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BROMBERG&NEWMAN P.C.

Serving the Legal Needs of **Dietary Supplement Companies**

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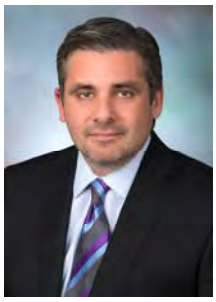

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Kevin Bell is an IP attorney who focuses practice focuses primarily on litigating complex disputes involving patents, trademarks, trade secrets, trade dress and unfair competition before federal courts and agencies, the International Trade Commission and various alternative dispute resolution forums. Kevin has extensive experience in licensing intellectual property and regularly provides strategic counseling to clients regarding development and enforcement of intellectual property portfolios.

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Richard represents companies in patent, trademark, unfair competition, trade secrets, trade regulation and other complex litigation at the trial and appellate levels and before the International Trade Commission. He has litigated patent, trademark, unfair competition, trade secrets and copyright cases in District Courts and the Court of Appeals for the Federal Circuit. Richard is actively engaged in investigations and regulatory issues at the Federal Trade Commission and Food and Drug Administration.

DIETARY SUPPLEMENT LEGAL UPDATE (JULY 2018)

A variety of legal and regulatory challenges exist in the dietary supplement industry, including federal and state legislatures, agencies and courts. Some recent significant developments are summarized below. For additional information, contact Kevin M. Bell or Richard J. Oparil of Porzio's Washington office.

Senate Confirms New FTC Commissioners

The Senate has confirmed the five persons nominated by President Trump to serve as FTC commissioners. Republican now control the agency.

The confirmed nominees are:

- Joseph Simons, a Republican, most recently worked as co-chair of the antitrust practice at Paul, Weiss, Rifkind, Wharton & Garrison.
- Noah Phillips, a Republican, was Chief Counsel to Senator John Cornyn, the Republican Whip.
- Christine Wilson, a Republican, was Senior Vice President for Regulatory and International Affairs at Delta Air Lines.
- Rohit Chopra, a Democrat, was a senior fellow at the Consumer Federation of America, formerly served as the CFPB's Student Loan Ombudsman.
- Rebecca Slaughter, a Democrat, was Chief Counsel to Senator Chuck Schumer, the Senate Minority Leader.

The FTC has been operating with just two commissioners consisting of Acting Chairman Maureen Ohlhausen and Commissioner Terrell McSweeny. Ohlhausen, a Republican whose term expires in September 2018, has been nominated to serve as a judge on the U.S. Court of Federal Claims. Since Wilson was appointed to fill Ohlhausen's seat and the Senate has not yet confirmed Ohlhausen as a judge, it is uncertain when Wilson will be sworn in as an FTC commissioner. McSweeny resigned effective April 28.

On May 15, the Commissioners, in a three to two vote, confirmed Andrew M. Smith to be the head of the Consumer Protection division. As an attorney at Covington & Burling, Smith, had represented Facebook, Uber and Equifax in matters before the Commission.

SARMs Legislation Introduced

Senators Orrin Hatch and Sheldon Whitehouse recently introduced the SARMs Control Act of 2018 (S. 2742). Selective androgen receptor modulators (SARMs) are synthetic drugs designed to mimic the effects of testosterone. The legislation extends the Drug Enforcement Administration's authority to regulate anabolic steroids to include SARMs.

SARMs are marketed as dietary supplements for athletes, recreational bodybuilders, and members of the armed forces, but are banned in all professional and college sports. The U.S. Anti-Doping Agency and the Department of Defense Operation Supplement Safety program have warned about the risks of SARMs, including heart attack or stroke and liver damage. The FDA recently issued warning letters to three companies for distributing products that contain SARMs, noting that the products are unapproved drugs that have not been reviewed by the FDA for safety and effectiveness.

