

Practice Areas

- Intellectual Property
- Patents

Honors

- *Benchmark Litigation*; Litigation Star (2019 – 2024)
- *Chambers USA*; Leading Lawyer (2021 – 2024)
- *Managing Intellectual Property IP Star*; Patent Star (2019 – 2024)
- *Benchmark Litigation*; Top 250 Women in Litigation (2018 – 2024)
- *Crain's New York Business*; Notable Women in Law (2021)
- *World IP Review*; WIPR Leader (2024)
- *Best Lawyers in America*, Litigation - Intellectual Property, Litigation - Patent (2025)

Education

- J.D., Fordham University School of Law, 2003, *magna cum laude*; *Order of the Coif*
- Ph.D., Biology, Massachusetts Institute of Technology, 1998, *National Science Foundation Fellow*
- B.A., Biological Sciences, University of Chicago, 1992, *Phi Beta Kappa*

Memberships

Irena Royzman, Ph.D.

Partner

New York

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Irena Royzman is a nationally recognized life sciences IP litigator, representing pharmaceutical and biotechnology innovators in their highest stakes disputes.

With a Ph.D. in biology from MIT and the Whitehead Institute, where she was a NSF fellow, Irena represents plaintiffs and defendants in their most complex pharmaceutical and biotech patent cases. Over the last 20 years, pharmaceutical and biotechnology innovators have relied on Irena again and again for cases involving small molecules, biologics, recombinant DNA technology, gene therapy, gene editing, manufacturing processes, formulations and drug-eluting medical devices, including numerous multi-billion dollar cases involving many of the world's best-selling drugs.

Irena has significant experience in litigation under the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA), as well as *inter partes* review (IPR) proceedings, license disputes and matters with parallel ex-U.S. litigation and proceedings in foreign patent offices. Irena also helps life sciences companies and organizations develop the law in the most important cases for the biopharma industry. She has been principal counsel on numerous amicus briefs to the United States Supreme Court and the Federal Circuit in key biopharma cases.

For plaintiffs, Irena has successfully defended generic challenges to patents protecting blockbuster medical therapies, including multi-billion dollar cancer, antiviral and anti-psychotic drugs. She has also represented an innovator in some of the first cases under the BPCIA, including the first involving an antibody. For defendants, she defeated a \$530 million claim of patent infringement of a competitor's biotech patent, obtaining dismissal of all claims and discovery sanctions against the patent owner. In another high-stakes case, she obtained summary judgment of noninfringement and exclusion of plaintiff's experts under *Daubert* as well as a full award of attorneys' fees.

A registered patent attorney, Irena also handles *inter partes* review (IPR) proceedings. For patent owners, she has obtained denial of IPR for patents protecting blockbuster drugs and has leveraged IPR for defendants to obtain freedom to operate.

Irena also coordinates U.S. proceedings with parallel ex-U.S. litigation and proceedings in foreign patent offices, recently obtaining freedom to operate for a biotech innovator's gene therapy. She provides strategic counseling in biologics and pharmaceuticals and advises clients on their IP portfolios and

- American Chemical Society
- American Intellectual Property Law Association, Amicus and Biotechnology Committee
- New York Intellectual Property Law Association, Board Member, Board Liaison for Amicus Briefs Committee, Co-Chair of Amicus Briefs Committee (2015 – 2017, 2020-present)
- Intellectual Property Owners Association, Pharmaceutical and Biotechnology Issues Committee

transactions. Irena also represents clients in high-stakes license disputes involving biotech patents, and, in a dispute concerning the use of a recombinant protein as an enzyme replacement therapy, obtained one of the largest settlement awards over the life of the contract.

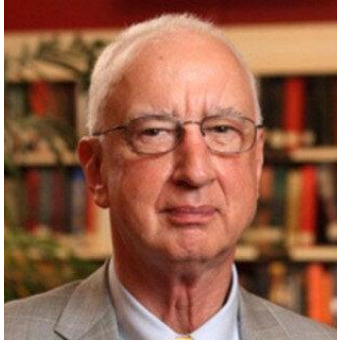
Chambers USA has recognized Irena as a leading lawyer in intellectual property, where clients have described her as “excellent,” “knowledgeable, aggressive” and “an incredibly smart lawyer.” *Benchmark Litigation* named her one of the “Top 250 Women in Litigation” for the last seven years and a litigation star in intellectual property in New York. Irena was also named to the *Crain’s New York Business* 2021 list of Notable Women in Law.

Irena writes and lectures widely on biopharma patent issues and biosimilar litigation. Irena also is frequently quoted on patent-related issues, including in the *Washington Post*, *Financial Times*, *Nature Biotechnology* and *Pink Sheet*.

