UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ROBERT E. FIGY,

Plaintiff,

v.

LIFEWAY FOODS, INC.,

Defendant.

Case No. 13-cv-04828-TEH

ORDER GRANTING DEFENDANT'S MOTION IN PART AND STAYING CASE

Now before the Court is Defendant Lifeway Foods, Inc.'s ("Defendant") motion to dismiss Plaintiff Robert Figy's ("Plaintiff") First Amended Complaint ("FAC"). In light of the parties' joint request to address a recent announcement by the Food and Drug Administration ("FDA") related to the subject matter of the case, the Court ordered supplemental briefing, in which Defendant requested that the Court dismiss or stay the case on the basis of the primary jurisdiction doctrine. Pursuant to Civil Local Rule 7-1(b), the Court finds this matter appropriate for resolution without oral argument, and hereby VACATES the hearing previously scheduled for May 12, 2014. For the reasons discussed below, the Court GRANTS IN PART Defendant's motion and STAYS the action pursuant to the doctrine of primary jurisdiction.

BACKGROUND

Plaintiff brings this suit on behalf of himself and a putative class of consumers who, within the last four years, purchased certain of Defendant's food products that he contends Defendant misbranded by deceptively referring to the added sugar contained in each product as "evaporated cane juice" ("ECJ"). Plaintiff, a resident of San Francisco, California, is a "health conscious consumer who wishes to avoid 'added sugars' in the food products he purchases." FAC ¶¶ 26, 70, Docket No. 23. Defendant is an Illinois corporation; it is a leading producer of kefir, a retail probiotic dairy beverage and product

similar to yogurt. *Id*. ¶ 27-28. Plaintiff alleges that Defendant uses the phrase ECJ on its packaging to make its products appear healthier than a product containing "added sugar" as an ingredient, which is what Plaintiff asserts ECJ actually is. *Id*. ¶ 40. Plaintiff alleges that Defendant violates the federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), as well as accompanying FDA regulations, when it refers to added sugar as ECJ. *See* FAC ¶¶ 23, 43-52. This is because the FDA requires an ingredient declared on a food label to be listed by its "common or usual name," 21 C.F.R. § 101.4(a)(1), and evaporated cane juice has a "standard of identity" that is not "juice," but is sugar or dried cane syrup. FAC ¶ 46. Plaintiff contends that listing sugar as ECJ is false and misleading because it fails to reveal the basic character of the food and its properties. *Id*. (citing 21 U.S.C. § 343(a)). Plaintiff further alleges that Defendant's failure to comply with these FDA regulations violates California's Sherman Food Drug & Cosmetic Law, Cal. Health & Safety Code § 109875, *et seq.* ("Sherman Law"). Plaintiff argues that the Sherman Law incorporates the FDCA regulations requiring that ingredients on food labels be identified by their "common or usual name," mandates that a product not listed by its common or usual name is misbranded, and prohibits the sale of misbranded products. FAC ¶¶ 47, 57-69 (citing 21 U.S.C. § 343(g) & (i), 21 C.F.R. § 101.4(a), Cal. Health & Safety Code § 110725(a)). Based on these allegations, Plaintiff brings claims under California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 ("UCL"), California's False Advertising Law ("FAL"), Cal. Bus. & Prof. Code § 17500, *et seq.*; the Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750, *et seq.*, and claims for breach of express and implied warranties, negligent misrepresentation, negligence, unjust enrichment, recovery in assumpsit, and declaratory relief.

DISCUSSION

Defendant moves to dismiss the FAC on several grounds, including based on the doctrine of primary jurisdiction. Defendant argues that because food labeling is within the special competence of the FDA, and the FDA is presently examining the very issue of the

propriety of labeling ECJ – which is central to all of Plaintiff's claims – the Court should invoke the primary jurisdiction doctrine and dismiss or stay the pending action. Plaintiff contends that the primary jurisdiction doctrine, and any guidance resulting from the FDA's present deliberations, would not change the FDA's "consistent and unwavering" position that ECJ is not the common or usual name of sugar or cane syrup, or the question of whether listing ECJ on food labels violates the law. Supp. Opp'n at 3, Docket No. 38. For the reasons discussed below, the Court concludes that the primary jurisdiction doctrine applies.