The Hatch/Whitehouse bill builds on the Designer Anabolic Steroids Control Act of 2014 by extending the DEA's authority to regulate anabolic steroids to include SARMs. Specifically, the bill would:

- Amend the Controlled Substances Act (CSA) to add SARMs to the list of Schedule III controlled substances, ensuring that SARMs are regulated in the same manner as anabolic steroids;
- Add a definition of the term "SARM," including a list of specified substances and a process for the Attorney General to add substances to the definition of SARM;
- Prohibit importing, exporting, manufacturing, distributing, dispensing, or possessing with intent to manufacture, distribute, or dispense any SARM, or any product containing a SARM, unless it is properly labeled;
- Add certain offenses related to SARMs to the definition of "felony drug offense" and the civil penalty provisions of the CSA; and
- Require that the FDA provide to the DEA information related to dietary supplements that the FDA determines may contain a SARM, as it already does for supplements that may contain anabolic steroids.

The bill was referred to the Senate Judiciary Committee.

Congressional Research Service Report on § 101 Patent Eligibility

The Congressional Research Service (CRS), part of the Library of Congress, has conducted an analysis of the relevant legal framework for the regulation and patentability of dietary supplements. It covers the following: (1) legal definitions of "dietary supplements," how they differ from the drugs that are regulated by the FDA, and what, if any, regulations cover dietary supplements; (2) how the Supreme Court's decisions interpreting 35 U.S.C. § 101, which defines patent-eligible subject matter, are likely to affect the future patentability of dietary supplements; (3) whether the U.S. District Court for the Southern District of California's recent decisions in Natural Alternatives International, Inc. cases correctly interpreted and applied the Supreme Court's recent § 101 decisions; and (4) broader issues related to the patentability of dietary supplements.

The CRS report said that the distinctions between dietary supplements and drugs are often difficult to discern, but dietary supplement regulations tend to be less rigorous than those covering drugs and tend to focus on post-market regulation of the supplement's labeling. In addition, while the Supreme Court's recent § 101 cases have seemingly applied certain exceptions to patentability more strictly, thereby arguably narrowing patent-eligible subject matter, the cases may guide dietary supplements manufacturers in determining which of their products are most likely to be eligible for patent protection. Finally, the recent cases invalidating Natural Alternatives International, Inc.'s patent claims covering a dietary supplement appear to involve a straightforward application of recent § 101 case law, but do not necessarily suggest that all patent claims concerning dietary supplements are similarly invalid.

A copy of the report is available from Porzio's Washington office.

FDA Issues Warnings on Sunscreen Pills

On May 22, FDA sent warning letters to companies illegally marketing dietary supplements that make unproven drug claims about sun protection without meeting FDA's standards for safety and effectiveness. FDA said the companies are "putting people's health at risk by giving consumers a false sense of security that a dietary supplement could prevent sunburn, reduce early skin aging caused by the sun, or protect from the risks of skin cancer." FDA instructed the companies to correct all violations associated with their products and were advised to review product labeling and websites to ensure that the claims do not violate federal law. Examples of claims include: "Enhances photoprotection," "It's basically an oral sunscreen," and "Every second you spend in the sun damages your skin. But Sunsafe Rx is always working: it protects your whole body," according to the FDA's letters.

FDA Issues Warning Letters on Kratom Products Marketed for Opioid Cessation, Pain, and Other Medical Uses

FDA has issued warning letters to three marketers and distributors of kratom products for illegally selling unapproved kratom-containing drug products with unproven claims about their ability to help in the treatment of opioid addiction and withdrawal. The companies also make claims about treating pain, as well as other medical conditions like lowering blood pressure, treating cancer and reducing neuron damage caused by strokes.

The FDA is concerned that kratom affects the same opioid brain receptors as morphine, and appears to have properties that expose users to the risks of addiction, abuse and dependence. There are no FDA-approved uses for kratom, and the agency has received concerning reports about the safety of kratom.

