

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 and What We Do

Amin Talati Wasserman, LLP is one of the country's leading regulatory, intellectual property and litigation boutique law firms, with offices strategically located in Chicago, Washington, DC, and Los Angeles. Across industries and categories, primarily the food, beverage, dietary supplement, cosmetic, drug and medical device sectors, our clients represent a "who's who" of forward-thinking companies and world-class brands.

We guide the businesses that turn to us through the entire lifecycle of their products, from development to clinical trials and regulatory approvals to trademark, patent and trade secret protection; we help them with import issues and the creation of effective and compliant advertising and labeling; with defense against challenges relating to intellectual property, supply chain challenges, consumer class actions and business litigation; and, finally, we take both buyers and sellers through due diligence and mergers, acquisitions and investments.

At Amin Talati Wasserman, we strive to consistently and efficiently produce first-class results, maintain the highest levels of satisfaction, and develop long-standing relationships with our clients.

For more information about our firm, visit www.amintalati.com.

The Team

We have a highly experienced and diverse group of attorneys and professional team. They share a common dedication to our clients and a passion for the industries we serve. Many have advanced degrees in food science and human nutrition, chemistry, biomedical engineering, pharmacy or biomedical science. Several lawyers at our firm served in judicial or industry-leading positions prior to joining us, including as federal prosecutor and as counsel to The Council for Responsible Nutrition.

Our regulatory, intellectual property and litigation groups are interdisciplinary yet distinct in leadership and depth.

Our Managing Partner is the loveable Ivan Wasserman, ivan@amintalati.com.



Primary Areas of Practice

- 1. FDA Compliance
- 2. FTC, NAD and State Advertising Compliance
- 3. Government Investigations and Litigation
- 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. California Proposition 65
- 9. Intellectual Property and Advertising Litigation
- 10. Supply Chain, Technology & Commercial Litigation
- **11.** E-Commerce & Online Marketplace Disputes
- 12. Due Diligence





FDA Compliance for Food, Beverage, Dietary Supplement, Cosmetic and Drug Products

With our unique practice areas and attorney backgrounds, we are able to bring a highly strategic and multifaceted approach to meeting the needs of FDA-regulated businesses. We offer industry-leading, comprehensive guidance that ensures our clients' products comply with all aspects of FDA, USDA, and 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
- Warning letters, recall and inspection responses and import detentions

Team: <u>Abhishek Gurnani</u>, <u>Ashish Talati</u>, <u>Ivan Wasserman</u>, <u>Jacqueline Kuler</u>, <u>Rend Al-Mondhiry</u>, <u>Angela Diesch</u>, <u>Evan Phelps</u>, <u>Jennifer Adams</u>, <u>Lauren Aronson</u>, <u>Karmina Fefferman</u>, <u>Natascia Taken</u> and <u>Rakesh Amin</u>.

For more information, please see <u>FDA Compliance</u>.

FDA Compliance for Medical Devices

Our team of nationally known FDA lawyers guides clients through every aspect of the highly regulated, complex and evolving medical device legal and regulatory landscape, including:

- 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 and IT Agreements
- Inspections
- Recalls
- Government, Competitor and Consumer Disputes

Team: Neil O'Flaherty, Abhishek Gurnani, Evan Phelps, Karmina Fefferman, Peter Paredes and George Spatz.

For more information, please see Medical Device Compliance.





FTC, NAD and State Advertising Compliance

Our top-ranked advertising team serves a world-class roster of clients evaluating scientific evidence for competence and reliability to ensure clients' express and implied claims are truthful and not misleading. Our attorneys are highly versed in the technical and scientific issues underlying claim substantiation and work closely with our clients' legal, marketing and research teams on the design of product claims as well as on the oversight and testing required to support them.

Our passion for innovation, something we share with our clients, puts us in a unique position to help them meet ever-changing advertising compliance obligations across all media, channels and platforms. We use substantiation expertise and creative approaches to developing compliant advertising campaigns.

Team: <u>Lauren Aronson</u>, <u>Ivan Wasserman</u>, <u>Abhishek Gurnani</u>, <u>Ashish Talati</u>, <u>Rend Al-Mondhiry</u>, <u>Jacqueline Kuler</u>, <u>Angela Diesch</u>, <u>Jonathan Krit</u>, <u>Jennifer Adams</u>, <u>Karmina Fefferman</u> and <u>Natascia Taken</u>.

For more information, please see FTC & State Advertising Compliance.

Government Investigation and Litigation

We recognize that significant financial and business repercussions are at stake for our clients in any government investigation or litigation.

Amin Talati Wasserman is highly regarded for its ability to handle inquiries and enforcement proceedings before numerous federal and state regulatory agencies. Our team seeks resolutions in the most expeditious and advantageous manner possible, whether through negotiated settlements or, when necessary, actual litigation.

