Shook, Hardy & Bacon L.L.P.

ISSUE 449 | AUGUST 10, 2012

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Senators Request Corn Ethanol Waiver

U.S. Senators Kay Hagan (D-N.C.) and Saxby Chambliss (R-Ga.) recently wrote a **letter** to U.S. Environmental Protection Agency (EPA) Administrator Lisa Jackson, asking the agency to use its waiver authority "to adjust the corn grain-ethanol mandate of the Renewable Fuel Standards (RFS)" in light of ongoing drought conditions. Signed by 26 senators, the bipartisan letter notes that the U.S. Department of Agriculture has already rated 50 percent of the nation's corn crop as poor or very poor while "stressful weather conditions continue to push corn yields lower and prices upward." The signatories have thus urged EPA to employ some of the "safety valves" built into the Energy Independence and Security Act of 2007 "that enable the agency to adjust the RFS in the event of inadequate supplies or to prevent economic harm to the country, a region, or a state."

"With record droughts across the United States causing corn supplies to shrink and prices to spike, an adjustment to the corn-ethanol mandate will provide relief from an emergency that is harming North Carolina's poultry and livestock producers and driving up food prices for consumers," said Hagan in an August 8, 2012, press release. "While I believe the RFS is helping to bring advanced biofuels to market that are critical to reducing U.S. dependence on foreign oil, the EPA should adjust the corn-ethanol mandate to reflect the new market conditions created by the worst drought in 50 years."

USDA's Biotech Advisory Committee to Discuss Compensation for GE Cross-Contamination

The U.S. Department of Agriculture (USDA) has **announced** an August 27-28, 2012, meeting of its Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) in Washington, D.C. USDA Secretary Tom Vilsack has specifically asked the committee to report on the types of compensation mechanisms that could be used "to address economic losses by farmers in which the value of their crop is reduced by the presence of GE [genetically engineered] material(s)." The committee will also discuss eligibility standards

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for triggering these mechanisms as well as other actions that may be appropriate "to bolster or facilitate coexistence among different agricultural systems in the United States."

According to USDA, "AC21 consists of members representing the biotechnology industry, the organic food industry, farming communities, the seed industry, consumer and community development groups, as well as academic researchers and a medical doctor." Members of the public who wish to the attend the meeting must register in advance with USDA. *See Federal Register,* August 6, 2012.

USPTO Issues Rule to Adopt Changes from International Accord on Registration of Marks

The U.S. Patent and Trademark Office (USPTO) has issued a **final rule** that incorporates certain changes that took effect in January 2012 under the Nice Agreement Concerning the Classification of Goods and Services for the Purpose of the Registration of Marks, to which the United States is a signatory. Among other matters, (i) Class 5 is changed from "dietetic substances adapted for medical use" to "dietary food and substances adapted for medical use"; and (ii) Class 32 is change from "non-alcoholic drinks; fruit drinks" to "non-alcoholic beverages; fruit beverages." USPTO's classification of goods and services under the Trademark Act is codified at 37 CFR part 6. *See Federal Register*, August 9, 2012.

EFSA Publishes Guidance on Health Claims

The European Food Safety Authority's (EFSA's) Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) has issued two guidance documents establishing "the scientific requirements for the substantiation of health claims related to functions of the **nervous system**, including psychological functions, and those related to **physical performance**." In particular, the new guidance documents address "which claimed effects are considered to be beneficial physiological effects, and which studies/outcome measures are appropriate for the substantiation of function claims and disease risk reduction claims." They are the final installments in a series of documents covering health claims related to gut and immune function; antioxidants and cardiovascular health; weight management; and bone, joint and oral health.

According to EFSA, the NDA Panel has also finished its further assessment of general function health claims, approving two additional claims that member states substantiated with supplemental data: (i) prunes and normal bowel function, and (ii) alpha-cyclodextrin and a lower rise in blood pressure after meals. The European Commission has already adopted 222 general function claims since EFSA first published 341 opinions on 2,758 applications in June

2011. The agency will continue to review new applications under the individual authorization procedure. *See EFSA News Story,* August 7, 2012.

LITIGATION

Ninth Circuit Allows Dairy Farmers to Pursue Damages for Misreported Milk-Pricing Data

The Ninth Circuit Court of Appeals has determined that the "filed rate doctrine" does not bar the state law-based claims of dairy farmers alleging that milk marketing cooperatives (handlers) provided erroneous reports to the federal government which relied on them to set a minimum price structure for raw milk sales; as a result, the farmers purportedly lost millions of dollars. ***Carlin v. DairyAmerica, Inc.*, No. 10-16448 (9th Cir., decided August 7, 2012)**. Each of the four named plaintiffs in this consolidated proceeding filed claims on behalf of a nationwide class alleging (i) negligent misrepresentation, negligent interference with prospective economic advantage and unjust enrichment, all under California common law; and (ii) violation of California's Unfair Business Practices Law.

