POLSINELLI

Chad A. Landmon

HATCH-WAXMAN & BIOLOGICS CHAIR

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Chad Landmon chairs Polsinelli's Hatch-Waxman & Biologics Practice and is a first chair trial lawyer known for his adept handling of patent litigation, the Food and Drug Administration (FDA) approval processes, and Administrative Procedure Act (APA) litigation, ensuring clients can efficiently and profitably bring their products to market.

He is recognized globally as a leading patent litigator by *IAM Patent 1000, Benchmark Litigation*, and *Law360*, and has successfully litigated over 60 cases in the past decade alone. His notable achievements include leading a groundbreaking case in which a court mandated the FDA to approve a product—a benchmark case covered extensively by the media. Recognized as a "Life Sciences Star" by *LMG Life Sciences* and a "Health Care/Life Sciences Trailblazer" by *The National Law Journal*, Chad has advised on nine of the top 10 generic drugs by cost savings and nearly half of the top 100 by sales volume.

Chad's practice uniquely combines his litigation experience with a deep understanding of navigating the complex FDA regulatory landscape and the unique issues that arise in challenging government agencies in APA litigation. He serves as first chair trial counsel in patent disputes while also handling FDA citizen petitions and APA litigation involving marketing exclusivities, patent listings, bioequivalence, labeling and other critical FDA approval issues, along with issues that arise in the health care industry. He works with clients spanning pharmaceuticals, biologics, medical devices, and human tissue products with billions of dollars in annual sales.

Beyond his primary focus, Chad manages cases involving the cross-section of antitrust and patent law, particularly those arising from settlements of patent disputes and Hatch-Waxman Act exclusivity disputes. His experience extends to navigating challenges posed by the Biologics Price Competition and Innovation Act and other litigation impacting the life sciences and health care industries.

Chad frequently speaks and writes about an array of issues relating to litigation in the life sciences industry, including skinny label litigation, the U.S. regulatory landscape generally, and issued relating to cell and gene therapies. He was active in local government in Southbury, Connecticut, for nearly a decade, including serving as an elected member of their Board of Selectmen. Additionally, Chad is a strong supporter of charity: water, a nonprofit that brings clean water to communities around the world.

Capabilities

- Intellectual Property
- Hatch-Waxman & Biologics
- Food, Drug & Device
- Life Sciences
- Intellectual Property Litigation
- Post Chevron Educational Resources & Updates
- Health Care Litigation

Education

- University of Connecticut School of Law (J.D., *with honors*, 1999)
- University of Connecticut (*summa cum laude*, 1996)

Bar Admissions

- Connecticut
- District of Columbia

Court Admissions

- U.S. Supreme Court
- U.S. Court of Appeals, District of Columbia Circuit
- U.S. Court of Appeals, Federal Circuit
- U.S. Court of Appeals, Fourth Circuit
- U.S. Court of Appeals, Sixth Circuit
- U.S. District Court, District of Columbia
- U.S. District Court, District of Connecticut
- U.S. District Court, Eastern District of Michigan
- U.S. District Court, Southern District of New York

Memberships

- U.S. District Court for the District of New Jersey's Local Patent Rules Committee, Member
- Food and Drug Law Institute
    - FDLI at the Forefront Committee, 2026
    - Update Magazine Peer Review Committee, 2024-2025
    - Annual Conference Planning Committee, 2022-2023
    - Medical Products Committee, 2018-2021
- Association for Accessible Medicines, Biosimilars Council, 2017-Present
- LexisNexis Practical Guidance Author
- Lexis Practical Guidance, Life Sciences Advisory Board Member
- Associate Editor, American Bar Association
    - *Pre-ANDA Litigation: Strategies and Tactics for Developing a Drug Product and Patent Portfolio*, Second and Third Editions
- American Bar Association, Section of Intellectual Property Law
- American Intellectual Property Law Association
- Connecticut Bar Association
- *Law360* Life Sciences Editorial Advisory Board, 2018-2020, 2025