A. The Primary Jurisdiction Doctrine

"The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). This "prudential" doctrine enables a court to determine that "an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch." *Id*. (citing *Syntek Semiconductor Co., Ltd. v. Microchip Tech. Inc.*, 307 F.3d 775, 782 (9th Cir. 2002)). "[I]t is to be used only if a claim requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency, and if protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *Id*. (citations and quotation marks omitted).

A court traditionally weighs four factors in deciding whether to apply the primary jurisdiction doctrine: (1) the 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. *Syntek*, 307 F.3d at 781-82. If applicable, the court can either stay proceedings or dismiss the case without prejudice. *Id.* at 782. In considering these factors, the "primary jurisdiction doctrine is designed to

protect agencies possessing 'quasi-legislative powers' and that are 'actively involved in the administration of regulatory statutes.'" *Clark*, 523 F.3d at 1115 (citation omitted). Several courts within this district have applied the primary jurisdiction doctrine "where a determination of a plaintiff's claim would require a court to decide an issue committed to the FDA's expertise without a clear indication of how the FDA would view the issue." *Hood v. Wholesoy & Co, Modesto Wholesoy Co.* LLC, No. 12-CV-5550-YGR, 2013 WL 3553979, at *5 (N.D. Cal. Jul. 12, 2013); *see also Reese v. Odwalla, Inc.*, No. 13-CV-00947-YGR, 2014 WL 1244940, at *3 (N.D.Cal. Mar. 25, 2014); *Astiana v. Hain Celestial*, 905 F. Supp. 2d 1013, 1016-17 (N.D.Cal. 2012); *Gordon v. Church & Dwight Co.*, No. C 09–5585 PJH, 2010 WL 1341184, at *2 (N.D. Cal. Apr. 2, 2010).

B. Application of the Primary Jurisdiction Doctrine

The Court finds that the Second, Third, and Fourth *Syntek* primary jurisdiction factors are met here. 307 F.3d at 781-82. Congress vested the FDA with comprehensive regulatory authority to address the issue of proper declaration of food labels. *Reese*, 2014 WL 1244940, at *4; *see generally* 21 U.S.C. § 301 *et seq.* & 21 U.S.C. § 341 *et seq.; Swearingen v. Santa Cruz Natural Inc.*, No. C 13-04291 SI, 2014 WL 1339775, at *2 (N.D. Cal. Apr. 2, 2014) ("Food labeling is within the special competence of the FDA"). The FDCA imposes a comprehensive regulatory framework that requires uniformity in administration. *See Astiana*, 905 F. Supp. 2d at 1015 (noting that "issues of beverage labeling have been entrusted by Congress to the FDA, pursuant to the FDCA (and its related regulations)."); *Reese*, 2014 WL 1244940, at *4 (citing 21 U.S.C. § 341 *et seq.*) ("Congress has vested the FDA with regulatory authority over food labeling, charging the agency with creating a uniform national scheme of regulation to ensure that food is labeled in a manner that does not mislead consumers").

The Court also finds that the First *Syntek* primary jurisdiction factor is met because the central dispute in this case is whether ECJ is the "common or usual name" of the ingredient used in Defendant's product and whether use of that ingredient name is misleading and prohibited under the FDCA, and in turn, the Sherman Law. Specifically,

Plaintiff's claims here depend on FDA regulations that require that manufacturers list ingredients "on the label or labeling of a food . . . by [their] common or usual name." 21 C.F.R. § 101.4(a)(1); *see* FAC ¶ 43. The regulations provide that the "common or usual name of a food may be established by common usage or by establishment of a regulation . . . ." 21 C.F.R. § 102.5(d). As noted by other courts in this district, whether ECJ may be properly used on food labeling "'fit[s] squarely within Congress' delegation of authority to the FDA." S*wearingen*, 2014 WL 1339775, at * 2 (citing *Clark*, 523 F.3d at 1115). Indeed, the FDA has issued previous draft guidance on the proper labeling of ECJ. The parties, however, disagree on whether that previous guidance resolved the issue of whether ECJ is the common or usual name of the ingredient at issue.

