treatment of cancer in a collaboration and license agreement with an international health institute
- Represented a generic pharmaceutical company in drafting invalidity opinions designed to precipitate a Hatch-Waxman proceeding.
- Led due diligence projects for a multinational pharmaceutical and biopharmaceutical company, one of which resulted in their purchase of another biotechnology company for over one million dollars.
- Provided IP counseling to a multibillion-dollar specialty biopharmaceutical company on number of potential drug and device acquisitions, including their publicly announced acquisitions of other entities in the medical space.
- Served as outside patent counsel to branded and generic pharmaceutical companies, life sciences companies, and chemical companies in acquisitions involving products ranging from multimillion-dollar annual sales to multibillion-dollar annual sales.
- Provided Hatch-Waxman defense for a global pharmaceutical company regarding a generic product for topical treatment of lice infestations, in addition to hydrocodone extended-release tablets.
- Performed FTO analysis for generic versions of Humira and Erbitux for a basic life sciences research company.
- Provided opinion counsel on design-around, non-infringement, and invalidity strategies in effort to assist the client in clearing the legal hurdles necessary to sales of lower priced generic versions of drugs in the U.S.

- Drafted opinions for Paragraph IV ANDA disputes, including noninfringement and invalidity and representation in ANDA litigation

## **Vaccines**

- Purchase by the U.S. bioscience joint venture between two multinational technology companies of a controlling interest in a pandemic influenza manufacturing company from its university and state governmental founders
- Represented a large company in advancing patent protections around the world for launch of a new vaccine directed to an unmet need.
- Represented a large company in advancing patent protections around the world for advancement and clinical testing of a first vaccine against a rapidly spreading viral infection known to infect livestock and humans.

## **Medical Device**

- Represented Novita Therapeutics LLC in spinout and add-on venture financing of two medical device technologies into new medical device ventures, Metactive Medical, Inc. and Flow Forward Medical, Inc.
- Sale of stock of medical device company Enturia Holding, Inc. to Cardinal Health, Inc.
- Negotiated recapitalization transaction and venture capital financing transaction for medical device company in the prenatal NICU equipment space
- Representation of a publicly traded micro-surgical instrument medical device company in establishing a strategic joint development agreement with a major national medical clinic
- Multiple venture capital financings by Open Prairie Ventures and the Kansas BioScience Authority in Novita Therapeutics LLC
- Performed patent due diligence on a target patent portfolio relating to various hemostasis products, including fibrin sealant compositions.
- Prepared and prosecuted patents covering smart catheters and drug eluting stents.
- Performed patentability and patent clearance analyses for a surgical clip/stapling system used for laparoscopic procedures.

## **Compounding Pharmacy**

- Sale of a major US compounding pharmacy to a leading European-based international compounding pharmacy conglomerate

## **Diagnostics**

- Sale of assets of Oncimmune (USA), LLC to Health Diagnostic Laboratory, Inc.
- Represented a national diagnostics company in structuring and documenting multiple-site clinical trials on new diagnostic testing protocol with Mayo Clinic, Laureate Institute for Brain Research, Inc., The McLean Hospital Corporation and the University of Minnesota
- Represented Beyond Battens Disease Foundation in negotiation of license for broad screening test for orphan pediatric diseases
- Served as Special IP and regulatory counsel to a national diagnostics company in initial public securities offerings and follow-on offerings

## **Animal Health and Agriculture**

- Represented founders in formation and funding of TechAccel LLC, the first private capital, co-development partner focused on the acquisition and advancement of technologies in partnership with leading global companies in agriculture, animal health and food sectors
- Served as special IP and regulatory counsel to Aratana Therapeutics, an animal-health biotech company, in initial public securities offering and follow-on offerings
- Corporate restructuring, technology in-licensing transactions, and venture capital funding for Centaur Animal Health

- Represented Australia's leading animal health company in navigating U.S. regulatory hurdles, establishing a sales and distribution network and to enter the United States market
- Represented a consortium of animal health manufacturers and distributors in transferring assets to, and acquiring new technology lines for, a new manufacturing and distribution system
- Negotiated strategic partnerships and research and development agreements for TechAccel with Kansas State University
- Structured angel investor funding and state tax credit program for initial investors in Aratana Therapeutics
- Represented the interests of Kansas City Area Life sciences Institute and other of the world's leading animal health companies in establishing the Center of Animal Health Innovation to help accelerate the development of early-stage animal health technologies

