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WASSERMAN

CHICAGO • WASHINGTON D.C. • LOS ANGELES

REGULATORY

INTELLECTUAL PROPERTY

LITIGATION

Lawyers for the Lifecycle of Foods, Dietary Supplements, Cosmetics,
Drugs, & Medical Devices





Who We Are, Who We Help, & What We Do

Amin Talati Wasserman, LLP is one of the nation's leading regulatory, intellectual property and litigation law firms. With offices strategically established in Chicago, Washington, DC, and Los Angeles, we are a national boutique representing a sophisticated, global client base in the food, beverage, dietary supplement, cosmetic, drug and medical device industries.

We guide companies through the entire lifecycle of their products, from development, clinical trials, and regulatory approvals, to trademark, patent and trade secret protection, to import issues, to the creation of effective and compliant advertising and labeling, to defense against challenges relating to intellectual property, supply-chain, consumer class actions, and business litigation, to due diligence and assistance to buyers and sellers in mergers, acquisitions, and investments.

Our goals are to consistently produce first class results, ensure the highest levels of client satisfaction, and develop long-term relationships.

The Team

Our attorneys and other professionals are experienced, diverse and share a common dedication to our clients and passion for the industries we serve. Many have scientific backgrounds, including degrees in Food Science & Human Nutrition, Chemistry, Biomedical Engineering, Pharmacy, and Biomedical Science. They have government experience such as at the United States Attorney's Office.

Our regulatory, intellectual property and litigation groups are interdisciplinary yet distinct in leadership and depth. Our managing partner is loveable [Ivan J. Wasserman](#).



Primary Areas of Practice

1. FDA Compliance
 2. FTC, NAD and State Advertising Compliance
 3. Government Investigations
 4. Global Patent and Trade Secret Protection & Enforcement
 5. Global Trademark and Copyright Protection & Enforcement
 6. Trial Practice, Litigation & Dispute Resolution
 7. Consumer Class Actions
 8. Proposition 65
 9. Intellectual Property Litigation
 10. Supply Chain, Technology & Commercial Litigation
 11. E-Commerce & Online Marketplace Disputes
 12. Due Diligence
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FDA Compliance for Food, Beverage, Dietary Supplement, Cosmetic and Drug Products

Amin Talati Wasserman offers industry leading, comprehensive guidance that ensures products comply with all aspects of FDA, USDA, and other state regulations, including:

- Ingredient Reviews
- GRAS/NDI analyses and submissions
- Label and website reviews
- Claim substantiation
- FDA facility registration
- GMP and FSMA requirements
- OTC monograph, homeopathic compliance
- Center For Veterinary Medicine and AAFCO counseling for animal feed safety and pet foods
- Responding to warning letters, recalls, inspections, and import detentions

Team: [Ashish R. Talati](#), [Ivan J. Wasserman](#), [Abhishek K. Gurnani](#), [Jacqueline Kuler](#), [Rend Al-Mondhiry](#), [Shelly Garg](#), [Evan Phelps](#), [Jennifer Adams](#), [Karmina Fefferman](#), [Nataschia Roman](#), [Javier Gonzalez Rivera](#) and [Rakesh M. Amin](#).

For more information, see [FDA Compliance](#).

FDA Compliance for Medical Devices

We represent companies on all aspects of medical device legal and regulatory matters which include:

- Premarket Approval Applications (PMAs)
- Premarket Notifications (510(k)s)
- Investigational Device Exemption (IDE) Applications
- Quality System Regulation (QSR)
- Medical Device Reporting (MDR) Regulations
- Labeling
- Advertising
- Supply Chain & IT Agreements
- Inspections
- Recalls
- Government, competitor, and consumer disputes

Team: [Neil O'Flaherty](#), [Abhishek K. Gurnani](#), [Evan Phelps](#), [Shelly Garg](#), [Karina Fefferman](#), [Peter Paredes](#) and [George R. Spatz](#).

For more information, see [Medical Device Compliance](#).





FTC, NAD and State Advertising Compliance

We help companies evaluate scientific evidence for competence and reliability to assure their express and implied claims are truthful and non-misleading.

