AXINN

Chad A. Landmon

Partner

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SPOTLIGHT

"He's not just the lawyer who goes to court and who manages and runs the litigation, he also gives us strategy and direction."
– *Chambers USA*

"Chad Landmon…has a wealth of trial experience." – *IAM Patent 1000,* World's Leading Patent Professional

"Landmon's intellectual property acumen and FDA savvy… is rare."
– *Law 360*

2020 *National Law Journal* Health Care/Life Sciences Trailblazer

PRACTICE AREAS

FDA

Intellectual Property

Litigation

Patents

EDUCATION

JD, with honors – University of Connecticut School of Law (1999)

BA, summa cum laude – University of Connecticut (1996)

PROFILE

Chad Landmon, Chair of Axinn's Intellectual Property and Food and Drug Administration Practice Groups, is a first chair trial lawyer who guides clients in simultaneously clearing both patent litigation and Food and Drug Administration (FDA) approval hurdles, enabling clients to bring their products to market in the most profitable manner possible.

Recognized among the world's leading patent litigators by *IAM Patent 1000*, *Benchmark Litigation*, and *Law360*, Chad has litigated more than 60 cases in the past decade alone. His experience includes leading a case described by media as the first in which a court has ordered the FDA to approve a product. Having advised on nine of the top 10 generic drugs ranked by cost savings and nearly half of the top 100 generic drugs by sales volume, Chad has been lauded as a "Life Sciences Star" by *LMG Life Sciences* and a "Health Care/Life Sciences Trailblazer" by *The National Law Journal.*

Chad's dual practice couples his litigation prowess with his adeptness in maneuvering through the complex FDA regulatory regime. In addition to serving as a first chair trial lawyer in numerous patent cases, he also handles FDA citizen petitions and litigates cases involving marketing exclusivities, patent listings, certification and notification requirements, bioequivalence, labeling, and other issues relevant to the FDA drug approval process. He represents manufacturers of pharmaceuticals, biologics, medical devices, and human tissue products with billions of dollars in annual sales.

Additionally, Chad handles cases that intersect antitrust and patent law, such as matters arising from the settlement of patent and Hatch-Waxman Act exclusivity disputes, the Biologics Price Competition and Innovation

ADMISSIONS

Connecticut

District of Columbia

U.S. Supreme Court

U.S. Court of Appeals for the District of Columbia Circuit

U.S. Court of Appeals for the Federal Circuit

U.S. Court of Appeals for the Fourth Circuit

U.S. Court of Appeals for the 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

Act, and other legislation impacting the life sciences industry.

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, and 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.

PROFESSIONAL ACTIVITIES

- Association for Accessible Medicines, Biosimilars Council (2017 – present)
- Food and Drug Law Institute, Update Magazine Peer Review Committee (2024 – 2025)
- Food and Drug Law Institute, Annual Conference Planning Committee (2022 – 2023)
- Lexis Practical Guidance, Life Sciences Advisory Board Member
- American Bar Association, Section of Intellectual Property Law
- American Intellectual Property Law Association
- Connecticut Bar Association
- Connecticut Intellectual Property Law Association
- Hartford County Bar Association
- Food and Drug Law Institute, Medical Products Committee (2018 – 2021)
- Law360 Life Sciences Editorial Advisory Board (2018 – 2020)

EXPERIENCE

Pharma Litigation

- 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 Axinn client 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. The suit sought to stop Norwich from gaining approval to market a rifaximin 550 mg tablet, a generic of Salix's Xifaxan®. Obtained judgment of invalidity on many of the asserted claims, which halted the trading of the plaintiff's parent company's stock after it plummeted following the decision. Axinn is currently handling the appeal in the Federal Circuit Court.
- 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. During the litigation and after Axinn conducted aggressive fact discovery, Shire dedicated its core method of use patent to the public, removing it from further dispute in the litigation.
- 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. Axinn developed a novel obviousness argument and aggressively litigated the case, leading to a favorable settlement on the eve of trial.

- 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, Axinn 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 Axinn's 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. Axinn then 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, Axinn 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, Axinn 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.

HONORS

- *Benchmark Litigation*, Connecticut Litigation Star: Intellectual Property (2020 – 2024)
- *IAM Patent 1000*, World's Leading Patent Professionals (2020 – 2023)
- *LMG Life Sciences*, Life Sciences Star (2019 – 2024)
- *The National Law Journal*, Health Care/Life Sciences Trailblazers (2020)

- *Best Lawyers in America* (2021 – 2024)
- *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, 2023)
- *Super Lawyers*, Connecticut Rising Star (2009 – 2012)