Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

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CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FSIS Extends Comment Period on Proposed Rule for Mechanically Tenderized Beef

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has **extended** the comment period for a proposed rule that would require "mechanically tenderized" labeling for raw or partially cooked needle- or blade-tenderized beef products, "including beef products injected with marinade or solution." According to FSIS, the rule would also require the labels of mechanically tenderized beef products destined for consumers, hotels, restaurants, or similar establishments to include "validated cooking instructions" to ensure safe handling and reduce the risk of foodborne illness. Acting at the request of two trade associations, the agency will now accept comments on the new labeling scheme until October 8, 2013. Additional details about the proposed rule appear in Issue **486** of this *Update*. *See Federal Register,* August 9, 2013.

FDA Approves Color Additive Made from Spirulina

The Food and Drug Administration (FDA) has **issued** a final rule providing "for the safe use of spirulina extract made from the dried biomass of the cyanobacteria *Arthrospira platensis (A. platensis),* as a color additive in candy and chewing gum." According to FDA, "Spirulina is a blue-green filamentous cyanobacteria that occurs naturally in freshwater and marine habits." Its extract primarily contains "the water soluble components of spirulina, namely phycocyanins and other proteins, polysaccharides, lipids, and minor amounts of components such as vitamins, minerals, and moisture."

FDA has also determined that "there is no need for a specific upper limit for the color additive or phycocyanin content," although the extract must abide by limits for lead, arsenic and mercury, in addition to testing negative for the microcystin toxin, "which is produced by some species of cyanobacteria that could be potentially present in the water where *A. platensis* is grown and harvested." Effective September 13, 2013, the final rule reportedly represents the first time a "natural" blue color additive has been approved for use on the

U.S. market. *See Federal Register,* August 13, 2013; *FoodNavigator-USA.com,* August 14, 2013.

FDA Updates Guidance on Medical Foods

The Food and Drug Administration (FDA) has published draft guidance titled "Frequently Asked Questions About Medical Foods; Second Edition" that provides additional information about the definition, labeling and availability of medical foods—"foods formulated to be consumed or administered orally or enterally under the supervision of a physician." The first edition of this guidance was issued in May 2007. Comments will be accepted until October 15, 2013. *See Federal Register,* August 13, 2013.

LITIGATION

Second Circuit Interprets Lanham Act in Russian Vodka Trademark Suit

The Second Circuit Court of Appeals, addressing an issue of first impression among the federal appellate courts under the Lanham Act, has affirmed a district court determination that Federal Treasury Enterprise Sojuzplodoimport (FTE) cannot pursue trademark infringement litigation as a "legal representative" of the Russian Federation because while that government designated FTE as its legal representative, it is not legally unable to bring the suit on its own behalf. ***Fed. Treasury Enter. Sojuzplodoimport v. SPI Spirits Ltd.,* No. 11-4109 (2d Cir., decided August 5, 2013)**.

So ruling, the Second Circuit held that the Lanham Act's use of the term "legal representative" requires in addition to an appointment that the appointing entity be unable to appear in the litigation. Another issue addressed was whether FTE was an "assign" of the Russian Federation under a series of documents created since 2002; the court concluded that the documents did not create an assignment. The issues arose in the context of litigation begun in 2004 and involved U.S.-registered trademarks related to "Stolichnaya"-brand vodka. FTE and its exclusive licensee, OAO "Moscow Distillery Cristall," alleged that the defendants' asserted title to the marks was invalid and that their use of the marks infringed the rights of the true owner, the Russian Federation.

Because the Second Circuit decided that FTE was neither an assign nor legal representative of the Russian Federation under the Lanham Act, it agreed with the district court that the plaintiffs lacked standing to sue for infringement under 15 U.S.C. § 1114(1). The court affirmed the dismissal of the plaintiffs' third amended complaint with prejudice.

SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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Court Allows Most Consumer Fraud Claims to Proceed Against Tea Company

A federal court in California has dismissed several of the claims in a putative nationwide class action alleging that Bromley Tea Co. makes unlawful and deceptive health-related claims on packaging labels and on its Website for the company's green and black teas. *Clancy v. The Bromley Tea Co.*, No. 12-3003 (U.S. Dist. Ct., N.D. Cal., order entered August 9, 2013).