FDA Commissioner Scott Gottlieb, M.D., said: "Despite our warnings that no kratom product is safe, we continue to find companies selling kratom and doing so with deceptive medical claims for which there's no reliable scientific proof to support their use. As we work to combat the opioid epidemic, we cannot allow unscrupulous vendors to take advantage of consumers by selling products with unsubstantiated claims that they can treat opioid addiction. Far from treating addiction, we've determined that kratom is an opioid analogue that may actually contribute to the opioid epidemic and puts patients at risk of serious side effects. If people believe that the active ingredients in kratom have drug-like effects that can treat pain or addiction, then the FDA is open to reviewing that data under our new drug approval process.

CBD Update

FDA has continued to issue warning letters to companies that promote products containing cannabinoids, including cannabidiol (CBD), as dietary supplements. Recent warning letters state that FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under DSHEA (21 U.S.C. § 321(ff)(3)(B)(ii)). Under that provision, if an article (such as CBD) has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA concluded that this is not the case for CBD.

FDA cites clinical investigations regarding CBD. Two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex. Under FDA's regulations (21 C.F.R. § 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products. FDA states that it is not aware of any evidence that contradict its conclusion that CBD products are excluded from the dietary supplement definition. The upshot is that CBD supplements will have a difficult time passing FDA muster. FDA has indicated, however, that it will prioritize enforcement for products that are marketed with drug or disease claims.

In June, FDA formally approved GW's Epidiolex product as a new drug to treat two rare forms of epilepsy — Lennox-Gastaut syndrome and Dravet syndrome. This is the first cannabis-derived prescription medicine available in the United States.

Hemp Farming Legislation Passed By Senate

A bill to legalize hemp as an agricultural commodity passed the Senate as part of the mammoth farm bill. Sponsored by the Majority Leader, Senator McConnell, the bill would remove hemp from the list of controlled substances, allow states to regulate the product, and make hemp farmers eligible for crop insurance. The House of Representatives passed a different version of the farm bill. The two houses must reconcile the differences before it can go to the White House for signature.

Food Labeling Extension

On May 4, 2018, FDA published a final rule officially extending the compliance dates for the final rules providing updated nutrition information on the label of food, including dietary supplements. The extension is to January 1, 2020 for manufacturers with $10 million or more in annual sales and to January 1, 2021 for manufacturers with less than $10 million dollars in annual food sales.

Bioengineered Labeling Rule

Also on May 4, the U.S. Department of Agriculture's Agricultural Marketing Service (AMS) published its long awaited proposed rule that will require food manufacturers and other entities labelling foods for retail sale to disclose information about bioengineered (BE) food and food ingredient content. The proposed rule is intended to provide a mandatory uniform national standard for disclosure of information to consumers about the BE status of foods. As expected, the proposed compliance dates for the BE rule are the same as those for the FDA's labeling changes to minimize the amount of changes that the industry will be required to make to its product labels. The comment period for the proposal is now closed.

Tariffs on Chinese Imports

In March 2018, the U.S. Trade Representative (USTR) proposed an additional duty of 25 percent on the list of products of Chinese origin. For example, if a good of Chinese origin is currently subject to a zero rate of duty, the product would be subject to a 25 percent rate of duty; if a good of Chinese origin were currently subject to a 10 percent duty, the product would be subject to a 35 percent duty; and so on. Some dietary supplements are on President Trump's proposed list of tariffs on imported Chinese goods. They include CoQ10 and vitamins E, B2 and B12, as well as ferments, excluding yeasts.

The full list is at https://ustr.gov/sites/default/files/files/Press/Releases/301FRN.pdf

On July 6, China responded to the initial action by imposing increased duties on goods of the United States. Four days later, the USTR then announced it would take further action in the form of an additional 10 percent duty on Chinese products of China with an annual trade value of approximately $200 billion. Among the products on the list are glycine, nonaromatic amino-acids, choline and beta-carotene and other carotenoid coloring matter. Comments are due on August 27.

The full list is at https://ustr.gov/sites/default/files/301/2018-0026%20China%20FRN%207-10-2018_0.pdf

NAD Recommends Discontinuing Unsubstantiated Advertising Claims

The National Advertising Division of the Better Business Bureau (NAD) has recommended that Evolution Nutraceuticals discontinue challenged advertising claims for the company's "Cardio Miracle" dietary supplement, including claims that the product will "Prevent or Reverse Heart Attack and Stroke." Cardio Miracle is a powdered supplement, containing more than 20 ingredients, that may be added to water or juice and consumed as a beverage.