Recognition

- *Thomson Reuters* Stand-out Lawyer – independently rated lawyers, 2026
- Recognized by *LMG Life Sciences* for Hatch-Waxman Patent Litigation, 2019-2025
- *Managing Intellectual Property*, IP Stars – Notable Practitioner, 2024-2025
- Selected for *Best Lawyers*® "Lawyer of the Year" for Litigation - Intellectual Property, 2023, 2025
- Selected for inclusion in *Best Lawyers in America*® for:
    - Litigation Patent, 2023-2026
    - Litigation - Intellectual Property, 2021-2026
- *Benchmark Litigation*, Connecticut Litigation Star: Intellectual Property, 2020-2026
- *IAM Patent 1000*, World's Leading Patent Professionals, 2020-2025
- *The National Law Journal*, Health Care/Life Sciences Trailblazers, 2020

- Named one of the *Best Lawyers in America,* 2021-2021
- *Law360*, Intellectual Property Rising Star, 2013-2014
- *Connecticut Law Tribune*, New Leaders in the Law, 2012
- *Hartford Business Journal*, 40 Under 40, 2011
- *Super Lawyers*, 2013-2020, 2022-2024
- *Super Lawyers*, Connecticut Rising Star, 2008-2012

Matters

- Served as lead appellate and trial counsel in obtaining a decision from the United States Court of Appeals for the Federal Circuit, affirming a decision entered after trial by the United States District Court for the District of Delaware (with Federal Circuit Judge William Bryson sitting by designation), that patents covering Zohydro® (hydrocodone extended-release capsules) and asserted against Alvogen Malta Operations Ltd. were invalid. The decision removed the patents as a barrier to Alvogen bringing its lower-cost generic product to market more than a decade before the patents were set to expire.
- Served as first chair trial lawyer, representing Norwich Pharmaceuticals Inc. in a patent infringement action filed by Salix Pharmaceuticals Ltd., Salix Pharmaceuticals Inc., Bausch Health Ireland Ltd., and Alfasigma S.P.A. relating to Norwich's efforts to market a rifaximin 550 mg tablet, a generic of Salix's Xifaxan®. Obtained judgment of invalidity on many of the asserted claims, including critical patents relating to polymorphs, which halted the trading of the plaintiff's parent company's stock after it plummeted following the decision.
- Coupling patent litigation and FDA strategy, represented Zydus Pharmaceuticals in defending cases involving multiple patents for the blockbuster drug Abilify® (aripiprazole). Defeated a request for a temporary restraining order and obtained a favorable claim construction and noninfringement judgment at both the district court and the Federal Circuit. Also defeated a lawsuit by the brand company against the FDA seeking to exclude Zydus and others from going to market based on a claim to orphan drug exclusivity.
- Represented Sun Pharmaceutical Industries Ltd. in obtaining a dismissal of a Lanham claim brought by Wyeth relating to the blockbuster drug Protonix. The case, which alleged that Sun had engaged in false advertising for its generic product, was dismissed based upon an argument that the claims were preempted by FDA law.
- After successfully arguing claim construction, reached a favorable settlement with a patent license and supply agreement involving a billion-dollar product that was described by the client as "company-changing."
- Following trial, obtained a favorable settlement enabling Actavis to bring its generic version of Shire's ADHD product Intuniv to market.
- Represented Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare in a Hatch-Waxman patent infringement action brought by Millennium Pharmaceuticals Inc. The litigation involved the drug bortezomib, which is marketed under the Velcade® brand. The patent at issue had previously been found valid by the U.S. Court of Appeals for the Federal Circuit.
- Represented Alvogen and 3M in a patent infringement action filed by Noven Pharmaceuticals involving four patents and 48 asserted claims. Developed significant noninfringement and invalidity theories on behalf of Alvogen, which settled the case prior to expert discovery.
- Obtained favorable settlement following expert discovery in patent litigation

concerning multibillion-dollar treatments for diabetes. Led and defended multiple fact and expert depositions.
- Successfully negotiated an extensive patent license and product distribution agreement relating to a blockbuster product on the eve of trial for a case involving complex patent, FDA, and business issues.