## Plant Science

- Facilitated the largest food-technology Series B financing to date. Polsinelli also represented this plant-based food company in their first round of financing and continues to serve as outside general counsel on an ongoing basis.
- Sale of a leading ag-bio control company to Monsanto Company
- Represented an emerging ag-bio company in a multimillion-dollar collaborative research and license agreement with a major crop sciences company

## BioSecurity

- Represented Kansas State University in matters relating to obtaining federal funding from the Department of Homeland Security for the construction of the \$1.2 billion National Bio and Agro-Defense Facility, the nation's newest federal laboratory located in Manhattan, Kansas

# Publications

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June 16, 2026

**National Media Coverage Following the Supreme Court's Decision in Hikma v. Amarin**

June 4, 2026

**Supreme Court Hands Generics a Unanimous Win on Skinny Labels in Hikma v. Amarin**

May 18, 2026

**Federal Circuit Addresses Prosecution History Estoppel, Disclosure-Dedication Rule in Affirming ANDA Product Noninfringement Decision**

May 5, 2026

**Clarity or Corporate Secret? Battle Brews Over FDA Letters**

*Quoted, Law360*

April 29, 2026

**Chad Landmon Discusses Supreme Court Oral Arguments in Hikma v. Amarin**

April 29, 2026

**How Skinny is Skinny Enough? Takeaways from the SCOTUS Oral Argument in the Amarin/Hikma Case**

April 23, 2026

**Medspas on Alert: The FDA Says You're a Dispenser Too**

April 22, 2026

**Tiny Chains, Big Changes? What FDA's Latest Actions Mean for Peptide Compounding**

April 10, 2026

**CMS proposes closing optional reimbursement pathways for new innovative medical devices and antimicrobials**

April 7, 2026

**Not Joking Around: FDA Offers Additional Clarification on Compounded GLP-1 Policy in April Fool's Day Announcement**

April 3, 2026

**Trump Administration Expands Section 232 Tariffs to Patented Pharmaceuticals and APIs**

March 19, 2026

**FDA turmoil reshapes biotech dealmaking terms**

*Quoted, Axios*

March 4, 2026

**FDA says it wants individualized medicines. Can we get there?**

*Quoted, Chemical & Engineering News*

February 18, 2026

**New FDA Drug Reforms: Congress Extends Voucher Incentive, Clarifies Orphan Exclusivity and Provides Greater Transparency for Q1/Q2 Generic Approvals**

