

Sanya Sukduang

Partner



ssukduang@cooley.com

+1 202 776 2982

Washington, DC

Intellectual Property
Intellectual Property Litigation
Life Sciences IP Litigation
Patent Office Litigation
Agricultural Sciences and Technology
Hatch-Waxman Litigation
Life Sciences

Sanya has more than 20 years of experience litigating life sciences patent disputes, including Hatch-Waxman abbreviated new drug application (ANDA) challenges for brand drug manufacturers, biological products and medical devices. Drawing from extensive litigation experience, Sanya also advises clients on an array of pre-litigation and acquisition due diligence investigations, as well as strategic patent portfolio planning.

Sanya concentrates on patent litigation before federal district courts and the US Court of Appeals for the Federal Circuit, as well as post-grant proceedings before the Patent Trial and Appeal Board (PTAB) of the US Patent and Trademark Office (USPTO), primarily in the areas of biotechnology, pharmaceuticals, biologics, diagnostics and medical devices. He has conducted all aspects of pre-trial, trial, post-trial and inter partes review (IPR) proceedings before the PTAB.

Sanya frequently lectures in the US and abroad on topics such as Hatch-Waxman litigation and biologics and biosimilars issues arising under the Biologics Price Competition and Innovation Act (BPCIA). He also has authored numerous articles on these topics. Sanya is the recipient of various awards and nominations, including repeated recognition as an IP Star by Managing Intellectual Property and as an Intellectual Property Life Science Star by LMG Life Sciences, along with multiple nominations for its General Patent Litigator of the Year – DC Metro award.

Sanya is committed to strengthening diversity within the firm and throughout the legal profession, and the National Asian Pacific American Bar Association ranked him on its 2013 Best Lawyers Under 40 list. He previously served as adjunct professor of patent law at the Howard University School of Law, and teaches Hatch-Waxman and BPCIA litigation at the American University Washington College of Law.

As part of his pro bono practice, Sanya served as lead trial and appellate counsel in an adoption proceeding, successfully assisting a foster mother's efforts to adopt her 3-year-old foster daughter.

Sanya's recent representative experience includes serving as:

- Lead counsel successfully representing **Horizon** against ANDA filer Dr. Reddy's in Hatch-Waxman litigation concerning Horizon's RAYOS product (prednisone) for the treatment of rheumatological diseases, resulting in a favorable settlement for Horizon – ***Horizon Therapeutics USA et al. v. Dr. Reddy's Laboratories et al.***
- Lead counsel representing **Liquidia** in trade secret case before the North Carolina Business Court brought by United Therapeutics concerning the development of PAH drugs – ***United Therapeutics Corporation et al. v. Liquidia Technologies, Inc.***
- Counsel for **Inovio Pharmaceuticals** in a contract and trade secret case against VGXI before the Pennsylvania Court of Common Pleas concerning plasmid DNA manufacturing technology – ***Inovio***

Pharmaceuticals, Inc. v. VGXI, Inc. et al.

- Trial counsel for **Thermo Fisher** in a breach of contract dispute against Arranta Bio concerning the manufacture of a proposed COVID-19 vaccine in the Delaware Court of Chancery – ***Thermo Fisher Scientific PSG Corp. v. Arranta Bio MA, LLC***
- Lead counsel representing **Horizon** against ANDA filer Apotex in Hatch-Waxman litigation concerning its Pennsaid 2% product (diclofenac sodium) for the treatment of osteoarthritis – ***Horizon Medicines LLC et al. v. Apotex Inc. et al.***
- Lead counsel representing **Vifor** in patent infringement litigation concerning the iron replacement product Injactafer – ***Biofer S.p.A. v. Vifor (International) AG***
- Counsel representing **Scilex** in Hatch-Waxman litigation concerning its ZTLido product for the treatment of pain associated with post-herpetic neuralgia – ***Scilex Pharmaceuticals, Inc. et al. v. Aveva Drug Delivery Systems, Inc. et al.***
- Lead counsel successfully representing **Liquidia** in Hatch-Waxman litigation and several IPR proceedings concerning its 505(b)(2) new drug application for inhaled powder Yutrepia (treprostinil) for the treatment of pulmonary arterial hypertension, resulting in invalidation of UTC's patents and clearing the way for Liquidia's launch – ***United Therapeutics Corporation v. Liquidia Technologies, Inc.***
- Lead counsel representing **Journey Medical** against ANDA filer Perrigo in Hatch-Waxman litigation concerning its Zilxi product for the treatment of rosacea, its Amzeeq product for the treatment of acne, and its Qbrexza product for the treatment of primary axillary hyperhidrosis, resulting in a favorable settlement for Journey and preserving its market exclusivity – ***Journey Medical Corporation et al. v. Perrigo Pharma International DAC***
- Lead counsel obtaining a favorable settlement for **Journey Medical** in Hatch-Waxman litigation against Teva concerning its Qbrexza product for the treatment of primary axillary hyperhidrosis – ***Journey Medical Corporation et al. v. Teva Pharmaceuticals, Inc. et al.***
- Lead counsel representing **Varun Gupta** in a trade secret misappropriation claim brought by Intel, resulting in successful resolution
- Lead counsel representing defendant **CSL Behring** in patent litigation concerning its biologic Haegarda for the prophylactic prevention of hereditary angioedema, resulting in a highly favorable settlement for CSL maintaining Haegarda on the market – ***Shire ViroPharma Inc. v. CSL Behring LLC****
- Co-lead counsel representing **Allergan** and **Pierre Fabre** against multiple generic drug manufacturers in ANDA litigation for their Fetzima (levomilnacipran) product for the treatment of major depressive disorder – ***In re Fetzima****
- Counsel representing **Biogen** in ANDA litigation against 27 generic drug manufacturers in multiple jurisdictions concerning its Tecfidera (dimethyl fumarate) product for the treatment of relapsing forms of multiple sclerosis – ***Biogen International GmbH et al. v. Amneal Pharmaceuticals LLC et al.****
- Lead counsel representing **ConforMIS** in 16 IPRs related to patient-specific surgical tools, resulting in successful resolution and leading to non-institution decisions in several proceedings – ***Smith & Nephew, Inc. v. ConforMIS, Inc.****
- Co-lead counsel successfully representing **Forest Labs** at trial and on appeal against multiple generic drug manufacturers in ANDA litigation for its Saphris (asenapine) product for the treatment of schizophrenia and bipolar disorder – ***Forest Laboratories, LLC v. Sigmapharm Laboratories, LLC****
- Co-lead counsel successfully representing **Forest Labs** at trial and on appeal against multiple generic drug manufacturers in ANDA litigation for its Savella (milnacipran) product for the treatment of fibromyalgia, resulting in a finding of infringement and validity of all asserted claims – ***Forest Laboratories Inc. et al. v. Apotex Corp. et al.****
- Lead litigation counsel representing **Antares** in litigation involving allegations of infringement concerning

