



Sarah Cooleybeck

Partner

Boston

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Sarah Cooleybeck, a partner in the firm's Business Department, has a broad life sciences practice that includes negotiation of complex licensing and collaboration agreements, intellectual property and licensing advice, and Hatch-Waxman and related regulatory strategy.

Sarah drafts and negotiates patent licenses, supply, manufacturing and quality agreements, collaboration and co-development agreements, and other strategic alliances, for both established and emerging companies. Sarah's licensing work is complemented by her in-depth knowledge of the regulatory environment in which life sciences companies operate, and by her patent litigation experience.

Sarah handles applications for Hatch-Waxman patent term extensions (PTE), requests for regulatory data exclusivity, citizen petitions, comments on draft FDA guidance, and other FDA regulatory matters. She also advises clients on patent disputes, including ANDA/Paragraph IV strategy, as well as disputes arising out of license and collaboration agreements.

With substantial Legal Project Management training and experience, Sarah ensures that her legal work is aligned with clients' business goals and budgets. She serves on the firm's Associate Review Committee.

BAR ADMISSIONS

- Massachusetts

COURT ADMISSIONS

- U.S. District Court for the District of Massachusetts
- U.S. Court of Appeals for the First Circuit
- U.S. Court of Appeals for the Federal Circuit

REPRESENTATIVE EXPERIENCE

- Represented Ginkgo Bioworks, Inc. in a collaboration and license agreement with Biogen (Nasdaq: BIIB) to develop a next-generation recombinant adeno-associated virus (AAV) production platform.

INDUSTRIES

Life Sciences

Healthcare

PRACTICES

Licensing & Strategic Alliances

Intellectual Property Litigation

Patent Prosecution, Strategy & Management

FDA

Patent, Trade Secrets & Related Rights Litigation

EDUCATION

Harvard Law School, J.D., *cum laude*, 1995

University of Michigan, A.B., *high honors*, 1990

- Drafted and negotiated a broad range of licensing, collaboration, co-development and option agreements for medical device, pharmaceutical, biotechnology and other clients, including:
 - ▶ Represented global biopharmaceutical company Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) in a partnership with Complement Pharma to co-develop a pre-clinical C6 complement inhibitor for neurodegenerative disorders
 - ▶ Represented Homology Medicines to license gene editing platform technology from [City of Hope](#) and AAV technology from Caltech
 - ▶ Advised medical diagnostics company Alere Inc. on licensing and intellectual property matters associated with potential sale of health care division
 - ▶ Negotiated licenses, sponsored research agreements, material transfer agreements, and options with academic institutions including MIT, Stanford, Michigan State, Yale, Columbia and Caltech
- Drafted and negotiated dozens of U.S. and international manufacturing, supply, quality, and distribution agreements in the life sciences industry, including:
 - ▶ Negotiated development, supply and distribution agreements for robotic surgical instruments on behalf of the U.S. subsidiary of a major Japanese conglomerate
 - ▶ Advised start-up company regarding agreements for development of device manufacturing processes, and manufacture and optimization of drug-filling equipment and processes
 - ▶ Represented drug delivery company on license of drug delivery device technology and related multi-party device and drug product supply agreements
- Advised and represented life sciences companies on Hatch-Waxman, Paragraph IV, FDA regulatory, and related patent and licensing issues, including:
 - ▶ Represented pharmaceutical companies in seeking Hatch-Waxman patent term extension and FDA regulatory exclusivity
 - ▶ Represented large biotechnology company in various disputes arising out of complex collaboration and license agreements
 - ▶ Advised health care company in connection with Paragraph IV patent infringement litigation against generic drug companies regarding therapeutic drug for end-stage renal disease, and resolved dispute regarding supply agreement for same drug

HONORS & INVOLVEMENT

Honors

- Harvard Law School, Harvard Law Review, Editor
- Served as a law clerk to Judge Patti B. Saris of the United States District Court for the District of Massachusetts

Involvement

- Board Member, Boston IP American Inn of Court
- Boston Patent Law Association

- Boston Bar Association
- American Intellectual Property Law Association (AIPLA)

PUBLICATIONS

- Co-author "Checklist for Life Sciences Licensing and Development Agreements" *Drafting & Negotiating Joint Venture, Licensing, Co-Development, Marketing & Distribution Agreements* (MCLE, Inc. 2014)
- "Current Issues in Hatch-Waxman Litigation: Moving Beyond the *Caraco* Dispute to the Question of Induced Patent Infringement in the Marketplace," *The IP Legal Browser* (Winter 2012)

SPEAKING ENGAGEMENTS

- "Overview of Patent and Trademark Issues: IP Protection for Drugs and Biologics" at American Conference Institute (ACI) FDA Boot Camp (Sept. 2012)
- "Marketing Exclusivities (Non-Patent): Challenges, Opportunities, and Current Controversies" at American Conference Institute (ACI) FDA Boot Camp Master Class (Sept. 2012)