The court rejected the defendant's challenge to the plaintiff's standing to assert claims as to products he had not purchased or statements he did not see before buying the products he did purchase. According to the court, "The named plaintiff has standing to assert claims relative to the products he purchased. He does not claim to have standing to assert claims related to other products. What he does claim is that he may be a potential representative of a class of people who have such standing. He may or may not be able to certify such a class, and he may or may not be an adequate representative. But applying the concept of standing to dismiss proposed class action allegations is a category mistake." The court also left to the class certification stage, for the same reasons, whether the plaintiff can represent class members who relied on different ads than those on which the plaintiff relied.

The court refused to strike the plaintiff's nationwide class allegations on the basis of *Mazza v. American Honda Motor Co.*, finding that a "detailed choice-of-law analysis is not appropriate at this stage of the litigation. Rather, such a fact-heavy inquiry should occur during the class certification stage, after discovery." The court further rejected the defendant's argument that the plaintiff's Sherman Law claims were preempted under the Food, Drug, and Cosmetic Act (FDCA). According to the court, the plaintiff was suing for violations of state law, "not attempting to impose requirements greater than those imposed by the FDCA," and his claim "does not depend on the FDCA, except in the sense that the Sherman Law mirrors the requirements of the FDCA." The court also stated that it "cannot conclude that Plaintiff has failed to assert a legitimate nutrient content claim under California law, which is identical to what the FDA [Food and Drug Administration] classifies as a nutrient content claim."

Finding the plaintiff's fraud-related claims pleaded with sufficient particularity, the court denied this part of the defendant's motion for judgment on the pleadings, but it dismissed with prejudice the plaintiff's unjust enrichment and restitution count as superfluous and the Song-Beverly Consumer Warranty Act and Magnuson-Moss Warranty Act claims because the products at issue are "consumables" that do not come within their ambit. The plaintiff had conceded that "every court to hear similar claims has dismissed them and state[d] that he is preserving the issue for any potential appeal." The court also found the federal warranty law inapplicable because it does not apply to warranties otherwise governed by federal law. According to the court, "the FDCA regulations at issue here are fatal to any Magnuson-Moss claim."

Court Unsympathetic to FDA Pleas for Delay in FSMA Rulemaking

A federal court in California has determined that the U.S. Food and Drug Administration (FDA) has not met the standard for the court to issue an order amending the deadlines set forth in its June 2013 order for promulgating and finalizing implementing regulations under the Food Safety Modernization Act (FSMA). *Ctr. for Food Safety v. Hamburg*, No. 12-4529 (U.S. Dist. Ct., N.D. Cal., order entered August 13, 2013). Information about the court's earlier order appears in Issue **489** of this *Update*.

Because the plaintiff agreed that the proposed sanitary transport rule deadline could be extended, however, the court granted FDA's motion only to this extent. The proposed rule must be published by January 31, 2014, and the court will allow comment on it until May 31. The final rule must be published as originally specified—no later than June 30, 2015. The court rejected FDA's request to extend the deadline for promulgation of the intentional adulteration rule and refused to grant it a stay, given that no notice of appeal had been filed.

Court Denies Dispositive Motion in Licorice Supply Chain Litigation

A federal court in California has denied a motion to dismiss in a contract dispute between the supplier of molasses allegedly contaminated with lead and the company that used the ingredient to make licorice subject to a nationwide recall. *Am. Licorice Co. v. Total Sweeteners, Inc.*, No. 13-1929 (U.S. Dist. Ct., N.D. Cal., order entered August 13, 2013).

Relying on a sales contract it had prepared, the molasses supplier contended that the plaintiff had failed to comply with its notice provisions and therefore was precluded from seeking relief for its alleged breach. Relying on a purchase order with different terms it had prepared and issued before the first shipment under the contract, the plaintiff candy maker argued that the shipments were subject to its terms.

The court was unwilling to determine as a matter of law whether the purchase order altered the terms and conditions of the contract, finding that "this issue is properly resolved by the jury, and that it is thus not a proper subject of this motion to dismiss." The court was also unwilling to determine at this stage "whether Defendant assented to the terms of the Purchase Order when it shipped the molasses in response to the Purchase Orders sent by Plaintiff over the spring and summer of 2012."

Criminal Trial Against Peanut Corp. Officials and Staff Continued

A federal court in Georgia has issued an order continuing the criminal trial against former Peanut Corp. of America officials and employees, including owner Stewart Parnell, until February 10, 2014. *United States v. Parnell*, No.

