

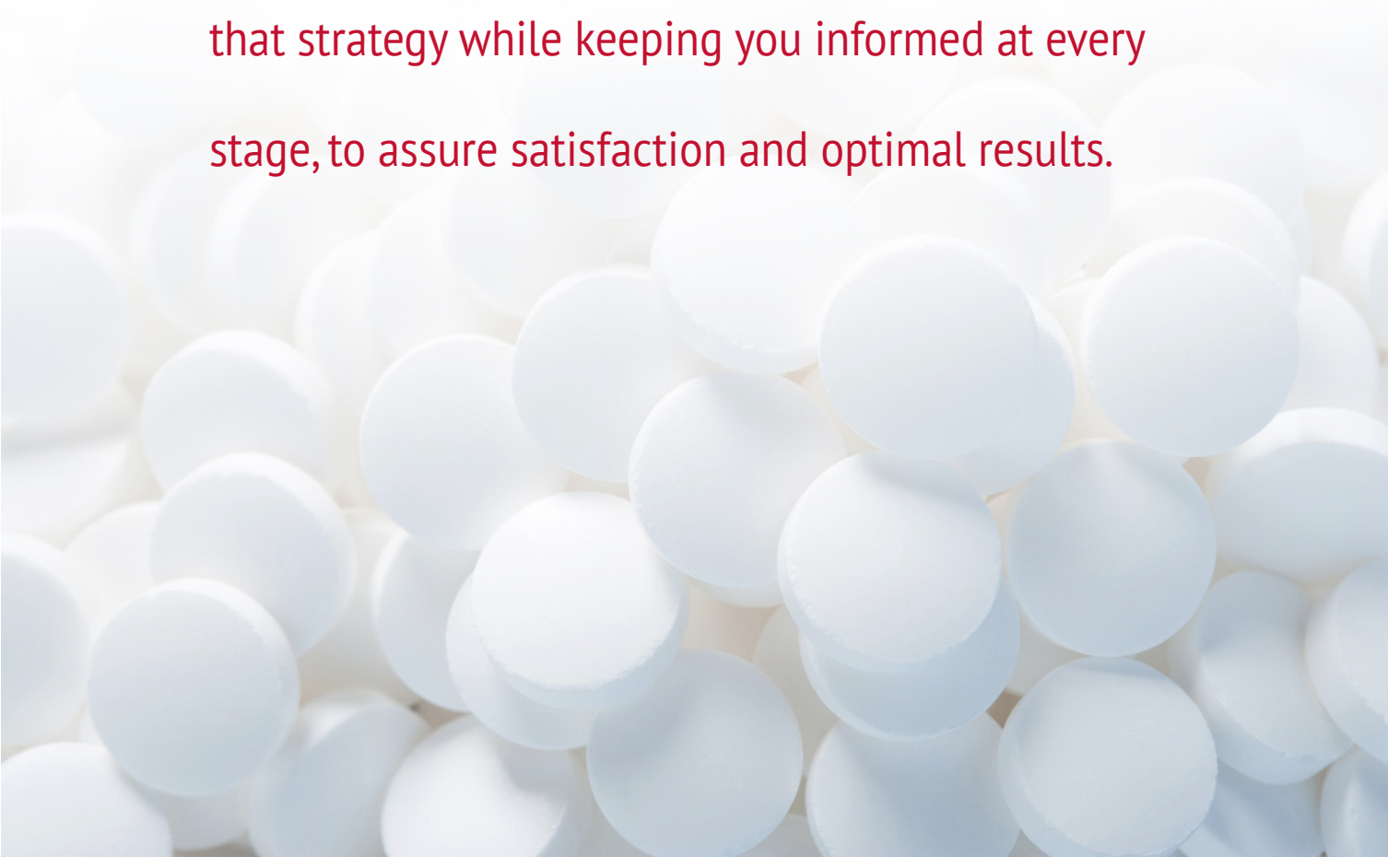


Pharmaceuticals & Biotechnology Practice



At AddyHart P.C., we believe the key to a successful client relationship is a true partnership. We also appreciate that every client's objectives differ.

In any case or matter we undertake, we will align our approach with your strategy. We then execute that strategy while keeping you informed at every stage, to assure satisfaction and optimal results.