The claims at issue included the following:

- "Cardio Miracle improves your body's ability to produce the powerful health molecule Nitric Oxide."
- "Nitric Oxide is scientifically proven to relax your blood vessels, effectively lowering your blood pressure."
- "Recent studies have found that this can also help with Neuropathy (loss of feeling in your fingers and toes) as well as dizziness."
- "Better Dental Health: Dentists have long known there was a connection between your gums and your heart. People who have suffered from Periodontal Disease have seen amazing improvements in gum depth in just a matter of weeks by taking a Nitric Oxide supplement."
- "Prevent or Reverse Heart Attack and Stroke."

The issue before NAD was whether Evolution provided evidence sufficient to demonstrate that Cardio Miracle and its ingredients would deliver the advertised health benefits to consumers. The advertiser did not submit any studies on the Cardio Miracle product itself or any studies examining the health-related effects of any ingredient in Cardio Miracle. NAD determined that the advertiser's evidence was insufficient to support any claims regarding the Cardio Miracle product and recommended that the advertiser discontinue all the challenged claims. Evolution agreed to comply with NAD's recommendations.

If an advertiser does not comply with NAD recommendations, it can refer the matter to the Federal Trade Commission.

Consumer Fraud Claims Under New Jersey and Pennsylvania Statutes Survive Motion to Dismiss

The case Greek v. Diet Works, LLC, brought in U.S. District Court for the District of New Jersey, involves allegations that Diet Works made false and misleading claims about its weight-loss dietary supplement, Diet Works Garcinia Cambogia. Plaintiffs allege that the labeling on the product includes at least five false and misleading claims: (1) "Healthy Weight Management"; (2) "Promotes Weight Loss"; (3) "Inhibits Fat Production"; (4) "Suppresses Carbohydrate Cravings"; and (5) "Garcinia Cambogia, the all-natural way to help reduce your appetite, burn more calories and suppress carbohydrate cravings to make losing weight faster and easier than ever!" According to plaintiff, the product's active ingredient, HCA, has been the subject of numerous scientific studies that clearly disprove each of those specific claims. Plaintiffs plead that Diet Works" had access to, but knowingly and/or recklessly ignored" this "overwhelming scientific literature refuting the fat burning, weight loss, and appetite suppression claims."

The Court ruled that plaintiffs provided sufficient specifics to substantiate their fraud allegations and put Diet Works on notice of the misconduct at issue. Plaintiffs quote the exact language on the product's label and explain why they believe each statement is false and/or misleading. Moreover, a plaintiff must establish three elements for a New Jersey Consumer Fraud Act (NJCFA) claim to survive a motion to dismiss: (1) unlawful conduct, (2) an ascertainable loss, and (3) a causal connection between the defendant's unlawful conduct and the plaintiff's ascertainable loss. The elements of a Pennsylvania Unfair Trade Practices Consumer Protection Law (UTPCPL) are similar to those under the NJCFA, except that a plaintiff must show "justifiable reliance" rather than simple causation. Here, the false and misleading claims are on the labeling of the product itself, and plaintiffs plead that they (1) read those claims, (2) relied on them, and (3) bought the Product as a result. Plaintiffs' factual allegations plead the requisite elements under the NJCFA and the UTPCPL, and Diet Works is on notice of the specific misconduct alleged. The claims were not dismissed.

FDA is Using New Methods to Prevent Illegal Products with Hidden Drug Ingredients from Entering the United States

In a March 21, 2018 blog post, Commissioner Gottlieb and others wrote that one of FDA's important public health functions is to closely monitor the FDA-regulated products arriving at the nation's international mail facilities (IMFs) every day to prevent unsafe, counterfeit, and unapproved products from entering the country. This sometimes includes interdiction of illicit products, in support of the U.S. Customs and Border Protection (CBP). But every year thousands of packages are found to contain FDA-regulated products and a surprising percentage of those products are illegal. These include unapproved products, counterfeit or substandard drugs, and supplements being sold for weight loss, sexual enhancement, bodybuilding or pain relief. Many products promoted as dietary supplements contain potentially dangerous undeclared drug ingredients.

