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AMY'S KITCHEN, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ROBERT E. FIGY, individually and on behalf of all others similarly situated,

Plaintiff,

v.

AMY'S KITCHEN, INC.

Defendant.

Case No. CV 13-03816 SI

DEFENDANT AMY'S KITCHEN, INC.'S SUPPLEMENTAL MEMORANDUM REGARDING PRIMARY JURISDICTION IN SUPPORT OF MOTION TO DISMISS FIRST AMENDED COMPLAINT

Hearing Date: April 25, 2014
Time: 9:00 a.m.
Courtroom: 10
Judge: Hon. Susan Illston

Action Filed: August 16, 2013

I. THIS COURT HAS NOW RULED ON THE PRIMARY JURISDICTION ISSUE THAT IS THE SUBJECT OF THIS SUPPLEMENTAL MEMORANDUM

On April 2, 2014, this Court dismissed another virtually identical evaporated cane juice ("ECJ") lawsuit filed by plaintiff Robert E. Figy based upon the doctrine of primary jurisdiction. *Swearingen v. Santa Cruz Natural, Inc.*, 2014 WL 1339775 (N.D. Cal. Apr. 2, 2014). In doing so, the Court not only ruled on the precise issue to be addressed in this memorandum – *i.e.*, whether this case should be dismissed under the doctrine of primary jurisdiction, particularly in light of FDA's notice regarding ECJ published in the Federal Register on March 5, 2014 (the "Notice") – but it expressly addressed and rejected the arguments made by plaintiff *in this case*:

> Plaintiffs in this case [against Santa Cruz Natural, Inc.] have not responded to the arguments raised in [Santa Cruz Natural's] reply brief regarding the March 5, 2014 notice. However, plaintiff Figy in a parallel proceeding before this Court filed a supplemental brief, addressing the March 5, 2014 notice. Supplemental Memorandum, *Figy v. Amy's Kitchen*, 13-CV-03816-SI, Docket No. 58 (N.D. Cal., filed Mar. 25, 2014). Accordingly, the Court will address the arguments raised in plaintiff's supplemental brief from the other proceeding in this order.

Swearingen, 2014 WL 1339775, at *3, n.1.

Nothing has happened since the Court issued its decision in *Swearingen* that impacts the analysis, and there is no way to distinguish *Swearingen*. The same order should be issued here.

A. The Court Properly Applied The Doctrine Of Primary Jurisdiction

On March 5, 2014, FDA published the Notice stating that it has "***not reached a final decision***" on the proper name for ECJ, that it is "***reopening the comment period to request further comments, data, and information***" about the ingredient, and that it "***intend[s] to revise the [2009 ECJ] draft guidance, if appropriate, and issue it in final form***." Dkt. 52, Ex. A (emphasis added). In *Swearingen*, the Court properly relied on this language in dismissing the case under the doctrine of primary jurisdiction. *Swearingen*, 2014 WL 1339775, at *3-5.

As this Court explained in *Swearingen*:

> Although no fixed formula exists for applying the [primary jurisdiction] doctrine, the Ninth Circuit has traditionally examined the following factors: "'(1) [a] need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration.'"

Swearingen, 2014 WL 1339775, at *2 (quoting *Clark v. Time Warner Cable*, 523 F.3d 1110, 1115 (9th Cir. 2008)). In light of the authority over food labeling that Congress vested with

FDA, the first three factors are unquestionably satisfied in this ECJ food labeling case:

> Food labeling is within the special competence of the FDA. "The issue of proper declaration of ingredients on food labels is one as to which Congress vested the FDA with comprehensive regulatory authority."

Id. (quoting *Reese v. Odwalla, Inc.*, -- F. Supp. 2d --, 2014 WL 1244940, *4 (N.D. Cal. Mar. 25, 2014) (citations omitted)); *see also* 21 C.F.R. § 101.4 (FDA's ingredient list regulation).

Not surprisingly, therefore, the Court in its *Swearingen* order focused on whether deferring to FDA under the doctrine of primary jurisdiction would give due regard to Congress' grant of power and FDA's expertise and would ensure uniformity in administration. *Id*., at *3-4. The Court properly concluded that applying the primary jurisdiction doctrine would accomplish these goals. *Id*.