12-12 (U.S. Dist. Ct., M.D. Ga., Albany Div., order entered August 15, 2013). The company was the source of a nationwide *Salmonella* outbreak in 2009, and the 76-count indictment charges four individuals with conspiracy, mail and wire fraud, obstruction of justice and other counts related to the distribution of adulterated and misbranded food. Details about the indictment appear in Issue **472** of this *Update*.

Class Charges Soup Maker and AHA with Deceptive Scheme

A New Jersey resident has filed a putative nationwide class action against the Campbell Soup Co. and American Heart Association (AHA) claiming that the "Heart-Check Mark" which AHA allows Campbell to place on more than 30 varieties of its canned soups in exchange for a fee misleads consumers into believing that these products meet AHA's heart-healthy nutritional guidelines when a single serving actually contains nearly three times the amount of sodium permitted under those guidelines. *O'Shea v. Campbell Soup Co.*, No. 13-4887 (U.S. Dist. Ct., D.N.J., filed August 13, 2013). According to the plaintiff, "Properly characterized, the real meaning of the AHA's Heart-Check Mark certification is, 'Unhealthy, but maybe not as bad for you as other products.'"

Also characterizing the certification program as a "scheme," the plaintiff alleges, "By the AHA selling, and Campbell's buying, the right to affix the AHA's seal of approval to its products, they falsely represent to the public that AHA-certified products manufactured by Campbell's possess some cardio-vascular benefit not enjoyed by products that have not been certified by the AHA. In truth, however, the *only* difference between AHA-certified Campbell's products and non-certified competing products is that Campbell's has paid money to the AHA to license its logo." The plaintiff contends that she and class members paid a premium price for the soup in reliance on the certification. Alleging violation of the New Jersey Consumer Fraud Act, breach of express warranty and unjust enrichment, the plaintiff seeks injunctive relief, actual and treble damages, restitution and/or disgorgement, attorney's fees, costs, and interest.

Putative Class Claims Tortilla Chips Falsely Advertised as "All Natural"

A Florida resident has filed a putative statewide class action against Gruma Corp., alleging that the company falsely advertises its Mission® Restaurant Style Tortilla chip products as "all natural" when they contain genetically modified organisms (GMOs). *Griffith v. Gruma Corp.*, No. 13-80791 (U.S. Dist. Ct., S.D. Fla., Palm Beach Div., filed August 12, 2013).

Alleging violations of the Florida Deceptive and Unfair Trade Practices Act and contending that her claims "mirror the labeling, packaging, and advertising requirements mandated by federal regulations and laws," the plaintiff claims that the products are misbranded and the labels are false and misleading

because GMOs are not natural and she understood that product representation to mean that the chips contained no GMO ingredients. Alleging damages in excess of $5 million, the plaintiff seeks injunctive relief, restitution, disgorgement, actual damages, attorney's fees, costs, and interest.

Nonagenarian Researcher Sues FDA for Failing to Ban Artificial *Trans* Fats

Four years after filing a citizen petition with the U.S. Food and Drug Administration (FDA) seeking a prohibition on the use of partially hydrogenated oils containing artificial *trans* fat in food for human consumption, 98-year-old University of Illinois Emeritus Professor of Comparative Biosciences Fred Kummerow has filed a lawsuit seeking an order compelling an agency response to his petition and a declaration that its failure to ban *trans* fats violates the Food, Drug, and Cosmetic Act. *Kummerow v. Hamburg*, No. 13-2180 (U.S. Dist. Ct., C.D. Ill., Urbana Div., filed August 9, 2013). The complaint details the history of the ingredient's invention and research, including the plaintiff's own, demonstrating its "harmful effects," including inhibition of an enzyme necessary to prevent blood clots in the arteries and veins. The plaintiff also distinguishes between artificial and natural *trans* fats, noting that he does not seek a ban on the latter.

According to the complaint, Kummerow learned in 2004 that his left coronary artery was 75 percent blocked and that he subsequently underwent coronary bypass surgery. He attributes the blockage to artificial *trans* fat and claims that a ban on partially hydrogenated oils "would help prevent these sorts of dangerous medical conditions." The complaint also alleges that artificial *trans* fat causes cardiovascular disease; type 2 diabetes; breast, prostate and colorectal cancer; Alzheimer's Disease and cognitive decline; and damage to vital organs. Alleging agency action unlawfully withheld and unreasonably delayed and action that is arbitrary, capricious and an abuse of discretion, the plaintiff seeks declaratory and injunctive relief, including a court-ordered deadline for action on his petition, attorney's fees and costs.