The Commissioner wrote that FDA is taking new steps to increase the scope and effectiveness of product inspection. One tool that FDA has deployed is advanced screening technologies that can allow FDA inspectors to screen packages containing suspected drug products more efficiently and reliably. FDA conducted a six-month pilot at two IMFs, testing whether it might be able to increase the number of packages we screen by making use of a portable screening device called an ion mobility spectrometer.

The device works by comparing the chemical signature of the unknown substance against the chemical signatures of known compounds in a process that takes less than 30 seconds. For a pilot study, the device was loaded with a custom-built library of pharmaceutical compounds to test whether products marketed for weight loss and sexual enhancement contained undeclared drug compounds such as sibutramine, phenolphthalein and sildenafil. About 65 percent of the samples screened tested positive for the presence of undeclared pharmaceutical ingredients, results that were confirmed in a FDA laboratory. As a result of the pilot study, FDA intends to expand the use of this new technology and add devices at two additional IMFs.

California Judge Issues Final Ruling Requiring Prop. 65 Warning Label On Brewed Coffee

In a widely reported case, the Superior Court of Los Angeles County ruled that Prop. 65 warnings should be displayed in stores that sell brewed coffee. The judge found that Starbucks and other coffee sellers did not show that the risk from consuming acrylamide, a possible cancer-causing byproduct created during coffee roasting, was offset by benefits from drinking coffee.

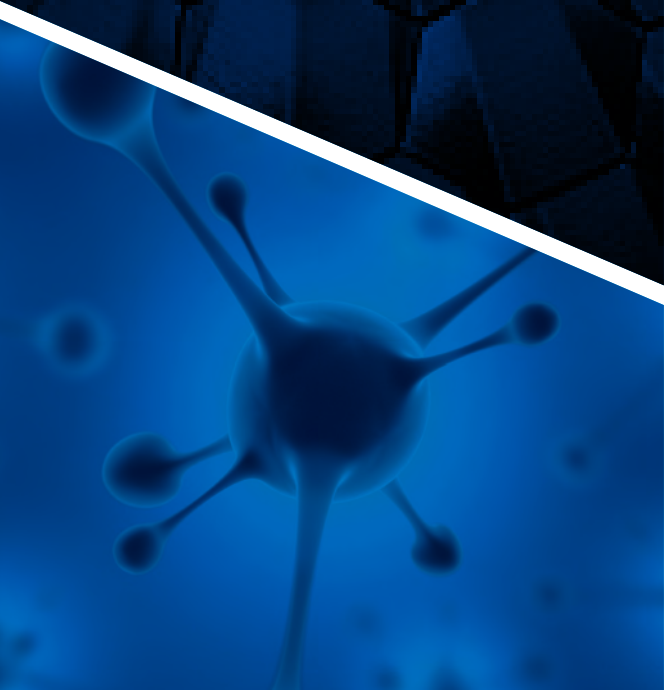
Roasting coffee beans produces a chemical, called acrylamide, which California has long listed as causing cancer. Acrylamide dissolves in water, which means that it can be found in brewed coffee. The Council for Education and Research on Toxics (CERT) brought suit against a large number of companies, including Starbucks, arguing that they were obliged to give the appropriate Prop. 65 warning to customers.

The Court found that the defendant companies had not provided a quantitative risk assessment, specifying the risk of acrylamide in coffee. Although evidence showed that roasting coffee beans is necessary to make coffee palatable and roasting coffee beans reduces microbiological contamination in coffee, defendants' proffered evidence that coffee itself confers some benefit to human health was disregarded. According to the Court, defendants failed to satisfy their burden of proving by a preponderance of evidence that consumption of coffee confers a benefit to human health. Because defendants failed to prove that coffee confers any human health benefits, they have failed to satisfy their burden of proving that sound considerations of public health support an alternate risk level for acrylamide in coffee.