FDA

- In what has been described as the first case in which a court has ordered the FDA to approve a product, secured summary judgment on behalf of Watson Laboratories Inc. in litigation against the FDA in the U.S. District Court for the District of Columbia. The case involved a dispute over the 180-day "first-to-file" marketing exclusivity for generic versions of the multibillion-dollar pioglitazone hydrochloride product Actos. The decision included an order enabling the client to bring its generic diabetes drug to market.
- Represented Endo Pharmaceuticals Inc. in obtaining final FDA approval for its generic Valcyte® product after asserting a novel argument to FDA regarding the forfeiture of the 180-day exclusivity period by a third-party. Intervened in a lawsuit brought in the U.S. District Court for the District of Columbia and successfully supported FDA’s decision that brought generic versions of Valcyte® and Nexium® to market, providing significant savings to consumers and payers.
- Obtained favorable decision from the U.S. Court of Appeals for the Fourth Circuit to enable Watson Laboratories (now Teva) to bring its generic version of Celebrex® to market. Earlier FDA and district court decisions had effectively barred Watson and others from bringing their drugs to market. The Fourth Circuit reversed and remanded the district court’s decision and the FDA’s determination, finding that Watson and other companies were eligible to share in a 180-day marketing exclusivity upon the launch of their generic drugs because a reissued patent was not part of the same “bundle of rights” as an original patent.
- Obtained a favorable decision for Alvogen Inc. after intervening in an action against the FDA by a competitor seeking a preliminary injunction against generic versions of the antibiotic Vancocin. In less than a week, successfully moved to intervene, submitted opposition papers, and defeated the request for a preliminary injunction, allowing Alvogen's version of Vancocin to remain on the market.
- Represented Alvogen and affiliates in filing a suit against FDA regarding the forfeiture of the 180-day generic exclusivity period relating to buprenorphine buccal film (sold under the brand name Belbuca®). After aggressively pursuing the matter through the filing of a motion for preliminary injunction, obtained a settlement with the generic company that had been deemed by FDA to be entitled to the 180-day exclusivity period.

Counseling

- Counseled a human tissue company on developing platform technology using adult stem cells. Guided client through designing around others' patents, securing its own patent protection, and negotiating a license in a critical technology area at a fraction of the demanded royalty.
- Provided patent and FDA counseling on numerous biosimilar products to assist clients with biosimilar product development efforts and to navigate patent and FDA approval issues under the Biologics Price Competition and Innovation Act.

Publications

May 5, 2026
Justices to side with generic drugmakers in patent spat, attorneys predict
Quoted, Westlaw

May 1, 2026
FDA Signals it Has No Appetite to Add Popular GLP-1 Drug Substances to the 503B Bulks List

April 30, 2026
SCOTUS judges favour fact-specific approach to landmark ‘skinny label’ dispute
Quoted, IAM

April 30, 2026
Hot Takes: What the Oral Arguments in Hikma/ Amarin Revealed
Quoted, IP Watchdog

April 29, 2026
Supreme Court Decision Hangs In Balance After Hikma-Amarin Skinny-Label Oral Arguments
Quoted, Generics Bulletin

April 29, 2026
High Court Seeks Path To Limited Ruling On 'Skinny Labels'
Quoted, Law360

April 29, 2026
Supremes weigh in on skinny labels in long-awaited argument
Quoted, BioWorld

April 29, 2026
How Skinny is Skinny Enough? Takeaways from the SCOTUS Oral Argument in the Amarin/Hikma Case

April 22, 2026
Tiny Chains, Big Changes? What FDA’s Latest Actions Mean for Peptide Compounding

April 7, 2026
Not Joking Around: FDA Offers Additional Clarification on Compounded GLP-1 Policy in April Fool’s Day Announcement

February 18, 2026
New FDA Drug Reforms: Congress Extends Voucher Incentive, Clarifies Orphan Exclusivity and Provides Greater Transparency for Q1/Q2 Generic Approvals

February 9, 2026
FDA Tightens the Belt on GLP-1 Compounding, Escalating Threat of Enforcement

February 4, 2026
‘These Decisions Created A Lot Of Uncertainty’ – Why The Supreme Court’s Skinny-Label Ruling Matters
Quoted, Generics Bulletin

January 22, 2026
High court picked Hikma’s ‘skinny label’ fight after letting the issue ‘percolate’
Quoted, Endpoints News

January 22, 2026
High Court’s ‘Skinny-Label’ Case Has Broader Implications (1)
Quoted, Bloomberg Law

January 20, 2026
Supreme Court Grants Cert. Petition in Hikma / Amarin Skinny Labeling Case

January 9, 2026
Could European Courts Soon Be Litigating and Enforcing U.S. Patents?

