

# Jonathan Davies

#### **Partner**



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Washington, DC

Intellectual Property
Intellectual Property Litigation
Life Sciences IP Litigation
Hatch-Waxman Litigation

Jonathan's practice focuses on patent litigation, with an emphasis on pharmaceutical and biotechnology cases, including Hatch-Waxman litigation related to abbreviated new drug applications (ANDAs) and biologics litigation under the Biologics Price Competition and Innovation Act (BPCIA).

Jonathan's litigation experience includes all aspects of pre-trial and trial district court practice, as well as appeals to the US Court of Appeals for the Federal Circuit. He also has represented pharmaceutical clients in inter partes review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB) of the US Patent and Trademark Office, and he frequently advises clients in infringement and validity opinions and other prelitigation due diligence investigations.

Before law school, Jonathan completed graduate studies in human physiology and conducted doctoral and post-doctoral research in cellular and molecular biology and genetics. His research focused on molecular mechanisms that regulate cellular growth and division, as well as the regulation of nuclear transport within cells.

Jonathan's pro bono practice includes representing a mother in a child custody case in the Superior Court of the District of Columbia. He also represented a student in litigation in DC Superior Court and the US District Court for the District of Columbia related to the improper destruction of the student's home.

Jonathan serves as an adjunct professor at the American University Washington College of Law, where he teaches a course on ANDA litigation and biosimilars litigation under BPCIA.

#### Jonathan's recent representative experience includes:

- 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.
- Representing Vifor in patent infringement litigation concerning the iron replacement product Injectafer –
   Biofer S.p.A. v. Vifor (International) AG
- Representing Scilex and co-plaintiffs in Hatch-Waxman litigation concerning their ZTlido product for the
  treatment of pain associated with post-herpetic neuralgia against ANDA filers Aveva and Apotex Scilex
  Pharmaceuticals, Inc. et al. v. Aveva Drug Delivery Systems, Inc. et al.
- Representing Liquidia in trade secret litigation related to its Yutrepia product for the treatment of pulmonary arterial hypertension - *United Therapeutics Corporation v. Liquidia Technologies, Inc.et*
- Representing Liquidia in Hatch-Waxman litigation and parallel IPR proceedings concerning its Yutrepia

product for the treatment of pulmonary arterial hypertension – *United Therapeutics Corporation v. Liquidia Technologies, Inc.* 

- Representing Journey Medical 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 against ANDA filer Perrigo Journey Medical Corporation et al. v. Perrigo Pharma International DAC
- Representing Journey Medical in Hatch-Waxman litigation concerning its Qbrexza product for the treatment of primary axillary hyperhidrosis against ANDA filer Teva – Journey Medical Corporation et al. v. Teva Pharmaceuticals, Inc. et al.
- Representing defendant CSL Behring in patent litigation concerning its biologic Haegarda for the prophylactic prevention of hereditary angioedema – Shire ViroPharma Inc. v. CSL Behring LLC\*
- Representing AbbVie in BPCIA litigation related to Humira AbbVie Inc. et al. v. Boehringer Ingelheim
   International GmbH et al.\*
- Representing Forest Labs in ANDA litigation for its Saphris product for the treatment of schizophrenia and bipolar disorder against multiple generic drug manufacturers – Forest Laboratories, LLC v.
   Sigmapharm Laboratories, LLC\*
- Representing BioDelivery Sciences International in Hatch-Waxman litigation concerning its Belbuca product for pain management *BioDelivery Sciences International, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*\*
- Representing BioDelivery Sciences International in Hatch-Waxman litigation concerning its Bunavail product for maintenance treatment of opioid dependence BioDelivery Sciences International, Inc. v. Actavis Laboratories UT, Inc. and Actavis, Inc.\*
- Representing AbbVie in Hatch-Waxman litigation related to its Norvir products for the treatment of HIV against multiple generic drug manufacturers in the US District Court for the Southern District of Ohio and the US District Court for the District of Delaware AbbVie, Inc. et al. v. Hetero USA, Inc. et al.\*
- Representing AbbVie in Hatch-Waxman litigation related to its Kaletra products for the treatment of HIV against multiple generic drug manufacturers AbbVie, Inc. v. Mylan Laboratories, Inc.\*
- Representing Astellas in Hatch-Waxman litigation related to its immunosuppressant drug Protopic –
   Astellas US LLC v. Nycomed US Inc.\*
- Representing Eli Lilly in Hatch-Waxman litigation related to its Cymbalta product against multiple generic drug manufacturers – Eli Lilly and Company v. Wockhardt Ltd.\*

#### Publications and media

- Co-author of "Inconsistent Positions at FDA and USPTO Render Patent Unenforceable," Cooley alert, September 2021
- 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," Law 360, June 2020
- 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

<sup>\*</sup> Representation handled prior to joining Cooley

#### Speaking engagements

- Co-presenter, "Life Sciences Litigation: Clinical Trials and Tribulations Prosecution and Litigation
   Implications of Clinical Trial IP and Prior Art," Cooley Rx series, May 2025
- Co-presenter, "Clinical Trials and Tribulations: Prosecution and Litigation Implications of Clinical
   Trial IP and Prior Art," Consero IP Forum for Life Sciences, December 2024
- Co-presenter, "Life Sciences Litigation: Implications and Perspectives on the FTC's Recent Orange
   Book Statements and Disputes" Cooley Rx series, February 2024
- Co-Presenter, "A CREATES Act Primer," Cooley Rx series, May 2023
- Presenter, "The Cost and Worth of a Patent: The Economics of a Paragraph IV Challenge," ACI
   Paragraph IV Conference, April 2023
- Presenter, "<u>Hatch-Waxman 101: The Skinny on 'Skinny Labeling</u>," Cooley CLE Speaker Series, January 2022
- Presenter, "The Current State of Patent Eligibility Jurisprudence: Redefining What Is Patent-Eligible
   Subject Matter Post-American Axle v. Neapco," ACI Paragraph IV Conference, November 2021
- Co-Presenter, "Hatch-Waxman 101: Safe Harbor," Cooley webinar, October 2021
- Co-Presenter, "Hatch-Waxman 101: Pre-Suit Investigation and Diligence," Cooley webinar, June 2021
- Co-Presenter, "<u>Hatch-Waxman 101 for the Emerging Life Science Company</u>," Cooley's 14<sup>th</sup> annual Life Sciences & Healthcare Innovation Program in conjunction with the J.P. Morgan Healthcare Conference, January 2021

### Education

The Ohio State University, Moritz College of Law JD, magna cum laude, 2008

The Ohio State University
PhD, Molecular Genetics, 2004

Pennsylvania State University MS, Physiology, 1999

Grove City College BS, Biology, 1997

### **Admissions & Credentials**

District of Columbia

Maryland

### **Court Admissions**

US Court of Appeals for the Federal Circuit

## Memberships & Affiliations

American Intellectual Property Law Association

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