$9-Million Proposed Settlement of Naked Juice Suits Garners Preliminary Approval

A federal court in California has issued an order granting the motion for preliminary approval of a class settlement in five lawsuits alleging that Naked Juice Co. misrepresented its beverages as "All Natural" and "Non-GMO." *Pappas v. Naked Juice Co. of Glendora, Inc.*, No. 11-8276 (U.S. Dist. Ct., C.D. Cal., order entered August 7, 2013).

According to the court, the proposed settlement was reached after the defendant's motion to dismiss was granted in part, extensive and contentious discovery was undertaken, and four mediation sessions occurred under the guidance of an experienced retired judge. Under the terms of the settlement,

the company will pay $9 million into a settlement fund that will be used to make cash payments to class members and pay the costs of notice and settlement administration, attorney's fees—not to exceed $3.1 million—and expenses, and incentive awards—$2,500 each for four of the five named plaintiffs.

Class members with purchase receipts dated during the class period can recover up to $75 each, and those without receipts can recover between $5 and $45. Remaining funds will be distributed to *cy pres* recipients identified as the Mayo Clinic (50%), National Association of IOLTA Programs (24%) and equal, pro rata shares to seven legal aid organizations (combined 25%). The court also noted that Naked Juice is required to adopt certain practices and make certain changes to its labeling and substantiation at an additional cost valued at some $1.4 million. The notice procedures include Internet and print programs.

One of the named plaintiffs, who did not seek an incentive award and will not be receiving one due to her lack of involvement in the proceedings, objected to the settlement, claiming that class counsel fees are too high, the *cy pres* recipients are improper and the notice is insufficient. According to the court, counsel fees, which will not be finally determined until later in the proceedings are not *per se* unreasonable or "greater than the percentage of fees and costs awarded in other consumer products class actions."

The court also found that the *cy pres* recipients are all proper as "sufficiently related to the underlying claims to warrant their receipt of potential *cy pres* awards." The legal organizations declared that they would use the funds for consumer protection work, and the Mayo Clinic stated that it would use the funds to "support its nationwide education and research efforts around nutrition, vitamins, and food and beverage labels." The court further determined that the class notice was sufficient, because the Internet ad campaign was not limited geographically and it was sophisticated and designed to target likely class members.

ITC Rejects Patent-Packaging Infringement Claim Against Liquor and Wine Importers

In the first investigation subject to a pilot program, the International Trade Commission (ITC) has agreed with an administrative law judge (ALJ) that a company alleging infringement of its patents for laminated packaging by the importers of liquor, wine, toys, electronics, and cosmetics failed to show that it had a domestic industry that would be harmed by the alleged infringement. *In re Certain Prods. Having Laminated Packaging, & Components Thereof*, No. 337-TA-874 (ITC, decided August 6, 2013). Several alleged infringers, including Camus Wine & Spirits Group of Cognac, France, were terminated from the investigation before it was resolved on the basis of settlement agreements with claimant Lamina Packaging Innovations, Inc. of Longview, Texas.

ITC has the authority to bar imports of products deemed harmful to a domestic industry and announced earlier this year that it would test expedited procedures in cases alleging unfair practices in import trade. Under the program, ITC identifies potentially dispositive issues and directs the assigned ALJ to rule on those issues early in an investigation through expedited fact-finding and an abbreviated hearing limited to those issues. While ITC upheld the ALJ's determination that the complainant did not satisfy the economic prong of the domestic industry requirement, it reversed the ALJ's findings that ITC may have violated the Administrative Procedure Act by failing to publish information about the pilot program ahead of time and directing the issuance of an initial ALJ determination within 100 days in this case.

Lamina reportedly objected to the expedited proceeding and indicated before ITC ruled that the company would consider taking an appeal to the Federal Circuit Court of Appeals. According to some commentators, who have watched the case closely, early action on threshold dispositive issues, such as whether a patent holder has invested in factories or hired a significant workforce thus establishing a domestic industry, could deter litigation filed by companies referred to as "patent trolls" or "patent assertion entities" that are in the business of buying and asserting patents and do not themselves use the patents to make things. *See ITC News Release*, June 24, 2013; *AmLaw Litigation Daily*, July 10 and August 12, 2013.