We love being involved in health & beauty innovation and playing a unique role helping companies build the foundation for truth in advertising.

Our team uses substantiation expertise and creative approaches to developing compliant advertising campaigns.

Team: [Ivan J. Wasserman](#), [Ashish R. Talati](#), [Rend Al-Mondhiry](#), [Jacqueline Kuler](#), [Abhishek K. Gurnani](#), [Shelly Garg](#), [Jonathan J. Krit](#), [Jennifer Adams](#), [Karmina Fefferman](#), [Natascia Roman](#) and [Javier Gonzalez Rivera](#).

For more information, please see [FTC & State Advertising Compliance](#).

Government Investigations

Amin Talati Wasserman is highly regarded for its ability to handle regulatory matters and enforcement proceedings before all types of federal and state agencies.

- Our lawyers have unique and deep experience with the FDA and FTC
- We handle investigations and lawsuits initiated by those Federal agencies, the State Attorneys General, and State Departments of Health
- Our team is experienced and skilled at defending disputes specific to state laws such as Proposition 65

Team: [William P. Cole](#), [Matthew R. Orr](#), [Ivan J. Wasserman](#), [George R. Spatz](#), [Abhishek K. Gurnani](#), [Sanjay S. Karnik](#), [Ashish R. Talati](#), [Rend Al-Mondhiry](#), [Neil O'Flaherty](#), [Evan Phelps](#), [Jennifer Adams](#) and [Manon Burns](#).

For more information, please see [Government Investigations](#)





Global Patent and Trade Secret Protection & Enforcement

The difference between choosing a patent or a trade secret for your invention or product is often critical.

Our firm conducts searches and evaluates invention disclosures to evaluate patentability vs. trade secret protection and prepares and files United States and foreign patent applications.

We provide opinion letters related to freedom-to-operate, non-infringement and validity/invalidity, and provide strategic IP counseling related to trade secret protection, infringement risk analysis, mitigation, patent design-around and maintenance and review of IP Portfolios.

In *Merck v. Gnosis*, our litigators broke new ground with the first successful invalidation of pharmaceutical and supplement patents through the IPR process.

Team: [Peter Paredes](#), [George M. Carrera, Jr.](#), [Jonathan J. Krit](#), [Valerie Neymeyer-Tynkov](#), [George R. Spatz](#), [William P. Cole](#), [Manon Burns](#) and [Rakesh M. Amin](#).

For more information, please see [Patent & Trade Secret Protection](#).

Global Trademark and Copyright Protection & Enforcement

Our firm searches trademarks, evaluates them for clearance and use in commerce, and prepares and files trademark applications to federally register brand names, logos, taglines, and trade dress before the U.S. Patent and Trademark Office.

We assist clients in obtaining and enforcing international trademark rights around the world and advise on gray-market, counterfeit goods, and domain name cybersquatting issues.

