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COMMENTARY

Will Evaporated Cane Juice Be Sweet for Class Action Plaintiffs?

The past few years have seen a remarkable growth in the number of class actions directed at food labels. Noteworthy about these cases is not merely how many have been filed but their nature as well. There's nothing novel about alleging that a product label (including a food label) is false or misleading. But many of the current cases focus not on the label's impact on consumers but on whether the label complies with the full regime of regulations that govern food labels. Indeed, many complaints assert that labels can be actionable *because* of an alleged regulatory violation, even in the absence of consumer deception. Dozens of pending complaints delve into rules familiar to food and drug regulatory lawyers but foreign to the vast majority of litigators.

This in turn leads to a host of questions that remain undeveloped in the case law (especially at the appellate levels). When does the misbranding of a product—a regulatory violation—create an actionable claim for consumers? When does compliance with regulations preempt a state-law cause of action? What is the impact of informal or nonbinding pronouncements of FDA officials? And what is the effect of the continued evolution of the regulatory law?

Many of these issues come to the fore in the multitude of cases alleging the term "evaporated cane juice" ("ECJ")—used on a number of food products—is an unlawful description of added sugar. Nearly all of them are pending before the Ninth Circuit in a case described below. The controversy over ECJ is being hashed out by the courts and by the Food and Drug Administration ("FDA" or "Agency"), but in both jurisdictions, the question is whether ECJ is misleading: Does the name accurately convey to consumers what the ingredient actually is?

Evaporated Cane Juice

Few, if any, ingredient names are currently more controversial than "evaporated cane juice." In recent years, sugar and other sweeteners have been vilified as empty calories, bad nutrition, and a significant contributor to the obesity rate. One scientist has gone so far as to call sugar a poison. In response, a new market for sweeteners has emerged, with consumers and companies alike trying to find the sweet spot between health-conscious eating and food that still satisfies consumers' tastes. Enter myriad alternative sweeteners: agave, honey, blackstrap molasses, stevia, raw sugar, and the controversial ECJ.

ECJ, like plain sugar, is made from sugar cane. The primary difference between plain sugar, or white sugar, and ECJ is that white sugar undergoes a second crystallization process, during which it is stripped of molasses. A leading manufacturer of ECJ contends that its reduced processing leaves ECJ with a darker hue, a different flavor, and additional nutrients that are not present in refined white sugar. However, others in the sugar and sweetener industries, including the patent holder for sugar cane juice concentrate, disagree that ECJ is materially different from sugar, pointing out that the nutrient profiles are nearly identical. The term has been used in ingredient statements since at least 1998.

FDA Regulatory and Enforcement History of ECJ

FDA laws and regulations require products to bear labels that are truthful and not misleading, which includes the requirement that each ingredient be declared by its common or usual name. FDA regulations require that "the common or usual name of a food, which may be a coined term, shall accurately identify or describe … the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name." The common or usual name of a food or ingredient can be established by common usage or by regulation. In the case of sugar, FDA regulations establish that sugar is the common or usual name for sucrose, and they define "sucrose" as "obtained by the crystallization from sugar cane or sugar beet juice that has been extracted by pressing or diffusion, then clarified and evaporated." The term "ECJ" is further complicated by FDA's heavy regulation of the term "juice," which is also defined by regulation.

In October 2009, FDA issued *Draft Guidance for Industry: Ingredients Declared as Evaporated Cane Juice* ("*ECJ Draft Guidance*"). Guidance documents are technically nonbinding policy statements indicating FDA's "current thinking" on any given subject. The Agency issues guidance documents to clarify statutory or regulatory requirements for industry, but, theoretically, they do not create new laws or regulations. Thus, FDA does not need to issue a guidance document on a subject in order to enforce the laws and regulations that pertain to the subject explained by a guidance document, and the document itself may reflect what FDA has been doing for some time. The public may comment on guidance documents at any time; however, FDA usually affords the public a specific comment period on a draft guidance in order to ensure those comments will be considered before FDA issues the final guidance.

The *ECJ Draft Guidance* is relatively short and serves to "advise the regulated industry of FDA's view that the term 'evaporated cane juice' is not the common or usual name of any type of sweetener, including dried cane syrup." FDA goes on to say that it considers the term ECJ to be false and misleading under the federal Food, Drug, and Cosmetic Act ("FDCA") because it fails "to reveal the basic nature of the food and its characterizing properties (i.e., that the ingredients are sugars or syrups)." Although FDA concedes that ECJ might be a juice in the broadest construction of the term, in the Agency's view, ECJ does not meet the definition of "juice" as contemplated by the regulation defining that term, nor as understood by consumers. FDA has received comments on the guidance document but has yet to finalize it.