1. Applying The Doctrine Of Primary Jurisdiction Allows The Court To Benefit From the FDA's Expertise On Food Labeling

Interpreting and applying FDA's ingredient name regulations and standards of identity in the context of ECJ requires expertise. As this Court recognized, "FDA regulations require that manufacturers list ingredients 'on the label or labeling of a food … by [their] common or usual name.'" *Id*., at *2 (quoting 21 C.F.R. § 101.4(a)(1)). The Court also recognized that 21 C.F.R. § 102.5(d) provides that the "common or usual name of a food may be established by common usage or by establishment of a regulation." *Id*. The regulations, however, do not define what constitutes "common usage" under 21 C.F.R. § 102.5(d). The FDA as a matter of general food labeling policy – not courts and juries on a case-by-case, product-by-product basis – should interpret and apply FDA's "common usage" regulation to determine whether ECJ's usage has been sufficiently "common" to support its identification as an ingredient on food labels.

"Common usage" is only one of the many complex issues underlying the ECJ "common or usual name" analysis. 21 C.F.R. § 102.5(a) requires the "common or usual name" to "accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients." Section 102.5(a) further provides that 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 regulations do not provide guidance on how to interpret and apply section 102.5(a). Nor do

they address a situation where the distinct analyses under sections 102.5(a) and 102.5(d) yield different names. These questions should be resolved by FDA, which not only has the expertise to apply its technical set of regulations to the ECJ question currently before the Court, but the authority to announce a policy generally applicable to the U.S. food and beverage industry as a whole.

The ECJ "common or usual name" analysis also implicates FDA's standards of identity. For example, 21 C.F.R. § 168.130 defines "cane sirup" as "the liquid food derived by concentration and heat treatment of the juice of sugarcane (*Saccharum officinarum* L.) or by solution in water of sugarcane concrete made from such juice." 21 C.F.R. § 101.4(b)(20) provides that "[f]or purposes of ingredient labeling, the term *sugar* shall refer to sucrose," and section 184.1854 defines sucrose as "the chemical β-D-fructofuranosyl-α-D-glucopyranoside." Evaporated cane juice is clearly not "cane sirup" under section 168.130, because it is not a "liquid food." Nor can ECJ be labeled as "sugar" under section 101.4(b)(20), because unlike refined sugar, ECJ is not constituted entirely of sucrose – it also includes molasses. That is why FDA in its 2009 draft guidance did not suggest that ECJ should be labeled as "cane sirup" or "sugar." Instead, FDA suggested a brand new name for comment – "dried cane sirup." But as the many comments to the draft guidance explained, dried cane sirup had never been used as an ingredient name and, thus, the name "dried cane sirup" is not established by "common usage" or "regulation." ECJ, on the other hand, has been established by "common usage." The resolution of these issues – including whether to establish a new standard of identity for ECJ – should be resolved by FDA after careful consideration of the pertinent data and the applicable regulations.

Indeed, removing any doubt that FDA – and not courts and juries – should answer these regulatory questions, FDA was unable to reach a decision on the name of the ingredient, despite having four years to consider over 60 comments in response to the draft guidance. As a result, it issued the Notice requesting further comments, data, and information about ECJ. The numerous questions asked in the Notice highlight the importance of having FDA decide the right name for the ingredient. And, not surprisingly, plaintiff's supplemental opposition does not address the "expertise" prong at all.

In contrast, this Court addressed the "expertise" prong in *Swearingen* and correctly concluded that the ECJ labeling issue should be left to FDA based on its expertise:

> [T]he determination of whether ECJ is the common or usual name of the ingredient is best left to the FDA for resolution. As the March 5, 2014 notice states, consideration of whether ECJ is the common or usual name of the ingredient involves consideration of ECJ's method of production, the differences between ECJ and other sweeteners, and its basic characterizing properties. Resolution of these issues requires the expertise of the FDA.

Swearingen, 2014 WL 1339775, at *3.

The Court got this exactly right in *Swearingen*, and the reasoning is directly applicable here and should be applied in this case to reach the identical result.

2. Applying The Doctrine Of Primary Jurisdiction Will Ensure Uniformity In Administration Of The Regulations

In *Swearingen*, the Court also concluded that "deferring to the FDA will allow for uniformity in administration on [the ECJ] issue." *Id*. More specifically, the Court correctly concluded that if it "were to proceed with this action and issue a decision that is contrary to the FDA's formal position on ECJ, it would disrupt the uniform application of the FDA's regulatory rules." *Id*.

