


## John Serio

PARTNER | BOSTON

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SECRETARY SAM METCALF

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John is a partner in the US intellectual property team, based in our [Boston office](#).

He focuses his practice on intellectual property related to biotechnology, pharmaceuticals, medical devices, chemistry, health care and analytic scientific equipment. His practice involves the drafting and prosecution of patents, right to use and patentability opinions, patent litigation, licensing of technology, and trademark issues. John has expertise in prosecuting patents domestically and worldwide. He has prosecuted a significant number of patents that have been successfully enforced and/or licensed. He has extensive experience in Food and Drug Administration regulatory issues.

Throughout his intellectual property law career, John has gained experience advising clients on IP issues and strategy related to the acquisition, collaboration and licensing of life science technologies. In addition to his experience with patent law, he provides strategic legal oversight in order to mitigate business risk when evaluating potential product candidates for development or acquisition. He regularly assists foreign-based life science companies and is qualified to provide assessment and counsel concerning cross border transactional matters related to pharmaceutical and medical device patent portfolios and regulatory strategy.

John regularly assists clients whose products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act concerning all aspects of product development and approval of drugs and medical devices. He represents manufacturers and distributors in obtaining approval to market drugs, medical devices, over-the-counter products, foods, dietary supplements and cosmetics. John counsels on all aspects of marketing of FDA products, including providing advice on labeling, advertising, manufacturing and distribution. John's expertise in FDA regulation extends to the regulation and labeling of food. He has extensive experience in the recall of products regulated by the FDA. He also negotiates and prepares clinical trial, distribution, supply, contract manufacturing and quality agreements. John is a thought leader on the state regulation of clinical trials and the use of social media in direct-to-consumer advertising of pharmaceuticals.

John also advises companies on the labeling, packaging and testing of textiles, toys and consumer products. He further assists clients with regulatory requirements of the USDA, EPA and state regulatory requirements such as Proposition 65.

He is an accredited speaker with the American College of Pharmaceutical Education and has extensive experience writing and presenting on a wide variety of FDA and patent-related topics.

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## Track record

### Fortune 500 client

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.

### Medical imaging company

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.

### Freedom to operate opinions

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

### FDA

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

### Clinical trials

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

### Pharmaceutical litigation

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

## Food Modernization Act

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

## Patent portfolio

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

## CERN Research Consortium

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

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## Talks

- "Private Practice and In-House Counsel: Managing Expectations, Fee Structures and Budget Pressures," Life Sciences Patent Network (LSPN) Conference - May 3, 2023, panelist
- "State Laws Governing Clinical Trial Regulatory Compliance Interactive Web Seminar," Barnett International, April, 2021
- "CMC Patent Opportunities," Global Regulatory Affairs CMC; Chemistry, Manufacturing & Controls Conference, Philadelphia, PA, October 2019
- "Patent Basics for the CMC Professional," Global Regulatory Affairs CMC; Chemistry, Manufacturing & Controls Conference, Philadelphia, PA, October 2016
- "GLOBAL LICENSING - EYEGATE - CASE STUDY," ACC CCI Panel Discussion, February 2016
- "Maintaining CMC Due Diligence During Licensing Activities," Global Regulatory Affairs CMC; Chemistry, Manufacturing & Controls Conference, Philadelphia, PA, November 2015
- FDA Social Media Guidance Panel, October 2014
- "Food & Drug Administration (FDA) Overview," Speaker, Chilean Entrepreneurial Summit, October 2014
- "FDA Food Labeling," Presenter, Québec New Exporters Trade Mission, July 2014

## External publications

*'Withers Advises H2 Clipper on New Blockchain Solution to Hydrogen Supply Chain,'* The Patent Lawyer - October 8, 2024, quoted

*'Withers Advises H2 Clipper on New Blockchain Solution to Hydrogen Supply Chain,'* Talk of the Town: Attorney at Law Magazine - October 8, 2024, featured

*'International Law Firm Withers Bergman Upgrades to Larger Boston Office,'* Boston Business Journal - May 13, 2024, quoted

*'Withers Opens New Office In Boston's Financial District,'* Law360 - May 10, 2024, quoted

*'Outsourcing Strategies for Maximizing Drug Exclusivity,'* December 19, 2022, co-author

*'Quality Concerns to Resurface as FDA Resumes Foreign Inspections,'* Bloomberg Law - March 17, 2022, quoted

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

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

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

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

'FDA's Pfizer Vaccine Approval Adds Fuel to Biden Booster Plan,' Bloomberg Law - August 25, 2021, featured

'Withers Picks Red-Hot Kendall Square For New Mass. Office,' Law360 - July 8, 2021, featured

'Regulatory Actions for May 19, 2021,' BioWorld - May 19, 2021, featured

'Withers Launches Venture Capital and Life Sciences Team in Boston,' Intellectual Property Magazine - April 20, 2021, featured

'News Digest: On the Move,' World Trademark Review - April 20, 2021, featured

'6 Important Elements Of The New STRONGER Patents Act,' Biosimilar Development - January 2020

'FDA Approval and Licensing as Intellectual Property,' Chapter in MCLE publication, Intellectual Property Law - January 2020

'Working the Busy Intersection of Law, Science and Business,' Corporate Counsel Business Journal - March 2019

'The ABCs of a Product Recall,' Focus Newsletter - December 2014

'Maybe it's not the real thing,' Pom Wonderful LLC v Coca-Cola Co (Supreme Court of the US) Case Analysis: Intellectual Property Magazine - July/August 2014

'State-by-State Clinical Trial Requirements Reference Guide 2013,' Barnett Educational Services, 2013

'Flurry of Supreme Court Decisions Keeps Local IP Bar Busy,' Massachusetts Lawyers Weekly, July 2014, quoted

'Managing the Risks and Regulatory Issues Associated with Successful Pharmaceutical Social Media Monitoring and Marketing,' White Paper, September 2007

## Admissions

Massachusetts

United States District Court for the District of Massachusetts

U.S. Patent and Trademark Office

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## Education

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

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

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## Languages

English

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## Memberships

Greater Boston Chamber of Commerce Life Sciences Alliance

Boston Patent Law Association

Boston Bar Association

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## Key dates

Year joined: 2021

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