February 12, 2026

**A New "Made in America" Push for Hospitals: CMS Seeks Input on Domestic Sourcing for PPE and Essential Medicines**

February 9, 2026

**Opinion: 2025 Reshaped the FDA. What Will 2026 Hold?**

*Co-Author, BioSpace*

February 9, 2026

**FDA Tightens the Belt on GLP-1 Compounding, Escalating Threat of Enforcement**

February 4, 2026

**'These Decisions Created A Lot Of Uncertainty' – Why The Supreme Court's Skinny-Label Ruling Matters**

*Quoted, Generics Bulletin*

February 3, 2026

**Four Biotech Companies on Track to IPO this Week Despite the Government Shutdown**

*Quoted, Dealbreaker*

January 27, 2026

**FDA guidance eases wearables oversight. But experts have questions about what's next.**

*Quoted, Medtech Dive*

January 22, 2026

**High Court's 'Skinny-Label' Case Has Broader Implications (1)**

*Quoted, Bloomberg Law*

January 22, 2026

**High court picked Hikma's 'skinny label' fight after letting the issue 'percolate'**  
*Quoted, Endpoints News*

January 20, 2026

**Supreme Court Grants Cert. Petition in Hikma / Amarin Skinny Labeling Case**

January 15, 2026

**Industry Says FDA Loosening Regs On Wearable And Digital Products Is Good For Innovation**  
*Quoted, Medtech Insight*

January 14, 2026

**Federal Circuit Strikes Life Sciences Patent Over Insufficient Disclosure of Particular Species**

January 8, 2026

**Polsinelli Life Sciences Spotlight - Volume 3 - Turning Insight into Action: A Life Sciences Playbook for 2026**

January 5, 2026

**Calls for Leadership Stability and Rare Disease Follow-Through at FDA in 2026**  
*Quoted, BioSpace*

January 5, 2026

**How To Meet FDA Expectations For Hybrid And Decentralized Trial Oversight**  
*Featured, Clinical Leader*

December 31, 2025

**Pharma Patent Trials Loom in 2026 for Wegovy, Covid-Vaccine Tech**  
*Quoted, Bloomberg Law*

December 22, 2025

**FDA Policy Tracker: 2025 Was a Year of Change**  
*Quoted, BioSpace*

December 17, 2025

**Polsinelli Eclipses \$1B Revenue Mark, Grows PEP to \$3M**  
*Featured, The American Lawyer*

December 11, 2025

**Return of the BIOSECURE Act: What Life Sciences Companies Need to Know**

December 9, 2025

**FDA's Drug Price Push in Biosimilar Plan Hinges on Other Reforms**  
*Quoted, Bloomberg Law*

November 17, 2025

**New USPTO IDS Fees Raise Strategic Stakes for Biotech Filings**

November 10, 2025

**New Continuation Fee Among 2025 USPTO Changes Impacting Biotech**

November 5, 2025

**USPTO Launches Streamlined Claim Set Pilot to Accelerate Patent Examination**

October 31, 2025

**New FDA Guidance Could Speed Biosimilar Approvals and Cut Costs**

October 14, 2025

**FDA's Deceptive Drug Ad Focus Leaves Telehealth Sites Guessing**

*Quoted, Bloomberg Law*

October 14, 2025

**Inside Sonex Health: CEO Bob Paulson on Minimally Invasive Solutions for Carpal Tunnel Syndrome**

*D.C. Download*

October 9, 2025

**Justices Urged To Clarify Patent Validity In Entresto Case**

*Quoted, Law360*

October 8, 2025

**Are Medical Device Manufacturers Exempt from FDA's Push for "Radical Transparency"?**

*Author, AAMI*

October 7, 2025

**Patent Drafters Beware: Omitted Provisional Language Can Alter Claim Scope**

September 29, 2025

**FDA Takes Aim at Drug Ads: What It Means for Compounding Pharmacies, Medspas and Telehealth Companies**

September 24, 2025

**Vanda Ruling Opens Door For Contesting FDA Drug Denials**

*Co-Author, Law360*

September 16, 2025

**Stealth, Barth Community Await FDA Verdict With 'Everything at Stake'**

*Quoted, BioSpace*

September 16, 2025

**Deference Ruling Could Close The FAR Loophole**

*Co-Author, Law360*

September 11, 2025

**Polsinelli Life Sciences Spotlight - Volume 2 - Adapting by Design: Navigating Complex Times in Life Sciences**

August 26, 2025

**Navigating the FDA: Why Early Strategic Planning is Critical**

*Author, Life Science Nation Newsletter: Next Phase*

August 14, 2025

**Dr. Connie Lehman on AI and the Future of Breast Cancer Prevention**

*D.C. Download*

August 12, 2025

**Recent Life Sciences Deal Trends**

*Author, Life Science Nation Next Phase Newsletter*

July 28, 2025

**Biotech Innovation**

*D.C. Download*

July 21, 2025

**FTC's Latest Effort To Dispute Improper Patent Listings Barely Made A Dent**

*Quoted, Generics Bulletin*

July 14, 2025

**Device Patents in the Orange Book: May 21, 2025, FTC Warning Letters Appear to have Minimal Impact**

July 3, 2025

**Supreme Court Halts Nationwide Injunctions with Major Implications for Ongoing Litigation**

June 18, 2025

**Opinion: Recent Precedent Shows Overseas Biosimilars Companies Can Be Sued in US**

*Author, BioSpace*

May 23, 2025

**Orange Book Listings: Republican Led FTC Picks Up Where Democrat Led FTC Left Off**

May 15, 2025

**Trump Administration Announces New Executive Order to Promote Domestic Production of Biopharmaceuticals**

May 14, 2025

**How will FDA changes reshape drug approval in 2025 and beyond?**

*Quoted, Chemical & Engineering News*

May 6, 2025

**Facing 'uncertainty on steroids,' biotech dealmakers tread more cautiously**

*Quoted, Biopharma Dive*

April 16, 2025

**A judge blocked the FDA's plan to regulate LDTs. What now?**

*Quoted, MedTech Dive*

April 14, 2025

**FDA After the Storm: Drug Review Delays and Increased Executive Oversight Expected**

*Quoted, BioSpace*

April 1, 2025

**In Landmark Ruling, Eastern District of Texas Strikes Down FDA's Final Rule Regulating Laboratory Developed Tests**

March 28, 2025

**GSA Expansion under Executive Order "Eliminating Waste and Saving Taxpayer Dollars by Consolidating Procurement"**

March 14, 2025

**Judge Connolly (D. Del.) Overturns \$96 Million Molecular Diagnostics Jury Verdict, Finds Patents Invalid Under § 112**