OTHER DEVELOPMENTS

Pew Report Points to Gaps in FDA Toxicity Data for Food Additives

The Pew Charitable Trusts' Food Additive Project has published a **paper** in *Reproductive Toxicology* claiming that gaps in the toxicity data for food additives raise questions about the Food and Drug Administration's (FDA's) safety assessments for these substances. Thomas Neltner, et al., "Data Gaps in Toxicity Testing of Chemicals Allowed in Food in the United States," *Reproductive Toxicology,* August 2013. Comparing data from FDA's Priority-based Assessment of Food Additives database, the Accelrys Toxicity Database of chemical studies and the U.S. National Library of Medicine's TOXLINE database, the study's authors apparently determined that "almost two-thirds of chemical additives appear to have been declared safe for use in food without the benefit of being fed to an animal in a controlled toxicology study," while approximately 78 percent of additives lack adequate data to estimate a safe level of exposure and 93 percent lack reproductive or development toxicity testing. They also reported that, according to FDA's own database, (i) "only one in five chemicals has been evaluated using the simplest lab animal test recommended by FDA to evaluate safety," and (ii) "only one in eight chemicals that FDA recommended be evaluated for reproductive or development problems had evidence it was tested for these effects."

Based on these findings, the authors ultimately recommended that FDA partner with industry, public interest organizations and scientists to "establish a strategy to prioritize and review chemical additives that have already been approved for use in food and food packaging." In particular, the study urges FDA to use "modern scientific tools" and "validated methods, such as computer-based modeling and cell-based studies," to augment current toxicity data and identify those additives that require additional testing.

"Although FDA is aware of the problem, it lacks the authority and resources to fill the information gaps," concludes the report, which directs FDA to model its data-collection protocols after the European Food Safety Authority and the Environmental Protection Agency's High Production Volume Challenge program. "Furthermore, once a chemical is approved, manufacturers have no incentive to add additional toxicology information because FDA neither has a reassessment program in place nor has authority to require additional testing… Therefore, a program is needed to effectively and efficiently fill the significant information gaps to ensure public health is protected." Additional details about the work of Food Additives Project Director Thomas Neltner appear in Issue **493** of this *Update*. *See Pew Charitable Trusts Press Release,* August 14, 2013.

Chipotle to Consider Antibiotic-Treated Beef

Citing a shortage of naturally raised beef due to last year's drought, Chipotle Mexican Grill Inc. has apparently told media sources that it may allow its restaurants to begin using beef treated with antibiotics. Although Chipotle only reached its goal to use antibiotic- and hormone-free meat a few years ago, the company reportedly said that it plans to review its "never-ever" antibiotic policy and possibly allow suppliers to sell animals that have been treated with antibiotics "when necessary." The policy change would still bar the use of beef from animals given antibiotics to prevent disease or promote weight gain.

"Many experts, including some of our ranchers, believe that animals should be allowed to be treated if they are ill and remain in the herd," Chipotle founder and co-CEO Steve Ells was quoted as saying. "We are certainly willing to consider this change, but we are continuing to evaluate what's best for our customers, our suppliers and the animals." *See USA Today* and *Bloomberg.com,* August 13, 2013.

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SCIENTIFIC/TECHNICAL ITEMS

Study Allegedly Links Glucose Levels to Increased Risk of Dementia

A recent study has reportedly concluded that "higher glucose levels may be a risk factor for dementia, even among persons without diabetes." Paul Crane, et al., "Glucose Levels and Risk of Dementia," *New England Journal of Medicine,* August 2013. Relying on data from 2,067 men and women enrolled in the Adult Changes in Thought study, researchers apparently used 35,264 clinical measurements of glucose levels and 10,208 measurements of glycated hemoglobin levels in tracking the development of dementia in 524 participants during a median follow-up of 6.8 years.

The results evidently suggested that among participants without diabetes, "higher average glucose levels within the preceding 5 years were related to an increase risk of dementia." In particular, the study's authors found that for those without diabetes, "risk for dementia was 18 percent higher for people with an average glucose level of 115 milligrams per deciliter compared to those with an average glucose level of 100 mg/dl." They also noted that in people with diabetes, "dementia risk was 40 percent higher for people with an average glucose level of 190 mg/dl compared to those with an average glucose level of 160 mg/dl."

"The most interesting finding was that every incrementally higher glucose level was associated with a higher risk of dementia in people who did not have diabetes," the study's lead author said in an August 7, 2013, press release issued by the University of Washington–Group Health. "There was no threshold value for lower glucose values where risk leveled off."

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