Although FDA issued the draft guidance only five years ago, the agency has been enforcing its underlying principles for at least 10 years. In 2004, FDA issued its first warning letter mentioning ECJ, stating "[y]our product label declares 'organic evaporated cane juice' in the ingredient list; however, the common or usual name for this ingredient is sugar." In another warning letter issued four years later, FDA reiterates that "'evaporated sugar cane juice' is not a common or usual name." Although the *ECJ Draft Guidance* has yet to be finalized, FDA nonetheless directed two food manufacturers to the document "for the proper way to declare [ECJ]" in two warning letters issued in 2012. None of the warning letters was issued solely for the ECJ ingredient labeling violation, nor was ECJ even the most egregious of the violations described in these warning letters, but the ECJ mentions are nonetheless informative. Plaintiffs frequently use warning letters as proof of FDA's interpretation of certain regulations, in spite of the fact that the Agency adamantly contends that these letters are informal administrative action, not subject to judicial review.

FDA does not appear to have taken any additional enforcement action on ECJ since the last warning letters were issued

in 2012. In March 2014, citing the desire to obtain additional data and information about ECJ and how it is manufactured, FDA reopened the comment period on the *ECJ Draft Guidance*. Most of the comments submitted during both comment periods are from industry and support the idea that ECJ is the common and usual name of an ingredient that is distinct from sugar, and that FDA should withdraw the draft guidance and discontinue any further enforcement action against ECJ. Still, a small but vocal minority of commenters, who claim to represent consumer concerns, hold firm that FDA should prohibit the term ECJ and require a term that more clearly indicates that the product is a crystallized sugar, arguing that the use of the term ECJ leads consumers to believe that the sweetener is a healthier version of sugar. FDA, which has been known to take years to finalize guidance documents, has not indicated when the Agency will take action on the *ECJ Draft Guidance*. At the end of the day, the ongoing litigation may effectively come to control how the sweetener is presented to consumers.

Consumer Protection Standards and Litigation

California's Consumer Protection Laws

California's consumer protection laws remain particularly relevant for food label suits, and the current wave of ECJ suits is no exception. In particular, class action plaintiffs have flocked to the Northern District of California, which some have nicknamed the "Food Court." This popularity stems from a combination of reasons. First, California's Sherman Food Drug & Cosmetics Law ("Sherman Law") and the California Health & Safety Code regulations, which expressly adopted the requirements of the FDCA and the Nutritional Labeling and Education Act, offer several benefits to plaintiffs.

The Sherman Law, unlike the FDCA, provides plaintiffs with a private right of action via the California Unfair Competition Law ("UCL"), the False Advertising Law ("FAL"), and the Consumer Legal Remedies Act ("CLRA"). Plaintiffs claim that this private right of action allows plaintiffs to base a lawsuit on alleged technical violations of FDA regulations. Defendants' arguments that such claims are preempted by the FDCA have been rejected by some district courts, although the issue remains unresolved at the appellate level.

Other plaintiffs take advantage of the fact that certain words, such as "natural," have not been defined by FDA. They claim that a food is not natural if overly processed, or if its ingredients are derived from genetically modified organisms. Plaintiffs use the Sherman Law, UCL, FAL, and CLRA as the basis for liability when they can allege that the products fall short of the federal requirements for making these food label claims.

Other factors contribute to the Northern District's popularity. California houses the largest concentration of consumers. Food and beverage class actions usually involve very small individual claims for relief, but the per-plaintiff multipliers can be huge in a state like California, potentially containing more than 80 million consumers, or 12 percent of the U.S. population.

ECJ Suits

ECJ cases are common in the Northern District of California. These cases allege that defendants misleadingly describe sugar as ECJ. Plaintiffs often rely on the 2009 FDA draft guidance as their theory of recovery, arguing that FDA has advised industry not to refer to cane sugars as ECJ because it is not a juice as defined in the regulations.

Dismissals of ECJ suits have often hinged on the issue of primary jurisdiction. The primary jurisdiction doctrine allows courts to stay proceedings or dismiss complaints without prejudice pending the resolution of an issue within the special competence of an administrative agency. Courts apply this doctrine when questions of fact require specific administrative expertise or discretion, or when the uniformity of a ruling is required in the interest of broader regulation. Essentially, even though the court could decide an issue, the court will defer to the relevant agency to make the determination.