The filed rate doctrine ""is a judicial creation that arises from decisions interpreting federal statutes that give federal agencies exclusive jurisdiction to set rates for specified utilities, originally through rate-setting procedures involving the filing of rates with the agencies.' 'At its most basic, the filed rate doctrine provides that state law, and some federal law (e.g., antitrust law), may not be used to invalidate a filed rate nor to assume a rate would be charged other than the rate adopted by the federal agency in question.'"

Detailing the complex milk-pricing system in the United States and how the federal government learned about the defendants' alleged erroneous reports at a time when it could not recalculate the prices, the court concluded that (i) the filed rate doctrine could be applied in the dairy-pricing context, but (ii) it would not preempt this litigation. According to the court, it will not have to second-guess a federal agency or substitute its evaluation of a proper rate for the agency's determination because the agency already concluded that the misreporting "contaminated the minimum price setting process." The court also concluded that "the statutory goals as to an orderly mandate of marketing conditions and the protection of milk producers would both be served by imposing consequences on handlers for misreporting data that resulted in incorrect . . . pricing and multimillion dollar losses for dairy farmers," particularly given that allowing the claims to move forward "is the only way to remedy the injuries suffered by the milk producers."

Federal Magistrate Refuses FDA Request for Stay in Livestock Antibiotics Dispute

A federal magistrate judge in New York has determined that the Food and Drug Administration (FDA) must begin proceedings to withdraw its approval of the use of certain antibiotics in livestock for non-therapeutic purposes on the agency's timeline, thus denying FDA's request for a stay while the matter is pending on appeal before the Second Circuit. *NRDC v. FDA*, No. 11 Civ. 3562 (JCF) (U.S. Dist. Ct., S.D.N.Y., decided August 8, 2012). In June, the court determined that FDA arbitrarily denied petitions filed by advocacy organizations in 1999 and 2005 requesting the initiation of these proceedings. More information about the case appears in Issue 442 of this *Update*.

The magistrate first ruled on the Natural Resource Defense Council's (NRDC's) motion to strike a document from the record; it was an Animal Health Institute statement "expressing general support for the FDA's plans to reduce the non-therapeutic use of medically-important antibiotics in animal feed through a voluntary guidance program." According to NRDC, the statement was not part of the record before the agency when the challenged decisions were made. The court agreed, further noting that it did not provide any useful background on the issue of whether FDA violated its congressionally mandated duty of initiating withdrawal proceedings 30 years ago when it issued a regulation "providing that the agency would propose to withdraw approval of all [non-therapeutic] uses of antibiotics in animal feed unless drug sponsors and other interested parties" could resolve its growing concern over "the public health risk to humans and animals of antibiotic resistance caused by such uses."

The magistrate also decided that the plaintiffs had not sufficiently supported their abbreviated timeline for agency action, finding that it was based on unsupported assumptions. While the court rejected the government's request that no deadlines be imposed, it adopted FDA's alternative proposed timeline. FDA must issue revised notices of opportunity for public hearing for penicillin and tetracyclines in 17 months, and the agency will have an additional 41 months for the hearing process.

Regarding FDA's request for stay on the ground that the proceedings would divert significant resources and "compromise FDA's ability to pursue its goals with respect to antimicrobial resistance and animal drug licensing," the court noted that the only task on FDA's schedule during the pendency of the appeal "is the beginning of the literature review—an entirely internal process which, even if 'resource-intensive' is hardly likely to infringe significantly on the FDA's operations." The court also commented that FDA's insistence that its voluntary program will succeed lacked any support in the record. Thus, "engaging in the mandated withdrawal procedures promptly will allow drug sponsors the opportunity to show that the challenged drug uses are safe."

Longneck Beer Bottles Not Unreasonably Dangerous in Texas Bars

A Texas appeals court has dismissed product liability and negligence claims filed by a woman injured when she was struck twice in the face with a longneck beer bottle during a birthday celebration at a bar known for its violence. *Gann v. Anheuser-Busch, Inc.*, No. 08-11-00017-CV (Tex. App., 8th Dist., El Paso, decided July 25, 2012). Affirming the trial court's grant of the defendants' motion for summary judgment, the appeals court determined that the plaintiff "failed to produce more than a scintilla of evidence that the longneck bottle was defectively designed so as to render it unreasonably dangerous and failed to establish that Appellees owned her a legal duty to protect her from the criminal acts of a third person."