- Our lawyers have extensive experience handling matters before the FDA and FTC.
- We handle investigations and defend enforcement actions initiated by state attorneys general and state health departments.
- We defend disputes specific to state laws, such as Proposition 65.
- We create strategies to help deter or mitigate the risk of enforcement actions and litigation.
- We help our clients design and implement best-in-class compliance practices.

Team: William Cole, Lauren Aronson, Abhishek Gurnani, Ivan Wasserman, Matthew Orr, George Spatz, Jennifer Adams, Manon Burns, Rend Al-Mondhiry, Ashish Talati, Neil O'Flaherty, Angela Diesch and Evan Phelps.

For more information, please see <u>Government Investigations</u>.





Global Patent and Trade Secret Protection & Enforcement

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

We conduct searches and evaluate invention disclosures in order to assess patentability versus trade secret protection and then prepare and file U.S. and foreign patent applications.

We provide opinion letters related to freedom-to-operate issues, non-infringement and validity/invalidity, and we 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 *inter partes* review process.

Team: <u>Peter Paredes</u>, <u>George Carrera</u>, <u>Jr.</u>, <u>William Cole</u>, <u>Jonathan Krit</u>, <u>George Spatz</u>, <u>Manon Burns</u>, and <u>Rakesh Amin</u>.

For more information, please see <u>Patent & Trade Secret Protection</u>.

Global Trademark and Copyright Protection & Enforcement

Our global trademark services are full spectrum, including portfolio planning, clearance and registration (including searches, applications for registration, prosecution and post-registration maintenance), policing, and contested matters and dispute resolution.

Our expertise extends to advising on gray-market, counterfeit goods and domain name cybersquatting issues.

We send and respond to cease and desist demands and litigate likelihood of confusion and infringement issues in courts, before the Trademark Trial and Appeal Board in opposition and cancellation proceedings, on e-commerce platforms, such as Amazon IP, and at the NAD.

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

Team: Ryan Kaiser, George Spatz, Peter Paredes, Jonathan Krit, Lauren Aronson, Manon Burns, Ashley Rovner Watson and Rakesh Amin.

For more information, please see <u>Trademark & Copyright Protection</u>.





Trial Practice, Litigation & Dispute Resolution

Our team of experienced litigators handle a wide variety of civil lawsuits and other disputes in courts and other tribunals across the country. In each case, our primary goal is to achieve the best possible result for our client, whether by victory in court or by obtaining a favorable settlement.

Our attorneys resolve disputes through pre-dispute negotiation and use an efficient, well-honed approach to enforce or defend our clients' rights when it comes time to fight. At the outset of a potential dispute, we draw on our collective and in-depth industry-specific knowledge of issues around labeling, advertising, intellectual property, contracts, and supply chain in order to provide a prompt assessment and craft a pragmatic and focused strategy in line with our client's objectives.

Our goal is to expeditiously contain and extinguish disputes, whether inside or outside the courtroom, and our record of prevailing on dispositive judgments is second to none.

Team: <u>George Spatz</u>, <u>William Cole</u>, <u>Matthew Orr</u>, <u>Ryan Kaiser</u>, <u>Jonathan Krit</u>, <u>Richard Hyde</u>, <u>Manon Burns</u>, <u>Jennifer Adams</u>, <u>Abhishek Gurnani</u>, <u>Angela</u> Diesch and Lauren Aronson.

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 consumer class action team works seamlessly with our FDA and advertising compliance attorneys to guide clients through the class action minefield. We anticipate threats to clients' reputations, brand quality and product identity. When it becomes necessary to defend against a class action, we develop and execute creative and aggressive strategies to defeat class certification and claims of damages and protect our client's interests.

Team: Matthew Orr, William Cole, George Spatz, Manon Burns, Jennifer Adams,
Abhishek Gurnani, Rend Al-Mondhiry,
Ivan Wasserman, Ashish Talati, Angela Diesch,
Ryan Kaiser and Lauren Aronson.

For more information, please see **Consumer Class Actions**.





California Proposition 65

The consequences of failing to comply with Proposition 65 can be significant. In order to remain compliant with Prop 65, our team works with clients on warning and labeling requirements and developing laboratory testing programs to evaluate raw ingredients and products for heavy metal and chemical exposure. We also have extensive experience in and a strong track record of favorably defending Prop 65 disputes against the California attorney general's office and bounty hunters. We use toxicologists for exposure assessments to obtain leverage to ensure successful closeouts of challenges and a reduction in settlement demands.

Team: Matthew Orr, William Cole, Abhishek Gurnani, Jennifer Adams, Richard Hyde, George Spatz, Angela Diesch and Rakesh Amin.

For more information, please see **Prop 65**.

Intellectual Property and Advertising Litigation

When it comes to understanding the essence of a challenge or dispute, speed makes all the difference. With lawyers solely focused on IP litigation and who work alongside our substantive and industry experts, we quickly master the nuances and find solutions our competitors might miss.