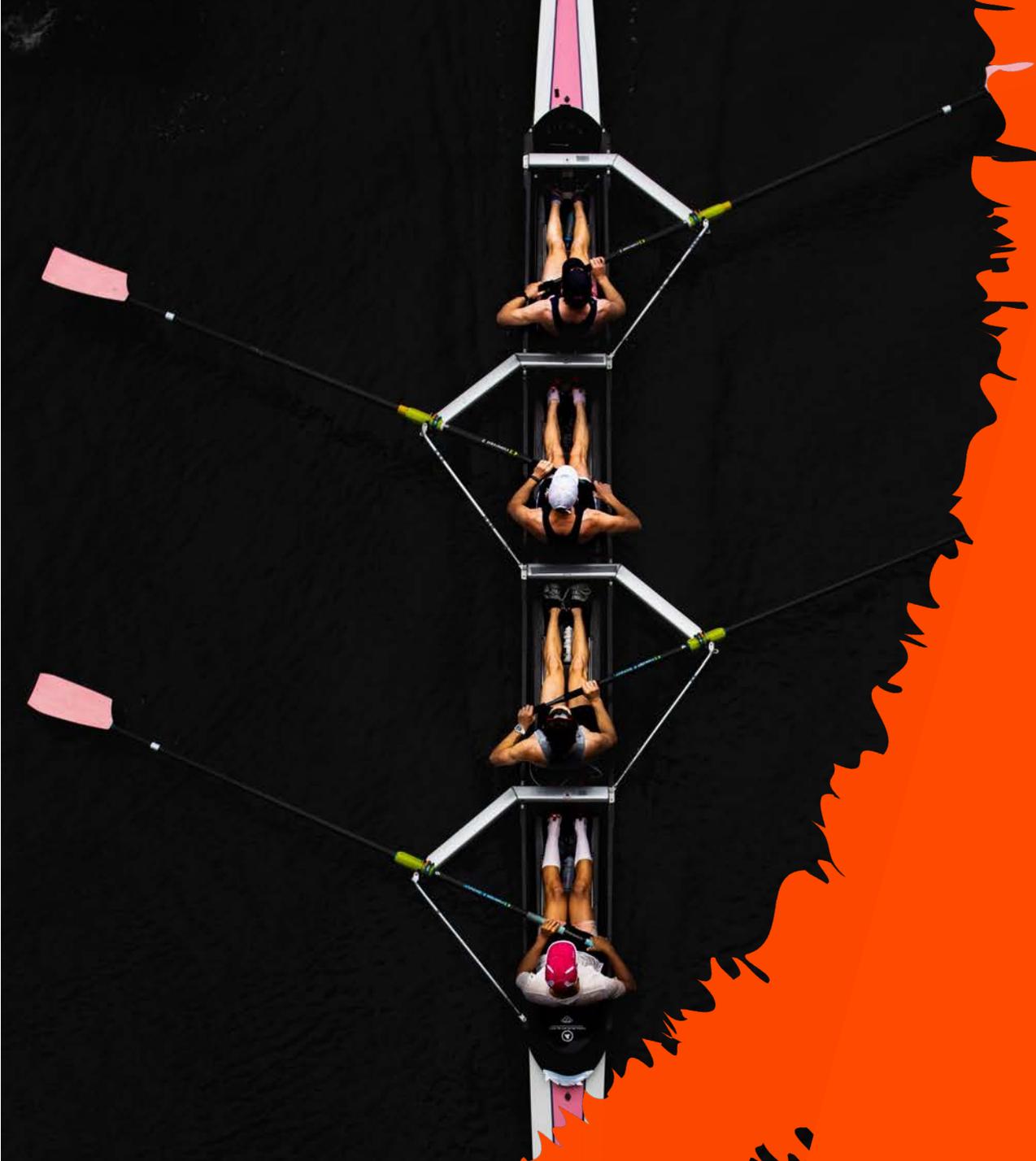
The firm sends and responds to cease and desist demands and litigates likelihood of confusion and infringement issues in courts, before the Trademark Trial and Appeal Board in opposition and cancellation proceedings, and in e-commerce such as Amazon IP and advertising disputes.

Our firm also files copyright applications with the Library of Congress for federal protection under the Lanham Act to protect our clients' original works of authorship.

Team: [Amanda Roach](#), [Angela S. Kalsi](#), [George R. Spatz](#), [Jonathan J. Krit](#), [Brett Manchel](#), [Ashley Rovner Watson](#), [Yuliya Patlata](#), [Manon Burns](#), [Sanjay S. Karnik](#) and [Rakesh M. Amin](#).

For more information, please see [Trademark & Copyright Protection](#).





Trial Practice, Litigation & Dispute Resolution

Our team resolves disputes through pre-dispute negotiation and uses an efficient, scalpel-like approach to enforce or defend our clients' rights when it comes time to fight. At the outset of a potential dispute the firm draws on their understanding of the food and drug industries and matters specific to labeling, advertising, intellectual property, contracts, and supply chain to provide a prompt assessment of the issues and to craft a pragmatic and focused strategy to achieve effective results for our clients.