Plaintiff contends that Defendant's use of ECJ on food labels violates the FDA's "longstanding and consistently held" position that listing ECJ on food ingredient lists is illegal because it is misleading and violates the "common or usual name" requirement. Supp. Opp'n at 1; *see also* FAC ¶¶ 38-59, 63, 98-104. Plaintiff further argues that the FDA-issued "Guidance for Industry: Ingredients Declared as Evaporated Cane Juice, Draft Guidance," ("2009 Draft ECJ Guidance"), issued in October 2009, never implied that the FDA ever had or would permit the use of the term ECJ; rather, it reaffirmed the view that ECJ is not the common or usual name of any type of sweetener, including that derived from dried cane syrup, and that the representation that ECJ is juice is considered by the FDA to be false and misleading under 21 U.S.C. section 343(a)(1) because it fails to reveal the basic nature of the food and its characterizing properties. *See* Supp. Opp'n at 3; *see also* 2009 Draft ECJ Guidance, Docket No. 39-1 at 3, Req. for Judicial Notice Ex. A.[1]

Defendant, however, emphasizes that the 2009 Draft ECJ Guidance represented only the FDA's preliminary thinking. For example, the 2009 Draft ECJ Guidance qualifies that this "draft guidance, *when finalized*, will represent the [FDA]'s current thinking on

[1] The Court grants Plaintiff's unopposed request to judicially notice various FDA publications and documents, including guidance documents, warning letters, and policy statements, attached as Exhibits A-J to Plaintiff's Request for Judicial Notice, Docket No. 39. *See* Fed. R. Evid. 201.

this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public." 2009 Draft ECJ Guidance at 1 (emphasis added). The 2009 Draft ECJ Guidance prominently notes that it "contains nonbinding recommendations," and is a "draft – not for implementation." *Id*. Far from boilerplate, these words of caution indicate that the FDA, the entity charged with creating and maintaining a uniform scheme of non-misleading food labels, was in the process of formulating a final position on the propriety of using the ingredient term ECJ in food labeling.

On March 5, 2014, the FDA, reaffirmed this conclusion when it issued a notice in the Federal Register reopening the comment period for draft guidance on the use of the term ECJ; the FDA requested comments, data, and information from the public ("2014 FDA Notice"). 2014 FDA Notice, Req. for Judicial Notice Ex. J, Docket No. 39-10; *see also* 79 Fed. Reg. 12507 (Mar. 5, 2014). The FDA stated, in part:

> We have *not reached a final decision on the common or usual name* for this ingredient and are reopening the comment period to request further comments, data, and information about the basic nature and characterizing properties of the ingredient sometimes declared as "evaporated cane juice," how this ingredient is produced, and how it compares with other sweeteners.

Id. at 12507 (emphasis added). The Comment period ends May 5, 2014. *Id*. Tellingly, the 2014 FDA Notice clarifies that the 2009 Draft ECJ Guidance was issued "to seek comment on [the FDA's] *preliminary* thinking regarding the use of the term [ECJ] on food labels to declare the presence of sweeteners derived from sugar cane syrup," and that the FDA has "not reached a final decision on the common or usual name for this ingredient." *Id*. (emphasis added). The 2014 FDA Notice also poses questions relating to how ECJ is manufactured, including how its method of manufacture differs from that of other sweeteners made from sugar cane (such as cane sugar and cane syrup), and asks whether the name ECJ "adequately convey[s] the basic nature of the food and its characterizing properties or ingredients, consistent with the principles in § 102.5(a)," which seeks to avoid confusion on food labels. *Id*. at 12508; *see also* 21 C.F.R. § 102.5(a) ("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."). In other words, the 2014 FDA Notice seeks comments on issues that directly relate to the substance of Plaintiff's claims here. The 2014 FDA Notice states that "[a]fter reviewing the comments received, [the FDA] intends to revise the draft guidance, if appropriate, and issue it in final form . . . ." *Id*. Thus, the FDA intends to issue guidance in final form, which will likely resolve the question disputed by the parties as to whether the FDA considers ECJ to be the common or usual name of the ingredient.