its Otrexup (subcutaneously injectable methotrexate), resulting in a successful settlement for Antares – ***Medac Pharma, Inc. et al. v. Antares Pharma, Inc. et al.****

- Counsel representing **Syngenta** in patent litigation involving glyphosate-resistant transgenic corn (GA21), leading to summary judgment of noninfringement and patent invalidity later affirmed by the US Court of Appeals for the Federal Circuit – ***Monsanto Co. v. Syngenta Seeds****
- Counsel representing **Eli Lilly** against several ANDA filers seeking FDA approval to market generic versions of its Cymbalta in Hatch-Waxman patent infringement litigation; the US District Court for the Southern District of Indiana entered judgment before trial in favor of Eli Lilly and against all the ANDA filers on all issues, resulting in orders and judgment maintaining Cymbalta's market exclusivity through the end of its patent life – ***Eli Lilly and Company v. Wockhardt Ltd.****
- Counsel representing **Acura** against several generic drug manufacturers in ANDA litigation concerning its Oxecta abuse-deterrent oxycodone product, resulting in a successfully negotiated settlement prior to trial – ***Acura Pharmaceuticals, Inc. v. Sandoz****
- Lead counsel representing **ConforMIS** in a case related to customizable knee implants, resulting in a successful settlement for the defendant – ***Bonutti Skeletal Innovations, LLC v. ConforMIS, Inc.****
- Lead counsel representing **Antares** in litigation involving issues on a patent directed toward the use of its Otrexup to treat autoimmune diseases, resulting in institution of an IPR and ultimately obtaining settlement of all IPR and litigation matters – ***Antares Pharma, Inc. v. Medac Pharma, Inc.****
- Lead litigation and ex parte reexamination counsel representing **Health Diagnostic Laboratory** in a suit brought by an exclusive licensee related to SLC01B1 genetic tests for statin-induced myopathy – ***Boston Heart Diagnostics Corporation v. Health Diagnostic Laboratory, Inc.****
- Lead counsel successfully representing **Health Diagnostic Laboratory** in an IPR brought by Boston Heart Diagnostics related to HDL's patent directed toward screening methods for pre-diabetes, resulting in the PTAB denying institution of the petition*
- Member of trial (equitable issues) and appellate team representing **Eli Lilly**, resulting in a landmark en banc opinion of the Federal Circuit confirming the existence of a separate written description requirement and overturning a \$65 million damages award*
- Counsel representing **GlaxoSmithKline** in litigation involving multiple ANDA challenges to Orange Book-listed patents covering its Paxil pharmaceutical product – ***GlaxoSmithKline v. Alphapharm****
- Interference and appellate counsel representing **Chen (Aventis)** in an interference proceeding, successfully prosecuting the anti-cancer taxane small molecule interference and prevailing at the USPTO and the Federal Circuit – ***Chen v. Bouchard****
- Trial and appellate counsel representing **Galderma** against generic drug manufacturers asserting multiple invalidity and unenforceability defenses in ANDA litigation, resulting in a district court ruling maintaining patent protection for Galderma's Differin 0.3% gel*
- Trial counsel representing the **Genetics Institute** in a 35 USC § 291 action related to truncated Factor VIII – ***Genetics Institute LLC v. Novartis Vaccines and Diagnostics, Inc.****