The latest ruling in the eight-year legal battle opens a path for CERT to ask for a permanent injunction that would require coffee sellers to warn consumers about the cancer risk associated with acrylamide. Many California coffee sellers, including Starbucks, already post signs with such warnings under the state’s Prop. 65 law requiring businesses to provide warnings about significant exposures to chemicals that cause cancer, birth defects or other reproductive harm.

Companies should also be aware of that new Prop. 65 regulations on the content and format of warning labels take effect on August 30, 2018. If you have any questions on these new rules and complying with them, contact Porzio.

PORZIO'S ATTORNEYS HAVE BEEN SERVING THE NEEDS OF THE DIETARY SUPPLEMENT INDUSTRY FOR OVER 20 YEARS. BASED IN WASHINGTON DC, THEY HAVE A DEEP UNDERSTANDING OF THE MARKETPLACE AND THE MYRIAD OF LEGAL, REGULATORY, AND PUBLIC POLICY ISSUES THAT MUST BE NAVIGATED BY ESTABLISHED AS WELL AS START-UP COMPANIES.



Since passage of the **Dietary Supplement Health and Education Act of 1994** (DSHEA), the dietary supplement industry has grown to more than $35 billion in annual sales. This robust growth of the industry reflects not only increased interest among consumers in these products, but also means new legal and regulatory challenges to overcome. Our Dietary Supplement practice includes the following:

INTELLECTUAL PROPERTY

Porzio's attorneys, including those with advanced science degrees registered to practice before the U.S. Patent and Trademark Office (PTO), offer full-service representation in patent, trademark, copyright, trade secret and unfair competition law to dietary supplement companies.

We provide fundamental services including U.S. and foreign patent preparation, patent and trademark prosecution, litigation, opinions, licensing, transactions, due diligence, and portfolio management. We have particular expertise in handling more specialized matters including complex administrative proceedings such as inter partes reviews (IPRs) reexaminations, reissues, interferences and appeals to the Board of Patent Appeals, as well as appeals to the Federal Circuit and proceedings before the International Trade Commission.

When a patent dispute arises, either before the PTO or in federal District Court, Porzio's experienced litigators work closely and collaboratively with the scientists to bring about a successful resolution as quickly and efficiently as possible. Porzio has advised and represented clients in patent, trademark, trade secret, unfair competition and copyright cases in several courts around the country, including federal and state courts in Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, Nevada, New York, North Carolina, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

REGULATORY AFFAIRS

Porzio's attorneys regularly represent dietary supplement companies that have issues before federal and state government agencies, including the Food and Drug Administration (FDA). Federal Trade Commission (FTC), Department of Justice (DOJ), Department of Agriculture (USDA), Department of Commerce (DOC), Department of Defense (DOD), Department of Interior (DOI), Drug Enforcement Agency (DEA), Customs and Border Protection (CBP) and State Attorneys' General.

We advise and counsel dietary supplement clients on complying with FDA and FTC regulations and guidance documents. Porzio's attorneys are experienced in advertising and promotion, claim substantiation, health claims, current good manufacturing practice (cGMP), warning letters and other matters before the FDA and FTC. Oftentimes, FTC and FDA investigations are run in parallel with investigations by the DOJ, United States Attorneys' Offices and State AGs. Porzio attorneys have particular experience in these matters.

Porzio attorneys routinely monitor and are in contact with regulators on new rules, guidance and policies. For example, Porzio participated with Natural Products Association on the FDA's revised New Dietary Ingredient Guidance shortly after it was issued and continues to update and advise clients on matters of importance regarding actions being taken in Washington, D.C.

