ArentFox Schiff LLP
Attorneys

Kevin M. Nelson

PARTNER

Kevin is an intellectual property attorney with a focus on large-scale complex patent infringement litigation.

Practices

Education

DePaul University College of Law, JD, 2001
Indiana University, BA, 1998

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For more than 15 years, he has guided clients through the legal and regulatory challenges and changes associated with obtaining approval to commercially market a product under the Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act. In addition to helping clients develop a strategy for filing an abbreviated new drug application (ANDA), Kevin has represented clients in every phase of patent litigation and has successfully argued before the United States Court of Appeals for the Federal Circuit. His matters have involved patents purportedly covering well-known pharmaceutical products and methods for using those products. He also has successfully represented clients in inter partes review (IPR) proceedings.

In the face of an evolving and uncertain biosimilar industry in the United States, Kevin has counseled clients on navigating the biosimilar legal and regulatory pathways. He has also advised clients on regulatory matters before the U.S. Food and Drug Administration, such as opposing citizen petitions. Rounding out his experience, Kevin has handled cases involving trademark and copyright infringement, false or unfair advertising, and unfair competition claims.

Client Work

- Obtained the first stay of district court litigation in view of pending *inter partes* review proceeding by a defendant generic pharmaceutical manufacturer.
- Led a team in securing a final written decision of unenforceability of all claims of two Orange Book listed patents related to methods for treating disease caused by thrombus.
- Lead trial attorney, including a recent case in which the district court found the asserted patent not infringed and invalid.
- Successful argument before the United States Court of Appeals for the Federal Circuit that resulted in a Rule 36 affirmance of district court judgement on all grounds.
- Defeated citizen petition that sought delay of market entry of generic manufacturer, resulting in a decision by the FDA that the petition was meritless.
- Argued discovery, Markman and dispositive motions in more than a dozen patent cases involving

pharmaceutical products across various therapeutic categories. Cases involved drug and finished dose formulation, crystallization and polymorphs, dosing schedules, drug indications and use, adverse events, pharmacokinetics, organic chemistry, process chemistry, analytical testing methods and results, and route of drug administration.

- Lead negotiator for several favorable settlement agreements that have allowed client early market entry.
- Trial attorney for series of cases that led to important changes in Hatch-Waxman law including law relating to the 180-day exclusivity period, limitations on willful infringement, and multiple 30-month stays of regulatory approval.

Professional Activities

Pro Bono

Kevin has provided pro bono representation to songwriters to assist them in obtaining royalties owed for use of their works.

Civic and Charitable Memberships

Along with his family, Kevin is involved in various fundraising and community outreach projects that are close to his heart. As a firm believer in the power of teamwork and fair play, Kevin often serves as a volunteer coach for several different youth sports.

Publications, Presentations, & Recognitions

Publications

- "IP Attorneys Propose a New Biosimilar Pathway in Case of ACA Repeal," (co-author) *The Center for Biosimilars* (Jul. 25, 2020)
- "A New Antitrust Approach After Humira 'Patent Thicket' Ruling," *Law360* (Jun. 26, 2020)
- "If Successful, Teva Suit Could Decrease Generic Competition," (co-author) *Schiff Hardin Insight* (Mar. 27, 2020)
- "Congress CREATES a New Action to Combat Drug Approval Delays," *Schiff Hardin Insight* (Feb. 18, 2020)
- "What If Pfizer Could Donate Data to NIH? One Proposal to Promote Public Good," (co-author) *Bloomberg Law* (Jul. 2, 2019)
- "Clearing Up 'Clear Evidence' and Implications for Labeling Post-Merck Decision," (co-author) *Pharmaceutical Executive* (May 23, 2019)
- "Time To Create A Viable Path To Biosimilar Interchangeability," *Law360* (May 21, 2019)
- "Three Trends Point to Biosimilars Market Boom Ahead of BPCIA 10th Anniversary," (co-author) *Pharmaceutical Executive* (Jan. 9, 2019)
- "Six Predictions for the 2018 Patent Environment," (co-author) *IPWatchdog* (Jan. 14, 2018)
- "FDA Requests Comments and Issues Notice of Public Hearing Related to Implementation of GDUFA," (co-author*) Duane Morris Alert* (Aug. 20, 2014)
- "Chapter 18: ANDA Preparation (with an Eye toward Approval and Litigation) and the FDA Review," (co-author) *Pre-ANDA Litigation: Strategies and Tactics for Developing a Drug Product and Patent Portfolio* (2014)
- "Strangelove: How We Learned to Love IPR for Pharmaceutical Patent Cases (Sort of)," (co-author) *GenericsWeb* (Jun. 2014)
- "FDA Biosimilar Rules Will Provide Testing Clarity," (co-author) *Law360* (May 27, 2014)
- "Inch-by-Inch: FDA's New Biosimilars Guidance Inches the Industry Closer to Clinical Testing Clarity," (co-author) *Duane Morris Alert* (May 15, 2014)
- "2 Traps For Unwary ANDA Filers," (co-author) *Law360* (Jan. 3, 2014)
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"FDA Releases Draft Guidance on Bioequivalence Requirements for ANDA Applicants," *Duane Morris Blog* (Dec. 6, 2013)