March 11, 2025

**Federal Circuit Affirms District Court's Obviousness Judgment on ImmunoGen Patent Application**

March 5, 2025

**Federal Circuit Refuses to Rehear Case Involving Orange Book Listing of Device Patents**

February 21, 2025

**FCPA Enforcement Paused At DOJ, But Biopharma Shouldn't Pause Compliance**

*Quoted, Life Science Leader*

February 20, 2025

**FDA Reels From 'Indiscriminate' Job Cuts Under Trump as Biopharma Appeals for Clarity**

*Quoted, BioSpace*

February 19, 2025

**Personal Jurisdiction Considerations for International Biosimilars Companies**

February 19, 2025

**Thousands of federal employees fired from US regulatory and science funding agencies**

*Quoted, Chemical & Engineering News*

February 19, 2025

**MAHA Commission expected to impact approach to medications, vaccines, research**

*Quoted, McKnights Senior Living*

February 13, 2025

**'No Job Security' at FDA as Trump Team Seeks to Dismantle Workforce**

*Quoted, BioSpace*

February 13, 2025

**Scientists, drugmakers brace for a Kennedy HHS after confirmation**

*Quoted, Chemical & Engineering News*

February 13, 2025

**Uncertainty builds amid Kennedy confirmation, Trumps orders**

*Quoted, BioWorld*

February 6, 2025

**Generative Artificial Intelligence Leveraged to Deliver Healthcare - Legal Risks and Issues**

February 6, 2025

**New PTAB Guidance on Enabling Requirement Under § 102 of the AIA and Construction of Chemical Compound**

January 27, 2025

**Is Teva-Amneal Inhaler Case A Double-Edged Sword For The Generics Industry?**

*Quoted, Generics Bulletin*

January 23, 2025

**Court Ruling Alters the Calculus for Orange Book Patent Listings**

*Co-Author, Life Science Leader*

January 8, 2025

**Polsinelli Life Sciences Spotlight - Volume 1 - Looking Back, Moving Forward: A Year in Life Sciences**

December 23, 2024

**Federal Circuit Decides Case Involving Orange Book Listing of Device Patents**

December 23, 2024

**FDA likely to see more legal challenges to rulemaking, guidance in 2025**

*Quoted, BioWorld*

October 28, 2024

**100-days-in: How Polsinelli hire is expanding the Hatch-Waxman group**

*Quoted, Managing IP*

October 11, 2024

**FDA Issues Exemptions from November 27, 2024 Compliance Deadline for Updated DSCSA Requirements**

September 23, 2024

**Chevron Deference Reversal: FDA Rulemaking and Legal Challenges After Loper Bright**

*Co-Author, LexisNexis Practical Guidance Journal*

July 29, 2024

**Challenges to LDT Final Rule Continue as Rule Goes into Effect**

July 19, 2024

**Loper Bright bringing more scrutiny, uncertainty to US agencies**

*Quoted, BioWorld*

July 18, 2024

**Congress looking for 'simple solutions' to Rx pricing quandary**

*Quoted, BioWorld*

July 17, 2024

**The FTC's Challenge to the Listing of Device Patents in the Orange Book: What Challenge?**

July 9, 2024

**The Corporate Transparency Act and Agribusiness and Ag Tech Companies**

July 2, 2024

**Federal Circuit Clarifies Rules for Skinny Labeling for Generics and Biosimilar Companies**

June 2024

**Generic Drugs and Patents**

*Co-Author, Bloomberg Law*

May 6, 2024

**FDA Finalizes Rule Regulating Laboratory Developed Tests**

April 19, 2024

**HRSA Aims for Swift Dispute Resolution with new 340B ADR Final Rule**

April 18, 2024

**FDA Preemption of State Law for False Labeling Survives Appeal to Supreme Court**

April 16, 2024

**What to Know About New York's New Supplement Law Going into Effect this Month**

February 27, 2024

**The Alabama Supreme Court's Decision in LePage v. Center for Reproductive Medicine PC: After Dobbs, IVF Services Now Caught in the Crosshairs**

February 13, 2024

**Revisiting Government March-In Rights Under Bayh-Dole: The FTC Weighs In**

January 16, 2024

**Rethinking Examiner Interviews – A Data-Driven Analysis**

July 11, 2023

**CMS Proposes \$9B in Relief for 340B Hospitals**

## Newsletters

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Polsinelli Life Sciences Spotlight - Volume 3 - Turning Insight into Action: A Life Sciences Playbook for 2026

Polsinelli Life Sciences Spotlight - Volume 2 - Adapting by Design: Navigating Complex Times in Life Sciences

Polsinelli Life Sciences Spotlight - Volume 1 - Looking Back, Moving Forward: A Year in Life Sciences