The Court's ruling is undeniably correct. FDA may find that ECJ is the proper name of the ingredient, or may provide for a grace period during which manufacturers are allowed to label the ingredient as ECJ before having to change to another name. In either case, plaintiff's effort to enforce a different requirement would be expressly preempted under the FDCA. *See* 21 U.S.C. § 343-1(a)(3) (reference therein to 343(i)(1) is to the "common or usual name" rule).

Moreover, as Amy's explained in its reply memorandum, courts across the country – and even within this district – may reach conflicting decisions as to whether ECJ is the common or usual name. Such inconsistent rulings not only would place manufacturers in the untenable position of having to produce different labels for different jurisdictions, they may also conflict with the decision that FDA ultimately reaches on the issue. As Judge Rogers said in *Reese*:

> Leaving aside the question of whether the Court can properly determine, in the first instance, if ECJ is or is not the "common or usual name" of this ingredient, ***the FDA's action clearly indicates that the agency is exercising its authority in this area***. In light of the fact that FDA has revived its review of the ECJ issue, ***the Court finds that the FDA's position on the lawfulness of the use of that term is not only, as stated in Hood, "not settled," it is also under active consideration by the FDA***. ***Any final pronouncement by the FDA in connection with that***

process almost certainly would have an effect on the issues in litigation here.

Reese, 2014 WL 1244940, at *5 (emphasis added).

The FDA's process under 21 C.F.R. §10.115 should be respected. It will allow FDA to utilize its expertise in applying and interpreting its own regulations, and then to issue final guidance applicable throughout the country to all food and beverage companies as to how ECJ should be identified on product labels. Food manufacturers like Amy's can then comply with such final guidance, whatever it may be. Deferring to FDA will ensure an orderly process of administering FDA's regulations without further confusion and inconsistency in the marketplace.

B. The Court Properly Rejected Plaintiff's Arguments Against Applying The Primary Jurisdiction Doctrine

In his supplemental memorandum filed in this case (Dkt. 58), plaintiff made numerous arguments in an effort to avoid the doctrine of primary jurisdiction. This Court already rejected such arguments. *Swearingen*, 2014 WL 1339775, at *3-5, n.1-4.

For example, plaintiff contends that the doctrine of primary jurisdiction is inapplicable because the Notice does not "create an administrative remedy for the redress of Plaintiff's injury." Dkt. 58 at 6. As this Court has already concluded, that argument is unavailing. *Swearingen*, 2014 WL 1339775, at *4, n.2. Even assuming plaintiff has a right to an administrative remedy, he has been afforded exactly that because he is, as he admits, able to participate in the proceedings by commenting on the draft guidance. *Id*. Moreover, the "present case requires the determination of issues that require the expertise of the FDA." *Id.*, at *4, n.2.

The Court also properly rejected plaintiff's arguments that FDA's "position" has always been that ECJ is not the common or usual name, and that "[t]he Notice makes clear that this was the FDA's position at the time the Draft Guidance was issued, and remains the FDA's position today." Dkt. 58 at 2:20-21. As the Court recognized, the 2009 draft guidance and the Notice establish exactly the opposite. *Swearingen*, 2014 WL 1339775, at *2-3. The 2009 draft guidance, among other disclaimers, includes a bright yellow box stating that it does ***not*** reflect FDA's position until the guidance is finalized – and the Notice expressly states that FDA has ***not*** reached a final decision regarding the labeling of ECJ. Dkt. 52, Ex. A.

As yet another meritless argument, plaintiff argues that it does not matter what FDA

concludes about the labeling of ECJ. But as the Court noted, "it is possible that future FDA action could find that the term ECJ is the common and usual name of that ingredient and is in compliance with the relevant statutes and regulations governing 'sugar.'" *Swearingen*, 2014 WL 1339775, at *4, n.3. Not only that, but FDA may provide a specific timeline under which manufacturers must comply with a different common or usual name. Any effort by plaintiff's class action counsel to impose a different timeline would be expressly preempted. 21 U.S.C. § 343-1(a)(3).

II. CONCLUSION

For the reasons set forth in *Swearingen* and *Reese* – and underscored above – the Court should dismiss this case pursuant to the doctrine of primary jurisdiction. FDA's regulatory process should be allowed to run its course. The practical problems with courts and juries attempting to interpret and apply FDA regulations – on a case-by-case, product-by-product basis, no less – are manifest. The agency with expertise over food labeling should be given the opportunity to address the ECJ labeling issue.

Dated: April 8, 2014

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