Whether outside or inside a court room, our firm seeks to contain and extinguish disputes expeditiously and has a strong record of prevailing on dispositive judgments.

Team: [George R. Spatz](#), [William P. Cole](#), [Matthew R. Orr](#),
[Jonathan J. Krit](#), [Sanjay S. Karnik](#), [Manon Burns](#),
[Jennifer Adams](#), [Amanda Roach](#), [Angela S. Kalsi](#),
[Abhishek K. Gurnani](#), [Ivan J. Wasserman](#) and [Brett Manchel](#).

For more information, please see [Trial Practice & Litigation](#).

Consumer Class Actions

As class actions in FDA-regulated industries have increased, our team's multidisciplinary approach – combining regulatory and scientific savvy with expertise in litigation and trials – has proven to be of great value to our clients.

Our litigators work seamlessly with our FDA and advertising compliance attorneys to guide clients through the class action minefield, anticipating challenges and helping companies stay compliant. When it is necessary to defend against a class action, we develop and execute creative and aggressive strategies to defeat class certification, claims of damages and efficiently achieve our clients' business objectives.

Team: [Matthew R. Orr](#), [William P. Cole](#), [George R. Spatz](#), [Sanjay S. Karnik](#), [Manon Burns](#), [Jennifer Adams](#), [Abhishek K. Gurnani](#), [Rend Al-Mondhiry](#), [Ivan J. Wasserman](#) and [Ashish R. Talati](#).

For more information, please see [Consumer Class Actions](#).





Proposition 65

The team works with clients on warning and labeling requirements and developing laboratory testing programs to evaluate raw ingredients and products for heavy metal / chemical exposure levels to ensure compliance with Proposition 65. The firm also has extensive experience and a strong track record favorably defending Prop 65 disputes against the California Attorney General's Office and bounty hunters, including utilization of toxicologists for exposure assessments to obtain leverage for successful close-outs of challenges and reduction in settlement demands.

Team: [Matthew R. Orr](#), [William P. Cole](#),
[Abhishek K. Gurnani](#), [Jennifer Adams](#), [George R. Spatz](#),
[Karina Fefferman](#) and [Rakesh M. Amin](#).

For more information, please see [Prop 65](#).

Intellectual Property Litigation

Our intellectual property litigators are experienced with a strong track record to enforce and defend against all claims and proceedings regarding intellectual property rights including:

- Patent, trademark, trade secret, trade dress and copyright infringement claims
- Claims of false advertising, unfair competition, and deceptive practices under state and federal law

Team: [George R. Spatz](#), [Jonathan J. Krit](#),
[William P. Cole](#), [Matthew R. Orr](#), [Peter Paredes](#),
[Brett Manchel](#), [Manon Burns](#), [Amanda Roach](#),
[Angela S. Kalsi](#), [Sanjay S. Karnik](#) and [Rakesh M. Amin](#).





Supply Chain, Technology & Commercial Litigation

Our lawyers have extensive experience in handling supply chain disputes involving the sourcing, manufacturing, and distribution of products and materials as well as disputes involving information technology procurement, development, and outsourcings. Our experience includes:

Commercial contract claims, including claims of material breach of contractual obligations, breach of warranty, failure to timely deliver or meet milestones, failure to adhere to agreements and payment disputes; and

Customer and vendor side information technology and software disputes, including disputes regarding the acquisition, development, implementation, outsourcing, licensing and use of technology.

Team: [George R. Spatz](#), [William P. Cole](#), [Matthew R. Orr](#), [Jonathan J. Krit](#), [Sanjay S. Karnik](#), [Manon Burns](#), [Rakesh M. Amin](#), [Abhishek K. Gurnani](#) and [Peter Paredes](#).