The clear language in the 2014 FDA Notice reinforces the Court's conclusion that the doctrine of primary jurisdiction applies in this case. In so finding, the Court joins several district courts that have dismissed without prejudice or stayed similar suits challenging the use of ECJ on primary jurisdiction grounds following the 2014 FDA Notice, issued on March 5, 2014. *See Reese*, 2014 WL 1244940, at *5 (Gonzalez Rogers, J.) (staying action based on primary jurisdiction because the FDA's position on lawfulness of the term ECJ is under active consideration by the FDA and any "final pronouncement by the FDA in connection with that process almost certainly would have an effect on the issues in litigation here"); *Swearingen*, 2014 WL 1339775, at *4 (Illston, J.) (dismissing action without prejudice because application of primary jurisdiction doctrine "allows the Court to benefit from the FDA's expertise on food labeling and will ensure uniformity in administration of the regulations."); *Figy v. Amy's Kitchen, Inc*, No. C 13-03816-SI, 2014 WL 1379915, at *4 (N.D. Cal. Apr. 9, 2014) (Illston, J.) (same). The Court concurs with these courts' findings that application of the primary jurisdiction doctrine with respect to the FDA's position on ECJ will enhance the Court's decision-making efficiency by allowing the Court to benefit from the FDA's definitive guidance on the issue and assure uniform application of regulatory law by preventing the Court from potentially issuing a decision contrary to the FDA's formal position on ECJ, which it is currently and actively in the process of revising. *See Syntek*, 307 F.3d at 780-81.

The Court acknowledges that other courts in this district have generally declined to dismiss or stay actions challenging the use of ECJ on labels on primary jurisdiction

grounds based on the 2009 Draft ECJ Guidance alone. *See* Supp. Opp'n at 4 n. 5 (collecting cases). However, after the March 5, 2014 FDA Notice, only one court in this district to have examined the applicability of the primary jurisdiction doctrine to ECJ claims in light of the 2014 FDA Notice has declined to dismiss or stay the action. *See Swearingen v. Amazon Pres. Partners, Inc.*, No. 13-CV-04402-WHO, 2014 WL 1100944, at *4 n. 3 (N.D. Cal. Mar. 18, 2014) (declining to apply the primary jurisdiction doctrine to ECJ claims because "[i]t remains unclear when or if the FDA will conclusively resolve this issue"). Here, however, the Court concludes that the FDA is likely to make a final pronouncement with respect to whether ECJ is the common or usual name for the ingredient at issue, given that the comment period ends May 5, 2014, and that the FDA announced that it intends to finalize its guidance. *See* 2014 FDA Notice at 1 ("After reviewing the comments received, [the FDA] intends to revise the draft guidance, if appropriate, *and issue it in final form* . . . .") (emphasis added); *accord Reese*, 2014 WL 1244940, at *5; *Swearingen*, 2014 WL 1339775, at *4.[2]

The Court is not persuaded by the arguments Plaintiff raises in opposition. First, contrary to Plaintiff's position, the FDA has not definitively announced that listing ECJ as an ingredient is misleading or improper in light of the preliminary nature of the 2009 ECJ Draft Guidance and the subsequent 2014 FDA Notice that explicitly stated that the FDA has not reached a final decision on the common or usual name for ECJ. Second, Plaintiff argues that the FDA's reopening of the comment period has not signaled a reversal in its position regarding listing ECJ. The FDA may later confirm its preliminary position on ECJ, thus strengthening Plaintiff's position, but application of the primary jurisdiction doctrine in the interim will enhance the Court's ultimate decision-making efficiency by

