

Services & Industries

Life Sciences

OVERVIEW

Emerging and established life sciences companies face a wide range of complex and diverse legal and business challenges, from leveraging relationships to protecting intellectual property and funding product development.

In the rapidly evolving life sciences industry, Day Pitney offers full, integrated services to address corporate, transactional, litigation, intellectual property, labor, employment and benefits, financial services, environmental, real estate, regulatory, and tax needs. So, whether you're in the business of biotechnology, nanotechnology, pharmaceuticals, medical devices, research and development, instrumentation and equipment, healthcare services, or software, or you support any of the foregoing, we can help every step of the way. Our clients place a premium on forging partnerships and have recognized our dedication to client service and attention to detail.

We differentiate ourselves by taking the initiative to become knowledgeable about our clients' businesses, and we use that knowledge to create true partnerships. By virtue of our long-standing relationships with many of our life sciences clients, Day Pitney attorneys have developed deep industry experience that can help your company achieve your goals by delivering high-quality, innovative legal advice in a cost-effective manner.

Day Pitney provides a broad range of services to our life sciences clients, including counsel in the following related practice areas:

Corporate and Transactional Matters

Our attorneys have participated in numerous venture capital investments and other forms of equity and debt financings, mergers and acquisitions, and other strategic transactions. We have structured complex licensing, distribution, development and manufacturing agreements to allow our clients to meet their current and future business needs. Examples include:

- Formation, sale and dissolution of corporations, partnerships, and limited liability companies, including drafting and negotiating stockholders' and partners' agreements
- Counseling on strategic alliances, partnering relationships and commercial contracts, including technology-driven agreements; research, development and clinical trial agreements; cross-border licensing; and manufacturing, consulting and vendor agreements
- · Advice, preparation, and negotiation of software licensing and systems agreements, leases, and

purchase agreements

- Advice on and advocacy of commercial and asset-based lending, equipment leasing, acquisition financings, sale leaseback investment, and bank and other forms of debt and tax-exempt financing
- Tax counseling with respect to federal, state and local tax issues involving choice of entity, structures for transactions, taxable and nontaxable reorganizations, and specialized tax incentives, credits and deferrals

Litigation

In the complex and competitive life sciences industry, Day Pitney's team of litigators counsel and assist our clients in identifying, assessing, and avoiding litigation risks inherent in their business and, where necessary, pursuing and defending claims to protect their business. Whether the litigation involves products liability and mass torts, fraud, securities, or commercial disputes, Day Pitney's decades of experience in complex litigation matters bring invaluable resources to help resolve trial, appellate and administrative matters. Examples include:

- Unfair competition
- Insurance
- Antitrust
- White collar criminal defense
- Foreign Corrupt Practices Act
- Fiduciary liability
- ERISA, reimbursement and insurance coverage
- Government investigations and regulation
- Contract disputes
- · Environmental law
- · Creditors' rights
- Appeals
- Administrative
- Collection and general commercial litigation
- Alternative means of dispute resolution, including those related to intellectual property rights and trade secrets
- Construction, banking and securities

- Consumer finance
- Insurance coverage
- Real estate and environmental
- · Franchising and distributing

Intellectual Property

Day Pitney's team of intellectual property attorneys provides strategically focused advice regarding the complex issues that arise in patents and trademarks, websites and e-commerce, advertising and promotions, technology transfer and licensing, outsourcing, and other intellectual property matters, including strategic planning and protection programs. Examples include the following:

- Advising a leading global life sciences company on a series of development, patent license and research collaboration agreements in the fields of drug discovery, genomics and biochip analysis
- Represented a major pharmaceutical company in an action to correct inventorship of several patents issued to a former employee, involving off-label usage of a branded drug
- Representing a global leader of innovative detection, imaging, informatics and service capabilities in patent litigation
- Representing a global leader of innovative detection, imaging, informatics and service capabilities in trademark counseling and prosecution

Regulatory and Corporate Compliance

We understand the complex federal, state and international regulatory demands that life sciences companies face every day in the development of their products, operations and business relationships. Our regulatory counsel regularly advise our clients on Medicare/Medicaid reimbursement, Current Good Manufacturing Practices (cGMP), product advertising, sale of research and products (including FDA, FTC and BIS regulation), FDA drug and device approval, fraud and abuse, federal and state anti-kickback, HIPAA, HITECH and corporate compliance, government inspections and investigations, and privacy laws. Examples include:

- Representing a pharmaceutical company in all phases of planning, developing and executing drug product launch, including acting as a legal representative on the Advertising Review Committee and advising on marketing regulations, physician grants and physician advisory panels
- Ensuring compliance with governing board and corporate compliance programs

Labor and Employment

We provide complete labor, executive compensation, employment and benefits counseling, and litigation services to meet all of your operational needs. Examples include:

Management matters before the National Labor Relations Board and in collective bargaining

negotiations, labor arbitrations and related litigation

- Preventive labor relations, including preventing and responding to union organization efforts
- Employment discrimination suits and wrongful discharge suits based on public policy, employee handbooks, or employer manuals and policies, as well as whistleblower claims and various employment tort claims
- Covenants not to compete and to protect proprietary information
- Management employment law issues, such as employee rights in the workplace and developing and implementing detailed personnel policies and procedures
- Compliance with evolving workplace safety and health requirements of the Occupational Safety and Health Administration (OSHA) and with management matters in occupational disease and injury litigation
- Employee benefit plans, retirement plans, and executive compensation agreements and ERISA compliance
- Anti-harassment and anti-discrimination training seminars
- Alternative dispute resolution (ADR) procedures
- · Corporate immigration matters, including business, professional and investor visas

EXPERIENCE

Prior results do not guarantee a similar outcome.

