John C. Serio

Of Counsel

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Overview

John Serio is Of Counsel in the Intellectual Property and Technology group at Day Pitney. He focuses his practice on intellectual property matters involving biotechnology, pharmaceuticals, medical devices, chemistry, health care, and analytical scientific equipment.

With deep experience in patent law, John advises clients on the drafting and prosecution of U.S. and international patents, as well as on right-to-use and patentability opinions, enforcement and licensing strategies, and intellectual property litigation. He has prosecuted a significant number of patents that have been successfully enforced or licensed, particularly in the life sciences sector.

John also counsels clients on strategic IP issues related to the acquisition, collaboration, and licensing of life sciences technologies. He frequently advises foreign-based life sciences companies on cross-border transactions involving pharmaceutical and medical device patent portfolios and regulatory compliance.

In addition to his intellectual property practice, John has extensive experience with regulatory matters involving the U.S. Food and Drug Administration (FDA). He assists clients in obtaining FDA approval for drugs, medical devices, over-the-counter products, dietary supplements, foods, and cosmetics. He provides guidance on product labeling, advertising, manufacturing, distribution, and recalls, and regularly prepares and negotiates clinical trials, distribution, supply, contract manufacturing, and quality agreements. His regulatory work also includes counseling on compliance with USDA, EPA, and state regulations, including California's Proposition 65.

John is recognized as a thought leader in FDA regulatory issues, including the use of social media in pharmaceutical advertising and the state regulation of clinical trials. He is an accredited speaker with the American College of Pharmaceutical Education and frequently writes and presents on FDA and patent-related topics.

Experience

No aspect of this advertisement has been approved by the highest court of any state. Prior results do not guarantee a similar outcome.

Practices & Industries

Intellectual Property & Technology

Intellectual Property Litigation

Patent Prosecution & Counseling

Prosecuted and obtained high value foundational patents directed to DP-IV inhibitors that were licensed by leading large pharmaceutical companies

Developed an extensive patent portfolio for a laboratory robotics company acquired by a leading multi-national diagnostic company

Represented a member country in a CERN Research Consortium in an inter-agency arbitration proceeding resulting in a successful outcome

Managed and directed litigation, including oversight of junior litigation team, on behalf of a Fortune 500 client related to enforcement of its medical device portfolio, resulting in a successful settlement prior to trial

Assisted a medical imaging company in the preparation and filing of a 510(k) application for a radiological imaging device, resulting in FDA approval.

Developed a strategy and presentation related to Hatch-Waxman patent term extension for a pharmaceutical company in negotiations with a potential partner

Has rendered freedom to operate opinions involving pharmaceuticals and medical devices, resulting in successful product launches

Coordinated and negotiated with the FDA on behalf of client related to recall of pharmaceutical product without any further administrative action against client

Assisted pharmaceutical company in successfully negotiating clinical trial agreements related to international clinical trials

Represented a pharmaceutical company in litigation involving False Claims Act counts, resulting in successful dismissal of matter on all counts

Assisted numerous multi-national food companies in compliance with the Food Modernization Act and its related foreign verification requirements

Education and Credentials

Education

Western New England University School of Law, J.D.

University of Rhode Island College of Pharmacy, B.S.

Admissions

Commonwealth of Massachusetts

U.S. District Court, District of Massachusetts

U.S. Patent and Trademark Office

Affiliations

Boston Bar Association

Boston Patent Law Association

Recognition and Community

No aspect of this advertisement has been approved by the highest court of any state. Prior results do not guarantee a similar outcome. See Awards Methodology.

Recognitions

Chosen for inclusion as "Go To" Life Sciences Lawyer, by *Massachusetts Lawyers Weekly*, 2022-2024; 2026

Chosen for inclusion in the Top Recommended, Life Sciences, by *THE SPEAR'S 500*, 2023

News

Day Pitney's John Serio Named a 2026 Life Sciences "Go-To Lawyer" by Massachusetts Lawyers Weekly
Day Pitney Press Release, August 24, 2026

Day Pitney Deepens Intellectual Property Bench in Boston with the Addition of John C. Serio
Day Pitney Press Release, June 9, 2025

In The Media

"Private Practice and In-House Counsel: Managing Expectations, Fee Structures and Budget Pressures," Life Sciences Patent Network (LSPN) Conference, Webinar
May 3, 2023

Outsourcing Strategies for Maximizing Drug Exclusivity
Outsourced Pharma, December 19, 2022

Quality Concerns to Resurface as FDA Resumes Foreign Inspections
Bloomberg Law, March 17, 2022

U.S. Senate narrowly confirms Dr. Robert Califf to lead FDA for second time
Reuters News, February 15, 2022

Biden's FDA Chief Confirmed by Senate With Republicans' Help
Bloomberg Law, February 15, 2022

Patent Filing By Former Employees Leads Pfizer To File Trade Secret Suit
Pink Sheet, February 3, 2022

FDA Wants To Make Permanent COVID-19 Supply Chain Guidance To Prevent Product Shortages
Medtech Insight, January 11, 2022

FDA's Pfizer Vaccine Approval Adds Fuel to Biden Booster Plan
Bloomberg Law, August 11, 2021

"State Laws Governing Clinical Trial Regulatory Compliance Interactive Web Seminar," Barnett International
April 2021