Our Commitment to You

AddyHart's team has worked successfully with multiple life sciences companies and has been involved in litigation and licensing of dozens of pharmaceutical and biotechnology products, both branded and generic. We have handled many trials and Federal Circuit appeals, and we understand the legal, regulatory, and business considerations involved when bringing new products to market.

We work with clients to determine the most appropriate billing arrangement for each matter. We recognize the need for predictability in legal costs, and we are experienced in providing monthly, quarterly, and project estimates.

Practice Areas

ANDA/Hatch-Waxman Litigation

AddyHart's attorneys have successfully represented clients in numerous complex pharmaceutical patent litigations. Members of our team have defeated patents on multiple blockbuster drugs, including Restasis®, Lattise®, and Effient®. Our collective technical abilities, legal knowledge, and courtroom experience result in an unparalleled team for our clients during all stages of litigation. Our record of pretrial, trial, and settlement successes reflects our ability in this complex field.

Appellate Practice

AddyHart's appellate team is second to none. It is led by Meredith Addy, who clerked at the Federal Circuit and who has since led more than 60 Federal Circuit appeals; it is no surprise Addy is perennially listed as a Top Federal Circuit Practitioner. Backed by experienced appellate litigator and former Federal Circuit clerk Chad Pannell, our team's experience at the Federal Circuit rivals that of any law firm.

Post-Grant Review

AddyHart's attorneys have decades of experience with proceedings before the USPTO's Patent Trial and Appeal Board and its predecessor court, including interference proceedings and post-grant review. Our attorneys have represented generic pharmaceutical companies in parallel proceedings in both the district courts and the PTAB, and we are accustomed to adopting *inter partes* review as a strategic tool.

A Wealth of Experience

AddyHart's attorneys have worked on cases pre-trial, in litigations, and on appeals involving a full range of drugs and biologics.

Drugs

Arzerra®

Avastin®

Effexor XR®

Effient®

Hectorol®

Herceptin®

Humatrope®

Latisse®

Lumigan®

Lovenox®

Naropin®

Omnicef®

Plavix®

Protonix®

Protropin®

Pulmicort Respules®

Rituxan®

Synagis®

Treanda®

Representative Matters

Restasis® (cyclosporine A)

Allergan v. Teva

Successfully represented Akorn Pharmaceuticals through trial and appeal of patent litigation relating to Allergan's dry-eye drug Restasis®. Federal Circuit Judge William Bryson (sitting by designation in the Eastern District of Texas) found the Restasis® patents invalid as obvious, opening the door to less expensive generic alternatives. Representation continued through appeal, where Allergan assigned two Orange Book listed patents to the Saint Regis Mohawk Tribe, in a failed attempt to shield them from *inter partes* review.

Herceptin® (trastuzumab)

Chiron v. Genentech

Successfully represented Genentech on appeal over the blockbuster breast cancer drug Herceptin®. Chiron had alleged infringement by Genentech's Herceptin®, a humanized antibody for the long-term treatment of breast cancer. Chiron's asserted patent issued from a chain of applications filed in 1984, 1985, and 1986. Yet, Chiron's patent claimed chimeric and humanized antibodies that bound to the protein HER2. In confirming the patent's invalidity, the Federal Circuit held that the 1984 application predated chimeric antibodies and that the 1985 and 1986 applications were not enabled because the technology was nascent at the time of their filing, requiring undue experimentation.

Omnicef® (cefdinir)

Abbott Labs v. Sandoz

Successfully represented Sandoz in defending against a temporary restraining order and on appeal, resolving a Federal Circuit split on infringement of product-by-process claims. The court ruled in favor of our client that Abbott's product-by-process claims were not infringed and resolved *en banc* the long-standing conflict, holding that product-by-process claims cannot be infringed by "products made by processes other than the one claimed."

Latisse® (bimatoprost)

Allergan v. Apotex

Represented Sandoz through trial and appeal in a Hatch-Waxman litigation related to Allergan's bimatoprost, marketed as Latisse® for hypotrichosis. The asserted patents covered methods of promoting hair growth, including eyelash hair growth, using compounds that were previously known for treating glaucoma. The Federal Circuit vacated the district court's decision, holding the asserted patents would have been obvious to a person of skill in the art.

Attorneys



Meredith Addy, J.D., M.B.A., LL.M.