Specifically, the court found insufficient evidence that the risk of injury from the bottle's design outweighs its utility despite the plaintiff's assertions that "beer bottles are used commonly in assaults in the local community, . . . the longneck portion of the bottle is cosmetic and serves no useful purpose . . . and Anheuser-Busch uses stubby glass bottles and plastic bottles as containers for beer." The court faulted the plaintiff for failing to address whether (i) "manufacturing a stubby glass bottle or plastic bottle is economically feasible," and (ii) "eliminating the unsafe character of a longneck bottle significantly impairs its usefulness or significantly increases its costs." The plaintiff also apparently failed to address "what the expectations of the ordinary consumer are."

As to the plaintiff's negligence claims, while the court agreed with her that "it is reasonably foreseeable that a longneck bottle might be used as a weapon, she has failed to show why the general principle that no person has a legal duty to protect another from the criminal acts of a third person is inapplicable in this case."

California Court Dismisses Banana Plantation Lawsuit

A California Superior Court has reportedly dismissed a lawsuit filed by nearly 3,000 Philippine banana plantation workers who claimed that exposure to the pesticide 1,2-Dibromo-3-chloropropane (DBCP) more than 30 years ago caused physical and mental injury including sterility, testicular atrophy, miscarriages, and cancer. *Macasa v. Dole Food Co.*, No. BC467134 (Cal Super. Ct., decided August 8, 2012). More details about the litigation appear in **Issue 405** of this *Update*. According to a company spokesperson, the claims were fraudulent and should not have been brought because no reliable scientific evidence links DBCP agricultural exposures to the injuries alleged. The company reported that an identical lawsuit filed 13 years ago in the Philippines was also dismissed. The U.S. Environmental Protection Agency has apparently prohibited the pesticide's use in the United States, classifying it as a probable human carcinogen. *See Ventura County Star*, August 9, 2012.

Tuna Makers Agree to Settle Claims for Alleged Product Misrepresentations

The day after district attorneys for three California counties filed a lawsuit against tuna producers alleging that they make quantity misrepresentations "by failing to meet the standard of identity for canned tuna products seasoned or flavored with broth, as defined in the Code of Federal Regulations," it was **announced** that a $3.3-million settlement had been reached. *California v. Bumble Bee Foods, LLC*, No. 12-11729 (Cal. Super. Ct., filed August 2, 2012).

According to the San Diego County district attorney, a California Department of Food and Agriculture (CDFA) investigation discovered that the companies "failed to meet the required amount of tuna in cans packed with vegetable broth and added flavors." Under the terms of the agreement and without admitting liability, each company will provide $300,000 in canned tuna to California food banks, and costs and penalties will be divided among the counties with each receiving $969,500. CDFA will be paid investigative costs of $86,000. The companies also agreed "to follow federal packing standards for the fill of tuna in canned tuna products." *See San Diego County District Attorney News Release*, August 3, 2012.

California Resident Relied on Oxygenated Water Health-Benefit Claims

A Los Angeles County resident has filed a putative class action against the Austrian and British makers of "Oxygizer" water, claiming that the companies "falsely represent that through a patented process they are able to hyperoxygenate water and that consumption of Oxygizer leads to a number of purported beneficial health effects." *Ghazarian v. Oxy Beverages Handelsgesellschaft mbH*, No. BC489773 (Cal. Super. Ct., filed August 7, 2012).

Noting that people cannot absorb oxygen through their digestive systems, the plaintiff alleges that the defendants mislead consumers by falsely claiming their beverage can aid athletic performance, transport oxygen to every body cell, strengthen the immune system, and help office workers in large cities make up oxygen deprivation. The companies purportedly claim that scientific tests support their product representations and that their water is patented; the plaintiff alleges that these claims are also false and misleading. According to the plaintiff, the Federal Trade Commission has brought successful actions against other companies making similar claims about hyperoxygenated water products.

Seeking to represent a nationwide class of product purchasers, the plaintiff alleges fraud, negligent misrepresentation and violation of the Business & Professions Code (false statements and unfair business practices). The plaintiff asks the court to require that the defendants change the name of the product and cease making misrepresentations about its effects. Also sought are special, general and punitive damages; restitution; attorney's fees; and costs.

OTHER DEVELOPMENTS

Nestlé Hypo Allergenic Infant Formula Undergoing Testing in Australia

According to Nestlé Australia, some consumers feeding their babies NAN H.A. [hypo allergenic] 1 Gold® infant formula have complained about alleged adverse health effects. A news source indicates that purchasers have reported in online reviews that their children have experienced rashes, dark green stools, dehydration, and vomiting, among other symptoms. Calling product safety and quality a "non-negotiable priority for the company" Nestlé, which has been testing the product, further states on its Website that results "to date confirm there is no food safety issue." The company apparently re-formulated the product in 2011, replacing calcium chloride with potassium chloride to produce "a better taste and a smoother texture to the powder," and otherwise improving its "nutritional profile." *See Nestlé News Release*, August 8, 2012; *FoodProductionDaily.com*, August 9, 2012.