January 8, 2026
Polsinelli Life Sciences Spotlight - Volume 3 - Turning Insight into Action: A Life Sciences Playbook for 2026

January 5, 2026
Calls for Leadership Stability and Rare Disease Follow-Through at FDA in 2026
Quoted, BioSpace

December 31, 2025
Pharma Patent Trials Loom in 2026 for Wegovy, Covid-Vaccine Tech
Quoted, Bloomberg Law

December 22, 2025
FDA Policy Tracker: 2025 Was a Year of Change
Quoted, BioSpace

December 9, 2025
FDA’s Drug Price Push in Biosimilar Plan Hinges on Other Reforms
Quoted, Bloomberg Law

October 9, 2025
Justices Urged To Clarify Patent Validity In Entresto Case
Quoted, Law360

September 24, 2025
Vanda Ruling Opens Door For Contesting FDA Drug Denials
Co-Author, Law360

September 16, 2025
Deference Ruling Could Close The FAR Loophole
Co-Author, Law360

September 11, 2025
Polsinelli Life Sciences Spotlight - Volume 2 - Adapting by Design: Navigating Complex Times in Life Sciences

August 7, 2025
The 340B Rebate Pilot: Voluntary for Manufacturers, Costly for 340B Covered Entities

July 21, 2025
FTC's Latest Effort To Dispute Improper Patent Listings Barely Made A Dent
Quoted, Generics Bulletin

July 14, 2025
Device Patents in the Orange Book: May 21, 2025, FTC Warning Letters Appear to have Minimal Impact

June 10, 2025
US FTC Continues Effort To Eliminate Orange Book's Improper Patent Listings
Quoted, Pink Sheet

June 6, 2025
Trump's FTC Continues The Mission Of Eliminating Orange Book's Improper Patent Listings
Quoted, Generics Bulletin

May 23, 2025
Orange Book Listings: Republican Led FTC Picks Up Where Democrat Led FTC Left Off

May 15, 2025
Trump Administration Announces New Executive Order to Promote Domestic Production of Biopharmaceuticals

May 14, 2025
How will FDA changes reshape drug approval in 2025 and beyond?
Quoted, Chemical & Engineering News

April 16, 2025
A judge blocked the FDA's plan to regulate LDTs. What now?
Quoted, MedTech Dive

April 14, 2025
FDA After the Storm: Drug Review Delays and Increased Executive Oversight Expected
Quoted, BioSpace

April 1, 2025
In Landmark Ruling, Eastern District of Texas Strikes Down FDA's Final Rule Regulating Laboratory Developed Tests

March 14, 2025
Judge Connolly (D. Del.) Overturns $96 Million Molecular Diagnostics Jury Verdict, Finds Patents Invalid Under § 112

March 5, 2025
Federal Circuit Refuses to Rehear Case Involving Orange Book Listing of Device Patents

February 20, 2025

FDA Reels From ‘Indiscriminate’ Job Cuts Under Trump as Biopharma Appeals for Clarity
Quoted, BioSpace

February 19, 2025
MAHA Commission expected to impact approach to medications, vaccines, research
Quoted, McKnights Senior Living

February 13, 2025
Uncertainty builds amid Kennedy confirmation, Trumps orders
Quoted, BioWorld

February 13, 2025
‘No Job Security’ at FDA as Trump Team Seeks to Dismantle Workforce
Quoted, BioSpace

February 6, 2025
New PTAB Guidance on Enabling Requirement Under § 102 of the AIA and Construction of Chemical Compound

January 30, 2025
‘There’s a lot going on,’ attorneys say of federal freeze flip-flop
Quoted, McKnights Senior Living

January 27, 2025
Is Teva-Amneal Inhaler Case A Double-Edged Sword For The Generics Industry?
Quoted, Generics Bulletin

January 23, 2025
Court Ruling Alters the Calculus for Orange Book Patent Listings
Co-Author, Life Science Leader

January 8, 2025
Polsinelli Life Sciences Spotlight - Volume 1 - Looking Back, Moving Forward: A Year in Life Sciences

December 23, 2024
FDA likely to see more legal challenges to rulemaking, guidance in 2025
Quoted, BioWorld

December 23, 2024
Federal Circuit Decides Case Involving Orange Book Listing of Device Patents