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Meredith Addy, co-founder of AddyHart P.C., is a deeply experienced intellectual property litigator who specializes in cases before the U.S. Court of Appeals for the Federal Circuit, in the federal district courts, and at the USPTO's Patent Trial and Appeal Board. Her experience includes more than 80 federal district court cases and more than 100 appeals to the Federal Circuit. During her 25-year career, Meredith has worked with clients on multiple pharmaceutical and biologics products from pre-market entry through trial and appeal. Her litigation experience includes work on Hecitorol®, Latisse®, Lumigan®, Lovenox®, Naropin®, Omnicef®, Plavix®, Prilosec® and Pulmicort Respules®, among others. She has worked with major biotechnology companies in litigations and Federal Circuit appeals for drugs such as Arzerra®, Avastin®, Herceptin®, Humatrope®, Protropin®, Rituxan®, and Synagis®.

Addy's extensive list of legal recognition includes being perennially ranked Band I in Chambers USA, being shortlisted for Intellectual Property Woman of the Year by Chambers USA; being recognized as a Top 10 Illinois Super Lawyer on multiple occasions; and being listed as a Top 20 Federal Circuit Practitioner and as one of the Top 15 Illinois Patent Litigators by *Intellectual Asset Management* (IAM). She served on the Federal Circuit's Advisory Council for ten years and was a co-founder and the first president of the Richard Linn American Inn of Court, directed to intellectual property. She served on the Board of Directors for the Federal Circuit Bar Association and as chair and co-chair of the Amicus Committees for the American Intellectual Property Law Association and the Intellectual Property Law Association of Chicago.

Based in part on these accomplishments, *Law360* has named Meredith one of the Most Influential Women in IP Law. In addition, according to independent research cited in *Law360*, she is one of the five female private-sector litigators who have argued most frequently before the Federal Circuit in the last decade, and is one of only two of the five licensed to practice before the USPTO. Experienced in protecting and monetizing corporate intellectual asset portfolios, Meredith in 2015 also earned her M.B.A. from the University of Chicago's Booth School. She was a law clerk to The Honorable Paul R. Michel, US Court of Appeals for the Federal Circuit.



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Chad Pannell is a veteran patent litigator with 16 years of experience in private practice at AmLaw 100 firms. He is experienced in all areas of technology litigation and is particularly suited to patent cases involving the chemical arts. Chad has handled complex patent infringement, trade secret, and other intellectual property litigation for both plaintiffs and defendants, from pre-litigation counseling and investigations to

discovery, trial, and appeal. He has been named as one of Georgia's Legal Elite for IP Law and as an IP Star by *Managing IP* for multiple years. He was a law clerk to the Honorable Arthur J. Gajarsa, US Court of Appeals for the Federal Circuit in Washington, DC, and before that was a law clerk to The Honorable Stanley F. Birch, US Court of Appeals for the Eleventh Circuit in Atlanta. Chad has been a frequent speaker on BIO panels regarding developments in patent litigation. Trained as a chemical engineer, he worked in materials science engineering for Honeywell and Delta Airlines before becoming an attorney.



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Brandon Helms joined AddyHart P.C. as a partner in July 2022 with 15 years' experience in government and private practice. Most recently, he served for eight years as an Assistant U.S. Attorney (E.D Mich.), where his work included investigating and prosecuting criminal cases in health care fraud, immigration fraud, and white-collar crime such as bank fraud, along with civil cases under the False Claims Act. He also defended federal agencies and employees in civil suits alleging excessive force, medical malpractice, and employment discrimination. Before that, Brandon was a senior associate at AmLaw 100 firm Steptoe & Johnson LLP in Chicago, where he first-chaired and second-chaired multiple jury and bench trials in federal court; litigated Hatch-Waxman (ANDA) cases on behalf of generic drug companies and patent infringement actions involving semiconductor technology; drafted discovery documents, motions, and briefs through all phases of district court and appellate litigation; and took and defended depositions of fact and expert witnesses. Brandon began his legal career at Brinks Gilson & Lione (now Crowell Moring).



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Ben Cappel focuses his practice on patent infringement litigation in federal district courts, with a particular focus on Hatch-Waxman litigations. He is experienced in all aspects of these matters, from pre-litigation strategy, fact and expert discovery, through trial and appeals. In addition to his work in federal courts, Ben has represented multiple pharmaceutical companies in *inter partes* review proceedings before the PTAB. Notable matters he has been involved in include Restasis®, Treanda®, and Effient®. Before joining AddyHart, Ben practiced at Sughrue Mion.



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