* Representation handled prior to joining Cooley

Publications and media

- Co-author of "[FTC Issues Antitrust Warning Against 'Improper' Orange Book Patent Listings](#)," Cooley alert, October 2023
- Co-author of "[Federal Circuit's In re Cellect Decision Deals Blow to Patent Term Adjustment](#)," Cooley alert, October 2023
- Co-author of "[Orange Book Transparency Act Creates Some New Obligations](#)," Cooley alert, January

2021

- Co-author of "[New Law Establishes Purple Book Patent Disclosure Requirement](#)," Cooley alert, January 2021
- Co-author of "[FDA Opens Useful Dialogue on Orange Book Patent Listings](#)," Law360, June 2020
- Co-author of "[2019 Patent Law Decisions of the Federal Circuit](#)," American University Law Review, Volume 69, Issue 4, April 2020
- Co-author of "[Inter Partes Review in Generic Drug Litigation – Why the USPTO Should Exercise Its Discretion to Deny IPR Petitions in Appropriate Hatch-Waxman Disputes](#)," pharmaphorum, March 2014
- Quoted in "[Adapt or Die: How to Survive the Patent Cliff](#)," Life Sciences Intellectual Property Review, October 2013
- Co-author of "[Drug Patents Under Fire in Brazil](#)," Pharmaceutical Executive, June 2013
- Co-author of "Assessing Materiality and Intent in a Post-*Therasense* World," Bureau of National Affairs' Patent, Trademark & Copyright Journal, Volume 85, Number 522, February 2012
- Author of "FDA's Proposed Performance Goals for Biosimilar Applications May Provide Some Certainty for Biologics Companies," Bloomberg Law Reports, June 2011
- Co-author of "[Follow-On Biologics: Is Your Patent Portfolio Ready?](#)" Law360, March 2010
- Co-author of "[Follow-on Biologics: A Patent Litigation Perspective](#)," Pharmaceutical Commerce, August 2009

Speaking engagements

- Co-presenter, "[505\(b\)\(2\) Applications and Beyond: Prosecution and Litigation Strategies for Filing and Defending Against 505\(b\)\(2\) NDAs](#)," Cooley Rx series, October 2024
- Co-presenter, "[Weathering the Storm: In Search of a Safe Harbor](#)," Cooley at Mass Bio – Life Sciences IP Seminar, September 2023
- Co-presenter, "[Patent Claiming Strategies Do's and Don'ts](#)," Cooley Rx series, February 2023
- Co-presenter, "[Weathering the Storm: In Search of a Safe-Harbor](#)," Consero IP Forum for Life Sciences, December 2022
- Presenter, "[The Freedom to Operate Opinion: Practical Advice and Winning Strategies for Innovation and Negotiation](#)," ACI Life Sciences Due Diligence Conference, November 2022
- Presenter, "[The Future of Inducement Claims in the Hatch-Waxman Context: Reconciling the Demarcation Between Describing and Infringing Use and Encouraging That Use in a Label](#)," ACI Paragraph IV Conference, April 2022
- Presenter, "[Hatch-Waxman 101: The Skinny on 'Skinny Labeling](#)," Cooley CLE Speaker Series, January 2022
- Co-presenter, "[Hatch-Waxman 101: Safe Harbor](#)," Cooley webinar, October 2021
- Presenter, "[Analyzing the Difference in Pharmaceutical IP Litigation in Relation to Orphan Drugs](#)," Strategy Summit on Paragraph IV Litigation, September 2021
- Co-presenter, "[Hatch-Waxman 101: Pre-Suit Investigation and Diligence](#)," Cooley webinar, June 2021

Education

Washington College of Law American University
JD, 1999

Boston College
BS, 1996

Admissions & Credentials

District of Columbia

Maryland

US Patent and Trademark Office

Court Admissions

US Court of Appeals for the Federal Circuit

Rankings & Accolades

LMG Life Sciences: Shortlisted for General Patent Litigator of the Year – DC Metro (2016, 2017, 2021)

The Legal 500 US: Healthcare: Life Sciences (2021)

The Legal 500 US: Patents: Litigation (2021)

IAM Media: IAM Patent 1000 List for Patent Litigation (2018 – 2023)

LMG Life Sciences: Life Science Star – Intellectual Property (2012 – 2023)

Managing Intellectual Property: Shortlisted for Outstanding Litigator: District of Columbia (2017)

Managing Intellectual Property: IP Star (2022 – 2023)

National Asian Pacific American Bar Association: Best Lawyers Under 40 (2013)

Eli Lilly and Company: Quality Advocate Award (2011)

Memberships & Affiliations

American Intellectual Property Law Association

National Asian Pacific American Bar Association

Thai American Bar Association