



Khushbu Shah

Associate

New York

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Khushbu Shah is a life sciences patent litigator who represents pharmaceutical and biotechnology innovators in complex, high-stakes patent disputes.

Education

- J.D., Fordham University School of Law, 2024, Cum Laude; Ruth Whitehead Whaley Scholar; Staff member, *Fordham Intellectual Property, Media & Entertainment Law Journal*
- Ph.D., Medicinal Chemistry, Duquesne University, 2017, AAPS Graduate Student Award; Rho Chi Pharmacy Honor Society; Graduate Student Award for Excellence in Teaching

Memberships

- South Asian Bar Association of New York
- New York Intellectual Property Law Association

Dr. Khushbu Shah is a life sciences patent litigator with deep technical and legal expertise spanning small molecules and biologics. She represents leading pharmaceutical and biotechnology innovators in high-stakes U.S. litigation and complex multi-jurisdictional patent disputes.

Dr. Shah possesses in-depth technical knowledge of biologics and their development. Combined with her training in formulations and doctoral training in medicinal chemistry, where she synthesized and characterized dozens of novel compounds including Pemetrexed analogues, she brings a scientist's precision to patent litigation strategy. Her scientific background informs her understanding of both chemical and biological inventions, from synthesizing complex small molecules and peptides to analyzing antibody sequences and gene therapy vectors.

She has been part of litigation teams that have successfully defended major biopharma clients against coordinated challenges by multiple generic manufacturers to patents protecting multi-billion-dollar blockbuster therapies. Her practice also includes advising on pre-litigation patent strategy, conducting freedom-to-operate and validity analyses, and coordinating worldwide opposition and defense campaigns for products at all stages of development. She has counseled on complex patent landscapes for CAR-T therapies, gene therapy products, and other cutting-edge biologics.

Representative Engagements

- Successfully represented a major pharmaceutical company in defending patents covering a four-drug fixed-dose combination for treatment of HIV infection.
- Assisted in litigation involving a series of ANDA actions involving multiple generic challengers to patents protecting a blockbuster small molecule cancer drug.
- Represented two biopharma innovator companies in infringement actions involving a rare cancer therapy under the Hatch–Waxman Act (both ANDA and Section 505(b)(2)).
- Developed a global patent strategy, including European oppositions, for a biologic drug in key foreign jurisdictions.

- Advised on and assisted in implementing a global patent strategy (U.S. and ex-U.S.) for a biologic therapy, covering both defensive and enforcement-oriented approaches.
- Conducted IP due diligence for a CAR-T product, assessing the competitive landscape, and litigation strategy.

Languages

- Gujarati
- Hindi
- English

Admissions

- New York