Our clients benefit from a lean and highly skilled team of intellectual property litigators whose experience spans the full range of IP disputes: patent, trademark, copyright, false advertising, and trade secret.

Our approach is creative and tenacious, insightful and pragmatic. We analyze and discuss a potential array of responses from all-out battle to calculated fallback, and we work hand in hand with clients to resolve their most complex and high-stakes intellectual property disputes.

Team: George Spatz, Ryan Kaiser, William Cole, Jonathan Krit, Matthew Orr, Peter Paredes, Manon Burns, Richard Hyde, Ivan Wasserman, Lauren Aronson, Jennifer Adams, and Rakesh Amin.





Supply Chain, Technology & Commercial Litigation

Many of our clients are grappling with supplier issues and find themselves re-evaluating their contracts to ensure continued supplies going forward. Our lawyers have extensive experience handling supply chain disputes (sourcing, manufacturing, and distribution of products and materials) as well as disputes involving information technology procurement, development, and outsourcing. We work with clients to find solutions that address disruptions and any resulting contractual breaches.

Our experience in this area comprises: 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 resolution; and customer and vendor side information technology and software disputes, such as disputes regarding the acquisition, development, implementation, outsourcing, licensing and use of technology.

Team: <u>George Spatz</u>, <u>William Cole</u>, <u>Matthew Orr</u>, <u>Ryan Kaiser</u>, <u>Jonathan Krit</u>, <u>Richard Hyde</u>, <u>Manon Burns</u>, <u>Rakesh Amin</u>, <u>Abhishek Gurnani</u> and <u>Peter Paredes</u>.

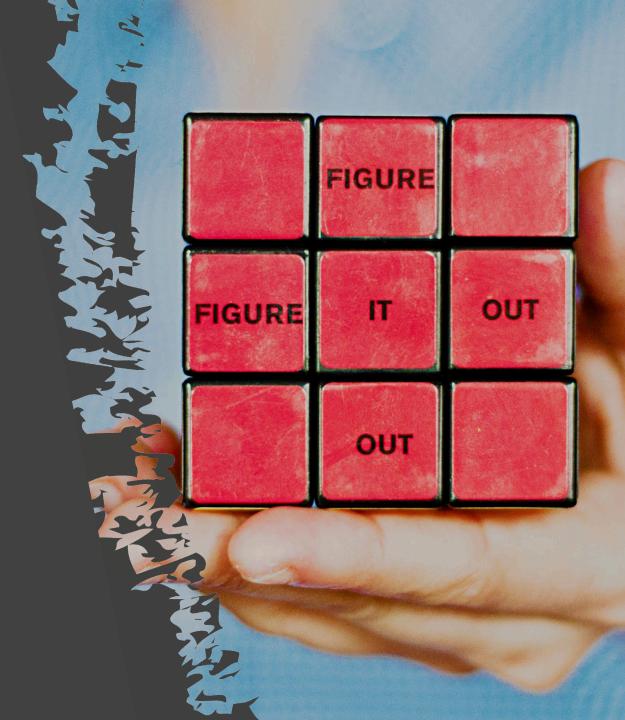
For more information, please see <u>Supply Chain & Technology Disputes</u>.

E-commerce & Online Marketplace Disputes

The rise of the online marketplace model is unstoppable and impacts businesses of all kinds. Although most online marketplaces make it easy for brands and retailers to advertise, sell and fulfill, disputes routinely arise. When they do, clients know they can turn to our litigators to resolve them.

Whether a dispute involves a particular platform, such as Amazon; centers on issues between buyers and sellers; calls for copyright, trademark, counterfeiting or false advertising take downs; or is related to hacking, our team develops creative, practical, and cost-effective solutions.

Team: <u>George Spatz</u>, <u>Ryan Kaiser</u>, <u>William Cole</u>, <u>Matthew Orr</u>, <u>Jonathan Krit</u>, <u>Richard Hyde</u>, <u>Manon Burns</u> and Lauren Aronson.





Due Diligence

We know that one size does not fit all, so we customize all due diligence projects to a specific transaction.

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

We are highly sought after when it comes to the following:

- Conducting regulatory, intellectual property and litigation due diligence assessments on targets before acquisition or investment
- Evaluating regulatory compliance, trademark, and patent portfolios
- Producing timely, productive, and efficient reviews and reporting based on specific client needs
- Assisting with representations, warranties and disclosure schedules in transactions

Team: Ivan Wasserman, Lauren Aronson,
Abhishek Gurnani, Ashish Talati, Neil O'Flaherty,
Evan Phelps, Ryan Kaiser, Jonathan Krit,
Rend Al-Mondhiry, Jennifer Adams, Peter Paredes,
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Thank You!



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