Representative Engagements

Patent Litigation - Hatch-Waxman

- Representing a major pharmaceutical company in an ANDA action involving challenges by multiple generic companies to patents protecting a blockbuster four-drug fixed-dose combination for the treatment of HIV infection.
- Representing a major pharmaceutical company in an ANDA action involving challenges by a generic company to four patents protecting a blockbuster cancer therapy. After trial, the district court rejected all the invalidity theories for each of the patents and the Federal Circuit affirmed.
- Successfully represented two pharmaceutical innovator companies in ANDA actions involving challenges by multiple generic manufacturers to formulation and manufacturing patents protecting a cancer therapy. After several of the defendants abandoned their invalidity and non-infringement theories and converted their PIV certification to a Paragraph III certification, obtained an injunction enjoining defendants from infringing the patents through their expiration and a report and recommendation finding the case to be exceptional for discovery misconduct and warranting attorneys’ fees.
- Successfully represented a major pharmaceutical company in ANDA actions involving challenges by multiple generic manufacturers to patents protecting a breakthrough treatment for cGVHD and certain B-cell cancers.
- Successfully represented a pharmaceutical innovator in a patent infringement action against a 505(b)(2) applicant involving a long-acting treatment for schizophrenia and bipolar disease.
- Successfully represented a major pharmaceutical company in an ANDA action involving challenges to eight patents protecting a combination drug treatment for HIV/AIDS.
- Successfully represented a major pharmaceutical company in an ANDA action involving challenges by multiple defendants to patents covering the crystalline form and processes for the manufacture of a blockbuster drug. Obtained summary judgment



Hon. Paul R. Michel (Ret.) – United States Court of Appeals for the Federal Circuit

The Honorable Paul Redmond Michel was appointed to the United States Court of Appeals for the Federal Circuit in March of 1988 by President Ronald Reagan. On December 25, 2004, he assumed the duties of Chief Judge. After his elevation to Chief Judge, he served as one of 27 judges on the Judicial Conference of the United States, the governing body of the Judicial Branch. In 2005 he was appointed by Chief Justice Rehnquist to also serve on the Judicial Conference's seven-judge Executive Committee. On May 31, 2010, Chief Judge Michel stepped down from the bench after serving more than 22 years on the court.

In his years on the bench Judge Michel judged thousands of appeals and wrote over 800 opinions, approximately one-third of which were in patent cases.

Prior to his appointment to the bench, Judge Michel was assistant district attorney in the Office of the Deputy District Attorney for Investigations in Philadelphia from 1966-74, as well as a Second Lieutenant in the United States Army Reserve from 1966-72. From 1974-75, he was the Assistant Watergate Special Prosecutor, and from 1975-76 was assistant counsel to the United States Senate Select Committee on Intelligence. He then became the deputy chief and Koreagate prosecutor for the Public Integrity Section of the United States Department of Justice from 1976-88. He was the associate deputy U.S. attorney general in 1978 and in 1981 became counsel and administrative assistant to U.S. Senator Arlen Specter until his judicial appointment. He has served as adjunct faculty at several institutions of higher education including the George Washington University Law School and John Marshall Law School. In 2012 he joined the Intellectual Property Advisory Council at the University of Akron School of Law.

Judge Michel has been the recipient of numerous awards and was in the inaugural class of the IPWatchdog Masters™ Hall of Fame. He has also received awards including the Jefferson Medal, the Frederico Award, the Katz-Kiley Prize, the Eli Whitney Prize, the Sedona Conference® Lifetime Achievement Award, and awards by the ABA Section of Intellectual Property, AIPLA, IPO, the Linn Intellectual Property American Inn of Court, and other leading organizations. He was named one of the 50 most influential leaders in intellectual property in the world by Managing Intellectual Property magazine and inducted into Intellectual Asset Management magazine's International Hall of Fame.

A frequent speaker on IP subjects, he has also testified before Congress on patent reform legislation and has served as Special Advisor to the Patent Reform Task Force.

Judge Michel earned his B.A. from Williams College in 1963 and his J.D. from the University of Virginia in 1966.



Paul A. Coletti – Johnson & Johnson

Paul Coletti is Vice President, MedTech Intellectual Property strategies and Associate Patent Counsel for Johnson & Johnson, where he has worked since 1987. Paul's practice extends over all fields of patent law, including prosecution, litigation, and client counseling. He is also active in various patent and industry organizations, such as the USTR Industry Trade Advisory Committee for Intellectual Property, the US Chamber of Commerce, IPO, AIPLA and AdvaMed, and serves on the EPO-US Bar Liaison Committee, for which he is a past Chair.

Paul has a BS in Mechanical Engineering (1980) from Polytechnic Institute of New York (now part of NYU); an MS (1981), also in Mechanical Engineering from Purdue University; and a JD (1985) from the University of Notre Dame. Prior to joining J&J, Mr. Coletti served as an associate in a patent boutique in Chicago, where he dealt with all aspects of intellectual property law. He was employed for a time as an Member of Technical Staff at AT&T Bell Laboratories.



Larry Coury - Regeneron Pharmaceuticals, Inc.

Larry Coury is Vice President, Litigation and Dispute Resolution, at Regeneron Pharmaceuticals, Inc. in Tarrytown, NY.

Larry oversees a group of 17 people that run government investigations, general commercial litigation, patent litigation, legal technology, records management, and eDiscovery. His responsibilities for patent matters include litigation as well as post-grant review proceedings in the United States and foreign patent offices. Regeneron has a number of patent matters and litigations pending in various countries throughout North America, Europe, Asia, South America, and Australia.

Prior to joining Regeneron, Larry worked for 16 years in private practice at Fish & Neave, Paul Weiss, and Cravath.

Larry received his B.S. in Chemistry from the Massachusetts Institute of Technology, his Ph.D. in Biophysics from Harvard University, and his J.D. from Fordham Law School, where he was editor of the Intellectual Property Law Journal.

Larry is admitted to practice in the NY and CT state courts, the USPTO, various federal district courts, the Court of Appeals for Federal Circuit, and the United States Supreme Court.