



AMIN WASSERMAN GURNANI

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 Wasserman Gurnani is one of the country's leading regulatory, intellectual property, and litigation boutique law firms 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 innovators, entrepreneurs, 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 Wasserman Gurnani, we strive to consistently and efficiently produce first-class results, maintain the highest satisfaction levels, and develop long-standing relationships with our clients.

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

The Team

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

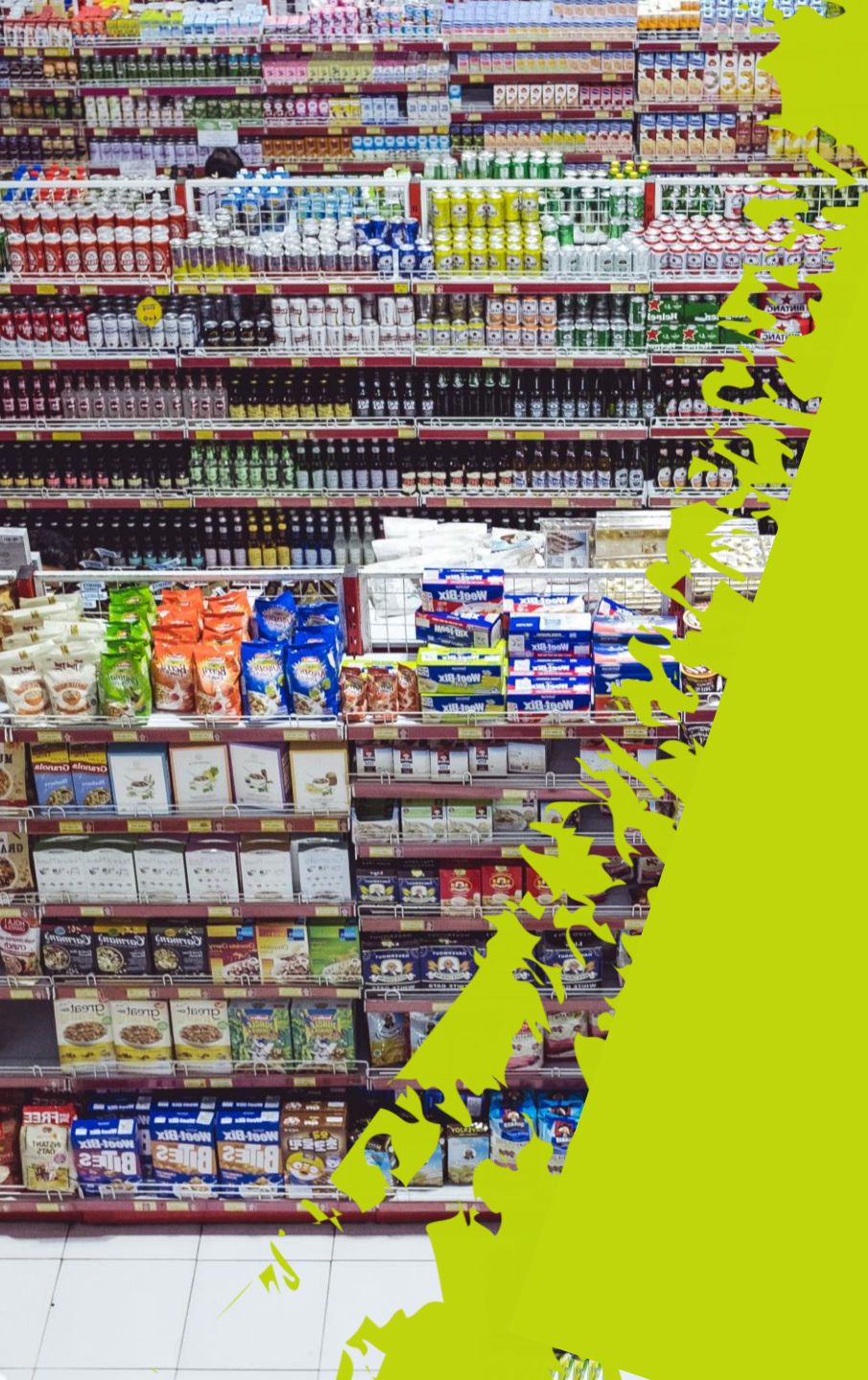
Our regulatory, intellectual property, and litigation groups are interdisciplinary yet distinct in leadership and depth.