LITIGATION

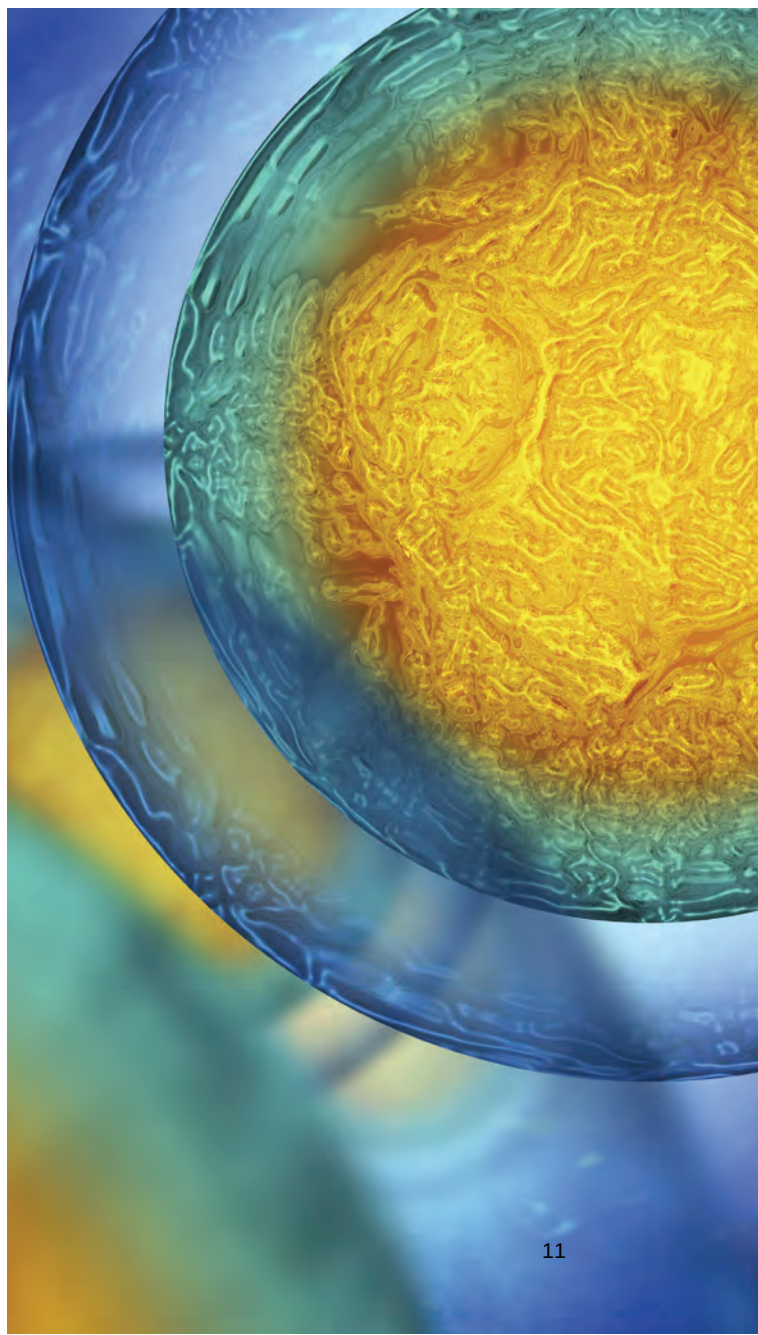
Porzio has a deep bench of attorneys in litigating intellectual property, deceptive trade practices (Lanham Act § 43(a)), breach of contract and product liability cases. Our knowledge of supplements and the science behind them provide clients with an added value that other firms do not have.

PROPOSITION 65

Porzio not only advises clients on complying with Proposition 65, it has also litigated warning letter cases in California courts. With the regulators issuing new rules, clients can expect to have new challenges in this area in the coming years.

PUBLIC POLICY AND ADVOCACY

Porzio's Washington, DC office is comprised of attorneys that were previously with the law firm of Patton Boggs LLP. On legislative matters before the U.S. Congress, they are in regular contact with Senate and House of Representatives Leaders, Committees, Members and senior staff. We represent clients in rulemaking proceedings before federal and state agencies. Our policy practice also involves working with clients on stratagies and advocacy training on how best to engage in grassroots lobbying efforts to better communicate their needs to their elected representatives.



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