

Nicole R. Sullivan, Ph.D.

Partner

New York

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Nicole provides clients of all sizes and stages of drug discovery with the guidance they need to obtain, protect, and manage their intellectual property assets. Clients trust Nicole to advise them on challenging intellectual property issues, relying on her strong legal and scientific knowledge and pharmacology and biomedical sciences training.

OVERVIEW

Nicole counsels clients regarding worldwide patent portfolio management and strategic development. Her practice involves domestic and international patent drafting and prosecution focused primarily in biotechnology, pharmaceutical, bioengineering biologics, and life sciences. Nicole's practice also involves due diligence investigations as well as freedom to operate and patentability opinions. In addition, her practice also includes litigation, including Hatch-Waxman litigation, and *inter partes* review proceedings.

Prior to practicing law, Nicole was a scientific advisor at an international patent law firm, and a senior research scientist at Wyeth Pharmaceuticals. At Wyeth, she worked in research and development in the Department of Pain's Molecular Pharmacology Group and served as a program leader for two drug discovery targets.

Nicole is co-author of several peer-reviewed scientific articles and has presented her research at national and regional scientific conferences. She also received a Pharmaceutical Research and Manufacturers of America Foundation's Advanced Predoctoral Fellowship in Pharmacology/Toxicology to support her predoctoral thesis work.

REPRESENTATIVE MATTERS

Freedom to operate for:

- Clearance of cellular immunotherapy platforms for major and mid-sized biotech companies.
- Clearance of viral delivery platforms for major and mid-sized pharmaceutical and biotech companies.
- Clearance of clinical phase II and III large and small molecules for major and mid-sized pharmaceutical and biotech companies.
- Clearance of vaccine platforms for major and mid-sized biotech companies.
- Clearance of antibody and antigen binding molecules for major and mid-sized pharmaceutical and biotech companies.

- Clearance of chimeric antigen receptor molecule structure for major and mid-sized biotech companies.
- Clearance of viral purification strategies for major and mid-sized pharmaceutical and biotech companies
- Clearance of cell culture methods for major and mid-sized pharmaceutical and biotech companies.

Conducted due diligence for:

- A major pharmaceutical company on its \$6.5 billion acquisition of a biotechnology company focused on treatment for hereditary angioedema (HAE).
- A major pharmaceutical company in its \$5.2 billion acquisition of a pharmaceutical company that specializes in treatments for rare diseases.
- A major pharmaceutical company in the sale of its oncology portfolio, which totaled \$2.4 billion.
- A major pharmaceutical company in its \$300 million acquisition of molecules for the treatment of degenerative eye diseases.
- A major pharmaceutical company in its \$260 million acquisition of a pharmaceutical company that specializes in treatments for rare diseases.
- A major pharmaceutical company in its \$160 million acquisition of an ophthalmology company.

Critical IP strategy and litigation experience includes:

- Managing and prosecuting global patent portfolios for small and large therapeutic molecules, vaccines, viral and cellular immunotherapies, medical devices, and genetically modified plants.
- Successfully prosecuting a global patent portfolio for a multibillion-dollar abuse-resistant small molecule product for the treatment of ADHD.
- Successfully prosecuting an extensive family of key Orange Book patents for a multibillion-dollar abuse-resistant product for the treatment of pain.
- Preparing noninfringement and invalidity opinions in small molecule, large molecule, and viral and cellular immunotherapy areas.
- Successfully defending multiple *inter partes* review proceedings brought by generic drug companies against a client's Orange Book patents covering a billion-dollar drug formulation for treating ADHD.
- Performing strategic planning and litigation for pharmaceutical companies in abbreviated new drug application (ANDA) litigation.
- Successfully defending a major pharmaceutical company in trade secret litigation involving ophthalmology clinical trials.

TOP AREAS OF FOCUS

- Academic + Research Institutions
- Health Care + Life Sciences
- Health Care + Life Sciences Intellectual Property
- Intellectual Property
- Patent Litigation
- Patent Prosecution, Counseling + Portfolio Management

ALL AREAS OF FOCUS

- Academic + Research Institutions
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Health Care + Life Sciences

- Health Care + Life Sciences Intellectual Property
- Intellectual Property
- Litigation + Trial
- Patent Litigation
- Patent Prosecution, Counseling + Portfolio Management

EDUCATION AND CERTIFICATIONS

EDUCATION

- Fordham University School of Law, J.D., 2012
- The University of Texas Health Science Center at San Antonio, Ph.D., 2001, pharmacology
- Baylor University, B.S., 1994, neuroscience

BAR ADMISSIONS

- New Jersey
- New York
- U.S. Patent and Trademark Office

COURT ADMISSIONS

- U.S. District Court, District of New Jersey

SPEAKING ENGAGEMENTS

- Speaker, “Issues Raised by Research Tool Patents,” CLE Presentation, October 2021.
- Speaker, “Patents 101: What Every Start-Up Needs to Know,” 2021 Life Sciences Future – MedTech Conference, July 16, 2021.
- Speaker, “Legal Standards of the On-Sale Bar and Prior Use Defense,” CLE Presentation, July 2021.
- Speaker, “Intellectual Property for Innovators Lecture Series,” St. Jude Lecture Series, April 2021.
- Speaker, “Startups and Life Science Patent Strategies,” SBDC @ UCI Beall Applied Innovation, March 17, 2021.
- Speaker, “Intellectual Property for Innovators Lecture Series,” New York University Lecture Series, October 2020.
- Speaker, “Patently Obvious – Inherency, Double Patenting, and AI,” CLE presentation, July 24, 2020.
- Speaker, “Battle Over CRISPR the Road Ahead,” St. Jude, May 12, 2017.
- Speaker, “NYC Bio’s Supreme Court Myriad Decision Panel Discussion,” July 2013.
- Speaker, “Lunch and Learn Discussing the Supreme Court’s Decisions in *Association for Molecular Pathology v. Myriad Genetics* and *Federal Trade Commission v. Actavis, Inc.*,” Novo Nordisk, June 2013.

PUBLICATIONS

- Co-author, “New York Narrows the Scope of Employee “Invention Assignment” Provisions,” *Troutman Pepper*, October 12, 2023.