Our Managing Partner is the loveable [Ivan Wasserman](mailto:ivan@awglaw.com), ivan@awglaw.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 can 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: [Abhishek Gurnani](#), [Ivan Wasserman](#), [Jacqueline Kuler](#), [Rend Al-Mondhiry](#), [Angela Diesch](#), [Evan Phelps](#), [Jennifer Adams](#), [Lauren Aronson](#), [Karmina Fefferman](#), and [Rakesh Amin](#).

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

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 and on the oversight and testing required to support them.

Our passion for innovation, which we share with our clients, puts us in a unique position to help them meet ever-changing advertising compliance obligations across all media and channels.

Our team's expertise in substantiation and creative approaches to developing compliant advertising campaigns is unparalleled. We are confident in our ability to help you navigate the complex landscape of advertising compliance across all platforms and media.

Team: [Lauren Aronson](#), [Ivan Wasserman](#), [Abhishek Gurnani](#), [Rend Al-Mondhiry](#), [Jacqueline Kuler](#), [Angela Diesch](#), [Jonathan Krit](#), [Jennifer Adams](#), and [Karmina Fefferman](#).

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 Wasserman Gurnani 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](#), [Neil O'Flaherty](#), [Angela Diesch](#) and [Evan Phelps](#).

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





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: [Peter Paredes](#), [George Carrera, Jr.](#), [William Cole](#), [Jonathan Krit](#), [George Spatz](#), [Manon Burns](#), and [Rakesh Amin](#).

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

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 [Trademark & Copyright Protection](#).





Trial Practice, Litigation & Dispute Resolution

Our team of experienced litigators handles 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 to provide a prompt assessment and craft a pragmatic and focused strategy in line with our client's objectives.

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

Team: [George Spatz](#), [William Cole](#), [Matthew Orr](#), [Ryan Kaiser](#), [Jonathan Krit](#), [Richard Hyde](#), [Manon Burns](#), [Jennifer Adams](#), [Abhishek Gurnani](#), [Angela 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, Angela Diesch, Ryan Kaiser and Lauren Aronson.

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





California Proposition 65

Proposition 65 compliance is crucial for businesses to avoid significant consequences. Our team specializes in providing effective solutions to help you comply with Prop 65. We can assist you with warning and labeling requirements, develop laboratory testing programs to evaluate your products for heavy metal and chemical exposure, and provide you with expert defense against Prop 65 disputes.

Our team has a proven track record of successfully defending Prop 65 disputes against the California attorney general's office and bounty hunters. We use exposure assessments from toxicologists to obtain leverage and ensure successful close-outs 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 re-evaluating their contracts to ensure continued supplies going forward. Our lawyers have extensive experience handling supply chain disputes (sourcing, manufacturing, and distributing products and materials) and disputes involving information technology procurement, development, and outsourcing. We work with clients to find solutions for disruptions and any resulting contractual breaches.

Our experience in this area comprises commercial contract claims, including claims of a 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: [George Spatz](#), [William Cole](#), [Matthew Orr](#), [Ryan Kaiser](#),
[Jonathan Krit](#), [Richard Hyde](#), [Manon Burns](#),
[Rakesh Amin](#), [Abhishek Gurnani](#) and [Peter Paredes](#).