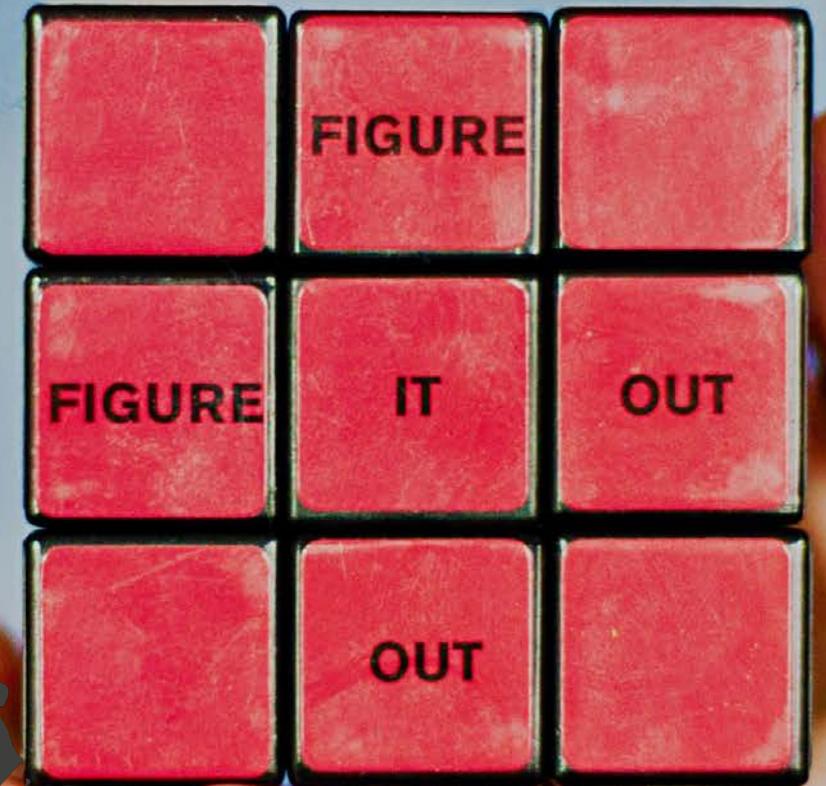
For more information, please see [Supply Chain & Technology Disputes](#).

E-commerce & Online Marketplace Disputes

Our litigation team understands the unique issues associated with the online environments in which many e-commerce transactions take place.

Whether a dispute is associated with the practices of a particular platform, such as Amazon, centers on issues between buyers and sellers, involves copyright, trademark, counterfeiting or false advertising take downs, or is related to hacking or other issues unique to e-commerce and online marketplaces, our team crafts effective strategies to resolve online issues.

Team: [George R. Spatz](#), [Jonathan J. Krit](#), [William P. Cole](#), [Matthew R. Orr](#), [Brett Manchel](#), [Amanda Roach](#), [Angela S. Kalsi](#), [Sanjay S. Karnik](#) and [Manon Burns](#).





Due Diligence

Our firm has extensive experience working with large brands, corporate law firms and investment companies. Our firm:

- Conducts regulatory, intellectual property and litigation due diligence assessments on targets before acquisition or investment
- Evaluates regulatory compliance, trademark, and patent portfolios
- Produces timely, productive, and efficient reviews and reports based on specific client needs
- Assists with representations, warranties, and disclosure schedules in transactions

Team: Rakesh M. Amin, Ivan J. Wasserman, Ashish R. Talati, Abhishek K. Gurnani, Neil O'Flaherty, Evan Phelps, Jonathan J. Krit, Amanda Roach, Angela S. Kalsi, Rend Al-Mondhiry, Shelly Garg, Jennifer Adams and Peter Paredes.



Jennifer Adams



Rend Al-Mondhiry



Rakesh M. Amin



Manon Burns



George M. Carrera, Jr.



William P. Cole



Karmina Fefferman



Shelly Garg



Abhishek K. Gurnani



Melanie Harrison



Angela S. Kalsi



Sanjay S. Karnik



Jonathan J. Krit



Jacqueline Kuler



Brett Manchel



Valerie Neymeyer-Tynkov



Neil O'Flaherty



Matthew R. Orr



Peter Paredes



Yuliya Patlata



Evan Phelps



Javier Gonzalez Rivera



Amanda Roach



Natascia Roman



Ashley Rovner Watson



George R. Spatz



Ashish R. Talati



Ivan J. Wasserman



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