October 28, 2024
100-days-in: How Polsinelli hire is expanding the Hatch-Waxman group
Quoted, Managing IP

September 23, 2024
Chevron Deference Reversal: FDA Rulemaking and Legal Challenges After Loper Bright
Co-Author, LexisNexis Practical Guidance Journal

September 10, 2024
Lilly Challenges US FDA Classification Of Obesity Drug Retatrutide, Citing Chevron

Overturn
Quoted, Pink Sheet Citeline Regulatory

August 6, 2024
What Challenges Will FDA Face In A Post-Chevron World?
Quoted, American Conference Institute

July 19, 2024
Loper Bright bringing more scrutiny, uncertainty to US agencies
Quoted, BioWorld

July 18, 2024
Congress looking for ‘simple solutions’ to Rx pricing quandary
Quoted, BioWorld

July 17, 2024
The FTC’s Challenge to the Listing of Device Patents in the Orange Book: What Challenge?

July 10, 2024
Longtime Axinn Atty To Chair Polsinelli's Hatch-Waxman Team
Featured, Law360

June 28, 2024
Pollution Curbs, Non-Compete Bans Put at Risk by Chevron Ruling
Quoted, Bloomberg

June 28, 2024
The Oversight of Food, Drugs, and Tobacco is Expected to be a Target
Quoted, The New York Times

June 26, 2024
After Stock Crash and Staff Cuts, Amarin Wins Bid to Revive Vascepa Patent Lawsuit
Quoted, Fierce Pharma

June 25, 2024
Amarin Revives Patent Suit Against Hikma for Vascepa Generic
Quoted, Bloomberg Law

June 25, 2024
CAFC Says Generic’s Public Statements Make Induced Infringement Claims Plausible,
Quoted, IPWatchdog

June 24, 2024
Device patents still listed, FTC embraces chance to expand review
Quoted, BioWorld

June 2024
Generic Drugs and Patents
Co-Author, Bloomberg Law

June 2024
Hatch-Waxman Overview

Author, Bloomberg Law

May 23, 2024
Effects of GSK v Teva Ripple after SCOTUS Denies Cert
Co-Author, Life Sciences IP Review

May 1, 2024
Debate over Orange Book device listings heard on multiple fronts
Quoted, BioWorld

April 2, 2024
For Medicare Drug Cost Suits, Final Price Could Be Key
Quoted, Law360

Spring 2024
Chevron Deference on the Brink: Small Fish May Mean Big Changes for FDA
Co-Author, FDLI's Update Magazine

March 1, 2024
Lung-Disease Drug Fight Exposes Fault Lines in Patent System
Quoted, Bloomberg Law

January 25, 2024
FDA's Califf is 'Very Worried' About Judges Overruling Agency Decisions
Quoted, Pink Sheet

January 19, 2024
IP Agencies Will Not Escape Pull of SCOTUS Ruling on 'Important' Chevron Doctrine
Quoted, World IP Review

January 19, 2024
Justices Seem Split Down Party Lines as Chevron Nears Chopping Block
Quoted, IPWatchdog

January 11, 2024
USPTO's New Enablement Guidelines Push for Consistency
Quoted, BioWorld

December 22, 2023
2024 Forecast: Biden Admin Efforts Show There's No Pricing Relief on the Horizon for Pharma
Quoted, Fierce Pharma

December 15, 2023
Key U.S. District Court Cases with Implications for IP in the New Year
Co-Author, IPWatchdog

November 17, 2023
US FDA letting FTC Decide if Orange Book Listings 'Improper'
Quoted, BioWorld

May 16, 2023
FDA's Digital Health Technologies Framework Addresses Important Challenges
Co-Author, Cell & Gene, Bioprocess Online, Clinical Leader, Med Device Online,

Outsourced Pharma, and Pharmaceutical Online

March 23, 2023
Resistance or Defiance? The FDA and the 11th Circuit Spar Over Statute on Orphan Drug Statutory Exclusivity
Co-Author, Clinical Leader

March 2, 2023
US Regulatory Landscape not Improving for Ultra-Rare Disease Therapies
Quoted, BioWorld

December 20, 2022
The Regulatory Labyrinth of Stem Cell Treatments
Co-Author, Cell & Gene