Before March 2014, primary jurisdiction challenges to these cases had been largely unsuccessful. Courts concluded that existing FDA regulations requiring labels to use the "common or usual name of food" were sufficient for the courts to decide the case, even though FDA was still developing its guidance on ECJ. After FDA reopened the comment period for the *ECJ Draft Guidance* in March 2014, the courts reversed course. At least 12 courts in the Northern District either stayed or dismissed cases based on FDA's primary jurisdiction over the issue.

A dismissal based on primary jurisdiction, however, is often only a temporary victory. As noted, these dismissals are generally without prejudice. The case might therefore resurface if FDA comes to an unhelpful conclusion, or even if too much time elapses before FDA says anything at all.

Although most ECJ suits have been dealt with on the grounds of primary jurisdiction, at least one has not: *Kane v. Chobani. Kane* may prove to be the most important of all these cases, as it seeks to answer many of the questions mentioned above that are yet unresolved in the case law. It is pending in the Ninth Circuit, and it provides the Ninth Circuit with a vehicle to decide a number of issues that could control the outcome of dozens of cases still working their way through the Northern District. This case, in particular, tests the plaintiff's theory that a regulatory violation in all cases means that there has been a violation of consumer protection laws. This theory has failed numerous times in the Northern District, but this is the Ninth Circuit's first opportunity to address the issue in the context of the current wave of food label cases.

In *Kane*, the plaintiff brought claims under the Sherman Law, CLRA, UCL and FAL, alleging, among other claims, that defendant's yogurt labels were deceptive because the labels do not identify ECJ as sugar. Plaintiffs asserted that they did not know ECJ was sugar and instead believed the sugar content declared in the yogurts' nutrition facts panel was naturally occurring, rather than added, and that they would not have purchased the products if they had known.

On February 20, 2014, the Northern District granted defendant's motion to dismiss with prejudice, holding that plaintiffs had not sufficiently proven standing. Under the California consumer protection laws, plaintiffs must show reliance and damage. The court found that because plaintiffs admitted they understood "dried cane syrup" to be sugar and could not "explain what they believed evaporated cane juice to be, if *not* a form of sugar," plaintiffs' assertion that they did not understand the same of ECJ was implausible.

On appeal to the Ninth Circuit, the plaintiffs/appellants argue that the district court erred in dismissing their claims because FDA guidance documents and warning letters put industry on notice that ECJ is a false and misleading ingredient name and therefore not legally permissible on food labels. The Ninth Circuit will have the chance to weigh in on whether ECJ is a deceptive term.

Other Means of Consumer Protection

Although these vehicles of consumer protection have not yet been utilized, both Section 5 of the Federal Trade Commission Act ("FTC Act") and "little FTC Acts" enforced by state attorneys general allow for government-initiated litigation. Section 5 of the FTC Act prohibits unfair or deceptive acts or practices. Under Section 5, FTC could bring actions against food manufacturers who label their products as containing ECJ, rather than sugar, if FTC were to determine that the term ECJ is likely to mislead a consumer acting reasonably under the circumstances, as long as the action is material (i.e., affects the consumer's decision to purchase the product).

Attorneys general can likewise bring lawsuits pursuant to state laws prohibiting unfair or deceptive acts or practices. Alternatively, attorneys general can use their *parens patriae* authority, an authority held by states and exercised by attorneys general to protect state interests. It is an open question whether attorneys general may use their *parens patriae* authority to sue the food industry, similar to the theory used during the tobacco litigation.

Conclusion

The ECJ litigation underscores the uneasy mesh between the judicial and administrative processes. While, at the highest level, these systems generally seek to protect consumers, they operate on different timetables, using different procedures and different substantive rules of decision.

FDA could potentially resolve the issue, but with no deadline for a final guidance and a history of lengthy consideration periods, courts might not wait for FDA to weigh in. Furthermore, in previous situations where courts have sought input from FDA, for example in defining "natural" in relation to "genetically modified ingredients," FDA has politely declined to provide clarification. This situation may be different, however, in that FDA appears to be actively pursuing a policy that would directly inform the court's decision.

FDA, which in some ways has more flexible tools than a court, may moot the debate through newly proposed and broadly

applicable nutrition labeling requirements. Given that a central issue surrounding ECJ is whether consumers can properly identify the ingredient as a sugar, enhanced labeling may provide a path to clearer understanding. If the proposed labeling requirements were finalized, FDA would require manufacturers to declare added sugars on the Nutrition Facts Panel, eliminating the confusion alleged in the *Kane* litigation.

The ECJ cases reflect only one of many label claims challenged in the new misbranding class actions. Many of these cases, and many of the ones that may follow, will be wars fought on two fronts, and they will require defendants to muster expertise in both litigation and food regulation.

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