- "What You Need to Know to Play the Pharmaceutical Patent Litigation Game: Best Practices, Emerging Trends, and Changes in the Generic Drug and Biosimilars World," Chapter in *Inside the Minds: Food and Drug Litigation Strategies*, Aspatore Books (2013)
- "FDA Sets Initial Fees and Deadlines for ANDAs and Related Submissions Under GDUFA," *Locke Lord Quick Study* (Oct. 25, 2012)

Presentations

- "COVID-19 Legal Issue Spotting for In-House Counsel," Webinar (Apr. 1, 2020)
- "Safe at Home: Business Protection Practices in Our New Normal," Webinar (Mar. 31, 2020)
- "Inherent Obviousness: A Case Study on a Less Known but Effective Defense", 9th Annual Pharma IPR Conference 2020, Mumbai, India (Mar. 4, 2020)
- "Obviousness at Another Glance: Exploring Secondary Considerations in ANDA Litigation," Paragraph IV Disputes Master Symposium – ACI's Hatch-Waxman Series (Oct. 3, 2017)
- "Who Wants to Be a Biosimilars Billionaire? How Two Recent Events May Shape the Future of the US Biosimilars Market," 6th Annual Pharma IPR Conference, Mumbai (Mar. 1, 2017)
- "It's Game Time! Tips for being litigation ready from the viewpoint of the Smartest Person in 108 years," The Keystone Conference presented by Cardinal IP, Keystone, Colorado (Dec. 11, 2016)
- "How Inter Partes Review has Become Part of the Litigator's Toolbox," The Keystone Conference presented by Cardinal IP, Keystone, Colorado (Dec. 10, 2016)
- "Interchangeable Biologics and Biosimilars: The Federal and State Perspective," AMCP Nexus 2016 (Oct. 5, 2016)
- "The Biosimilars Outlook in the EU and the U.S.," 12th EGA Legal Affairs Conference, Brussels, Belgium (Mar. 9, 2016)
- "A Biosimilar by Any Other Name: What the FDA's Draft Rules Mean for You," FDAnews, Webinar (Oct. 22, 2015)
- "BPCIA Litigation: Latest Developments for 2015 and Beyond Webcast," The Knowledge Group (Sep. 1, 2015)
- "The Legal and Regulatory Obstacles for Biosimilars," Bloomberg Intelligence's 3rd Annual State of Health Care Summit, New York, N.Y. (Feb. 13, 2015)
- "Recent Biosimilar Litigations — The Battle Can Now Begin," CBI's 10th Annual Summit on Biosimilars, Alexandria, Va. (Jan. 29, 2015)
- "The ABCs of IPRs: Understanding Inter Partes Review Proceedings and the Pros and Cons of Using IPR in Pharmaceutical Patent Cases," 7th Product and Pipeline Enhancement for Generics Conference, Alexandria, Va. (Jul. 30-31, 2014)
- "FDA's New Clinical Biosimilars Guidance: Best Practices to Preparing a Successful 351(k) Application," FDAnews, Webinar (Jun. 27, 2014)
- "Settling Pharmaceutical Patent Cases," American Intellectual Property Law Association, Webinar (Mar. 25, 2014)
- "Exploring Biosimilars to Expand the Company Reach and Broaden the Product Pipeline," 6th Product and Pipeline Enhancement for Generics Conference, Arlington, Va. (Jul. 23-25, 2013)
- "The Impact of FDA's Guidance on Biosimilars for the Generics Industry," 5th Product and Pipeline Enhancement for Generics Conference, Washington, D.C. (Jul. 17-19, 2012)
- "U.S. Patent Litigation Landscape: Pruning the Law of Direct and Indirect Infringement," Global Intellectual Property Convention 2012, New Delhi, India (Jan. 5-8, 2012)

Recognitions

- Life Sciences Star – Hatch-Waxman Patent Litigation, *LMG Life Sciences* (2020-2022)
- The Best Lawyers in America, *Best Lawyers* (2022)
- *The Legal 500 United States* – Patents: Litigation (2021)
- IAM Patent 1000 Patent Litigation, Illinois, Globe Business Media Group's The World's

Leading Patent Practitioners (2020)

- Illinois Leading Lawyer, Law Bulletin's *Illinois Leading Lawyers Network* (2014-2021)
- *Illinois Super Lawyers*, Thomson Reuters (2020)

Bar Admissions

Illinois

Court Admissions

US Court of Appeals, Federal Circuit
US District Court, Northern District of Illinois (Trial Bar)