



Kevin M. Nelson

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Overview

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

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.

Practices

- Hatch-Waxman and Biosimilars
- Intellectual Property
- International
- Patent Litigation
- Trademark

Industries

- Cannabis
- Pharmaceuticals

Experience

- 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.

Credentials

Education

- DePaul University College of Law, J.D., 2001
- Indiana University, B.A., Political Science, 1998

Bar Admissions

- Illinois
- U.S. Court of Appeals for the Federal Circuit
- U.S. District Court for the Northern District of Illinois (Trial Bar)

Insights

10.22.2020

In The News

Nelson Quoted on SCOTUS ACA Ruling to Determine Future Pathway to Biosimilars Approval

07.25.2020

Article

IP Attorneys Propose a New Biosimilar Pathway in Case of ACA Repeal

06.26.2020

Article

A New Antitrust Approach After Humira 'Patent Thicket' Ruling

06.24.2020

News Release

Firm and Four Attorneys ranked in the 2020 *IAM Patent 1000*

04.01.2020

Event

COVID-19 Legal Issue Spotting for In-House Counsel

03.31.2020

In The News

Nelson and Wallace Quoted on U.S. Government Potential to Seize COVID-19 Pharmaceutical Patents

03.31.2020

Event

Safe at Home: Business Protection Practices in Our New Normal

03.27.2020

Alert

If Successful, Teva Suit Could Decrease Generic Competition

03.18.2020

Alert

Clinical Trial Impact from Coronavirus: New FDA Guidelines for Safety and Integrity

03.05.2020

Event

Inherent Obviousness: A Case Study on a Less Known but Effective Defense

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Other Publications

- "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)
- "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)

Speeches & Presentations

- COVID-19 Legal Issues 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)

Citizenship

Pro Bono Activities

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.

AWARDS & HONORS

- **Illinois Leading Lawyer (2020)**
Law Bulletin's Illinois Leading Lawyers Network
- **Illinois Super Lawyers (2020)**
Thomson Reuters
- **Illinois Leading Lawyer (2019)**
Law Bulletin's Illinois Leading Lawyers Network
- **Illinois Leading Lawyer (2018)**
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Law Bulletin's Illinois Leading Lawyers Network (2014)