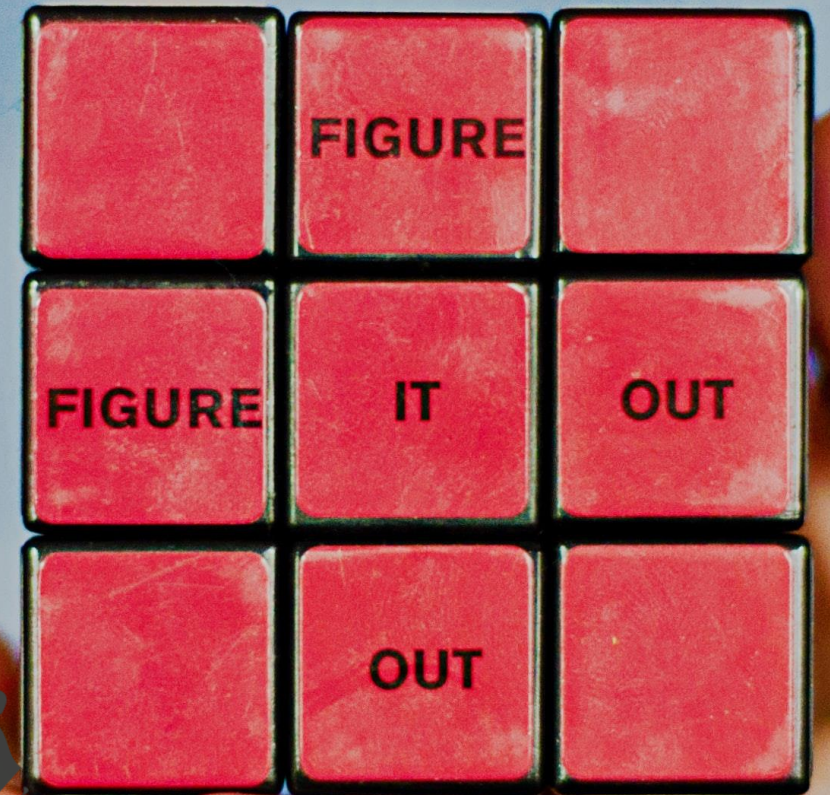
For more information, please see [Supply Chain & Technology Disputes](#).

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





Due Diligence

We know 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, Neil O'Flaherty,
Evan Phelps, Ryan Kaiser, Jonathan Krit,
Rend Al-Mondhiry, Jennifer Adams, Peter Paredes,
Matthew Orr and Rakesh Amin.



Jennifer Adams
jadams@awglaw.com



Rend Al-Mondhiry
ralmondhiry@awglaw.com



Rakesh Amin
ramin@awglaw.com



Lauren Aronson
laronson@awglaw.com



Andrew Baumann
abauman@awglaw.com



Manon Burns
mburns@awglaw.com



Jana Caracciolo
jcaracciolo@awglaw.com



William Cole
wcole@awglaw.com



Angela Diesch
adiesch@awglaw.com



Karmina Fefferman
kfefferman@awglaw.com



Abhishek Gurnani
agurnani@awglaw.com



Melanie Harrison
mharrison@awglaw.com



Richard Hyde
rhyde@awglaw.com



Ryan Kaiser
rkaiser@awglaw.com



Jonathan Krit
jkrit@awglaw.com



Jacqueline Kuler
jkuler@awglaw.com



Neil O'Flaherty
noflaherty@awglaw.com



Matthew Orr
morr@awglaw.com



Peter Paredes
pparedes@awglaw.com



Evan Phelps
ephelps@awglaw.com



Ashley Rovner Watson
arovnerwatson@awglaw.com



George Spatz
gspatz@awglaw.com



Ivan Wasserman
iwasserman@awglaw.com





AMIN WASSERMAN GURNANI

Chicago | Washington D.C. | Los Angeles

Please Contact Us to Learn More

CHICAGO

549 W. Randolph Street
Suite 400
Chicago, IL 60661

 312.466.1033

WASHINGTON

5185 MacArthur Boulevard NW
Suite 230
Washington, D.C. 20016

 202.496.4966

LOS ANGELES

515 South Flower Street
18th Floor
Los Angeles, CA 90071

 213.933.2330

info@awglaw.com



Thank You!



**AMIN
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GURNANI**

Chicago | Washington D.C. | Los Angeles