- Represented a pharmaceutical company in all phases of planning, developing and executing drug
 product launch programs, including drafting and negotiating advertising and marketing contracts,
 supply and distribution contracts, laboratory service agreements, CRO agreements, data transfer
 and licensing agreements, and consulting agreements; developing model entertainment and
 exhibition contracts; and preparing press releases, terms and conditions of sale, and return policies
- Served as lead counsel for a global pharmaceutical company in the acquisition of another industry leader, and provided advice in connection with corporate structuring issues, due diligence, labor and employment issues, and tax issues
- · Represented an acquirer in the purchase of a leading specialty biopharmaceutical manufacturer
- Served as outside general counsel for a specialty product manufacturer, including all aspects of general corporate, federal and state compliance, and strategic purchases and alliances
- Represented a biotechnology instrument developer and manufacturer in connection with the negotiation of a variety of collaboration agreements, research and development agreements,

license agreements, joint venture agreements, and supply agreements with academic institutions and commercial enterprises located in the United States, Canada and Europe

- Represented top-tier educational institutions and private enterprises on technology transfer matters such as entity creation, due diligence review, investment, research agreements, technology licensing and sales of businesses
- Served as sole outside counsel to a leading pharmaceutical company in connection with its acquisitions, dispositions and sale
- Advised a global pharmaceutical company on federal best-price regulations, including discount pricing and rebate programs
- Represented an international corporation, including a closing agreement between the client and the tax department of a large eastern state to resolve a state tax issue of first impression, limiting the client's potential SALT exposure to "water's edge" rather than worldwide income
- Represented an international pharmaceutical company with regard to all employee benefits and executive compensation matters and domestic and international transactions
- Served as national coordinating counsel, regional coordinating counsel and trial counsel in mass tort products liability claims, including pharmaceutical and medical device cases, toxic tort cases and mass disaster cases (for example, DES, asbestos, Fen-phen, breast implant matters)
- Represented a pharmaceutical company in defense of nationwide litigation brought by consumers, insurers and state regulators, relating to claims that the company wrongfully attempted to depress sales of the generic versions of a patented drug
- Represented a major pharmaceutical company in an action to correct inventorship of several patents issued to a former employee, involving off-label usage of a branded drug
- Represented numerous corporations in connection with the acquisition or sale of environmentally challenged property, including the issues of post-closing access, standards of remediation, interaction with state and federal agencies, and oversight
- Representing three major pharmaceutical companies in connection with land use matters, including expansion of existing office/manufacturing/research facilities, master planning issues and zoning approvals
- Represented an emerging drug delivery company in connection with its licensing and other strategic transactions
- Represented a publicly held medical device company in connection with its strategic and commercial transactions
- Represented an Ireland-based food and beverage company in connection with its acquisition of the assets of a U.S.-based sports nutritional supplements company out of bankruptcy
- · Represented a global food and beverage company in connection with a joint venture to acquire and

exploit Quercetin and Stevia farms in Brazil

- Represented the acquirer in the purchase of a leading specialty biopharmaceutical manufacturer
- Represented the seller of a privately held controlled substances manufacturer in its sale to a global pharmaceutical company

INSIGHTS

Thomas Zalewski Speaks at Licensing Best Practices Seminar

November 5, 2013

IP Attorneys Richard Brown and Cathy O'Connor Present on Patents, Copyrights and Trademarks

April 10, 2013

Thomas Zalewski Speaks to ChemPharma Professional Association

October 19, 2012

Paul Williams Speaks at CBA/ABOTA Program on Civility and Professional Behavior

December 5, 2013

Secretary of the State Issues Guidelines on Connecticut Model Entity Transactions Act, Effective January 1, 2014

December 30, 2013

NEWS

Leading Data Privacy and Cybersecurity Attorney William J. Roberts Joins Day Pitney's Hartford Office

February 28, 2022

Day Pitney Press Release

Careful Care: Health Care Companies Must Be Aware of Legal Risks That Come with New Technology

December 12, 2019

Tom Zalewski is quoted in an article, "Careful Care: Health Care Companies Must Be Aware of Legal Risks That Come with New Technology," published by *ROI-NJ*.

Day Pitney Hosts 2017 Lex Mundi Health Care And Life Sciences Practice Group Global Meeting

January 26, 2017

Day Pitney hosted the 2017 Lex Mundi Health Care and Life Sciences Practice Group Global Meeting at the firm's Parsippany, New Jersey office on Thursday, January 26, and Friday, January 27.

Attys React To High Court's FCA Liability Ruling

June 17, 2016

Susan Huntington was quoted in an article, "Attys React To High Court's FCA Liability Ruling," in Law360.

68 Day Pitney Lawyers Named to 2016 Best Lawyers List

August 24, 2015

Stamford, Conn., August 24, 2015 - Day Pitney is pleased to announce that 68 attorneys have been selected for inclusion in the 2016 Best Lawyers in America. Best Lawyers ranks lawyers through peer-review surveys, and has been published annually since 1983.

CONTACTS



Thomas A. Zalewski Parsippany, NJ tzalewski@daypitney.com T: (973) 966 8115