MEDIA COVERAGE

James Surowiecki, "Downsizing Supersize," *The New Yorker,* August 13, 2012

"In an era of political polarization, Michael Bloomberg has the rare ability to come up with policies that enrage everyone," opines *New Yorker* staff writer James Surowiecki in this August 13, 2012, article analyzing the mayor's plan to prohibit all New York City food vendors from selling sodas in sizes larger than 16 ounces. Surowiecki argues that despite bipartisan disdain for the proposal, Bloomberg's scheme "makes clever use of what economists call 'default bias,'" the tendency for consumers to choose certain options not because they reflect actual needs or desires but because they are presented as the default selection within the context of other choices. As Surowiecki recounts, researchers have allegedly shown that people calibrate their consumption habits by outside cues "like the size of a package or a cup" as opposed to feelings of satiety. "And since the nineteen-seventies the portion sizes offered by food companies and restaurants have grown significantly larger… and consumption has risen accordingly," he writes.

Surowiecki ultimately suggests that Bloomberg's ban "is designed to flip this effect on its head: if the largest soda you can order is sixteen ounces, a can of Coke may start to seem like more than enough." At the same time, he notes, the ban would function "as a kind of stealth tax" on consumers who wish to order two 16-ounce beverages in lieu of one 22-ounce serving. "If this all sounds as if New York's soda consumers were about to become the subjects

of an elaborate social-science experiment designed to reshape their behavior and desires, well, that's kind of true," concludes Surowiecki. "But then we've been the subject of just such an experiment, run by the beverage and fast-food companies, for the past forty years."

SCIENTIFIC/TECHNICAL ITEMS

Study Allegedly Links Diacetyl to Alzheimer's Disease

A University of Minnesota study has reported that diacetyl (DA), a food additive used to mimic butter flavors, allegedly "intensifies the damaging effects of an abnormal brain protein linked to Alzheimer's disease," according to a recent American Chemical Society press release. Swati More, et al., "The Butter Flavorant, Diacetyl, Exacerbates β-Amyloid Cytotoxicity," *Chemical Research in Toxicology,* August 2012. After noticing that the structure of DA resembles a substance "that makes beta-amyloid proteins clump together in the brain," researchers apparently sought to determine whether the food ingredient could also cause the clumping described as "a hallmark of Alzheimer's."

Their results evidently showed that DA at occupational exposure levels not only increased levels of beta-amyloid clumping but "enhanced beta-amyloid's toxic effects on nerve cells growing in the laboratory." Further experiments also suggested that DA "easily penetrated the so-called 'blood-brain barrier,' which keeps many harmful substances from entering the brain" and "stopped a protective protein called glyoxalase I from safeguarding nerve cells."

"We have now shown that DA potently enhances beta-amyloid toxicity toward neuronal cells in culture at concentrations that are normally found in body compartments upon occupational exposure," concluded the study's authors. "Whether toxic levels of diacetyl are achieved in various body compartments upon mere (over)consumption of DA-containing food substances is an unanswered but an important question… In light of the chronic exposure of industry workers to DA, this study raises the troubling possibility of long-term neurological toxicity mediated by DA." *See American Chemical Society Press Release,* August 1, 2012.

Research Targets Sports Drink Availability in Schools

A recent study funded by the Robert Wood Johnson Foundation (RWJF) has reportedly registered a significant decrease in the availability of soft drinks in secondary schools but "widespread access to other sugary beverages, such as fruit drinks and sport drinks." Yvonne Terry-McElrath, et al., "Trends in Competitive Venue Beverage Availability: Findings From US Secondary School," *Archives of Pediatric and Adolescent Medicine,* August 2012. After surveying the availability of competitive beverages in 1,900 public middle and high schools

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from 2006-07 to 2010-11, researchers with the University of Michigan's Institute for Social Research reported that the percentage of high school students with access to regular soda fell to 25 percent in 2010-11 from 54 percent in 2006-07, while the percentage of middle schoolers with access to regular soda declined to 13 percent in 2010-11, down from 27 percent in 2006-07.

At the same time, however, the survey purportedly revealed that 63 percent of middle and 88 percent of high school students still had access to some form of sugary beverage. In particular, the study's authors attributed this trend to sports drinks, "which were available to 55 percent of middle and 83 percent of high school students in 2010-11." They also noted that even though middle school students with access to sports drinks "declined significantly, from 72 percent to 55 percent, the same did not hold true for high school students," of whom 83 percent could still purchase sports drinks in school in 2010-11.

"Our study shows that, although schools are making progress, far too many students still are surrounded by a variety of unhealthy beverages at school," the study's lead author was quoted as saying. "It's critically important for the USDA [U.S. Department of Agriculture] to set strong standards for competitive foods and beverages to help ensure that all students across all grades have healthy choices at school." *See RWJF Press Release,* August 6, 2012.

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