[2] The Court notes that Judge Davila declined to apply the primary jurisdiction doctrine with respect to ECJ claims in *Pratt v. Whole Foods Market California, Inc.*, No. 5:12-CV-05652-EJD, 2014 WL 1324288, at *7 (N.D. Cal. Mar. 31, 2014) and *Leonhart v. Nature's Path Foods, Inc.*, No. 5:13-CV-0492-EJD, 2014 WL 1338161, at *7 (N.D. Cal. Mar. 31, 2014), but neither case referenced the 2014 FDA Notice. The Court finds that the 2014 FDA Notice is highly relevant with respect to the conclusion that the primary jurisdiction doctrine applies here, and thus declines to rely on these cases.

allowing the Court to benefit from the FDA's definitive guidance on the issue. Third, Plaintiff argues that the doctrine of primary jurisdiction cannot be properly invoked where there is no administrative remedy available to him. However, as noted by the *Swearingen* court, this case is unlike *Rosado v. Wyman*, 397 U.S. 397, 406 (1970), cited by Plaintiff, where the Supreme Court held that the doctrine of primary jurisdiction is inapplicable when the agency does not allow a plaintiff to "initiate or participate" in the administrative proceedings. *Id*. at 406, 426. Here, Plaintiff may participate in the public comment process.[3] Moreover, Plaintiff may reinitiate these proceedings before the Court should the FDA make its final guidance determination with respect to ECJ. Fourth, Plaintiff argues that any determination by the FDA on this issue will not affect the claims in this case because Defendant will be bound by FDA regulations regarding the listing of sugar. *See* Supp. Opp'n at 5-6. Plaintiff, however, has previously admitted that sweeteners derived from sugar cane can be listed by names other than sugar. *See* Supp. Opp'n at n. 2 ("If an ingredient falls within this definition of 'sucrose,' it must be called 'sugar.' FDA, however, does permit certain sweeteners derived from sugar cane to be referred to by slightly different names.") As noted by the *Swearingen* court, "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.'"

[3] This case is also unlike *Rhoades v. Avon Products, Inc.*, 504 F.3d 1151 (9th Cir. 2007), also cited by Plaintiff. In that case, the Ninth Circuit declined to apply the primary jurisdiction doctrine to the Patent and Trademark Organization ("PTO") because Congress had not designated it as the exclusive expert in the field and federal courts are "well-suited to handle" the trademark infringement declaratory relief claims at issue there. *Id*. at 1164 ("Allowing the district court to decline a declaratory relief action on a primary jurisdiction rationale is sensible only if the agency is better equipped to handle the action. Here, however, Congress has not installed the PTO as the exclusive expert in the field."). As noted by the *Swearingin* court, in contrast to *Rhoades*, "the issue of the proper labeling of food ingredients is one as to which Congress has vested the FDA with comprehensive regulatory authority," and "the present case requires the determination of issues that require the expertise of the FDA." 2014 WL 1339775, at * 4 n. 2 (citations omitted). That the FDA is uniquely suited to address the ECJ issue that is squarely before it now distinguishes the remaining authorities cited by Plaintiff. *See* Supp. Opp'n at 6 (citing *People of California v. Kinder Morgan Energy Partners, L.P.*, 569 F. Supp. 2d 1073, 1083 (S.D. Cal. 2008) & *Cannon v. Wells Fargo Bank N.A.*, 917 F. Supp. 2d 1025, 1039 (N.D. Cal. 2013) (rejecting application of primary jurisdiction doctrine where party did not ask for referral to federal agency)).

Swearingen, 2014 WL 1339775, at *4 n. 3. Thus, the future FDA determination on ECJ may affect the claims in this case.

In light of the active consideration by the FDA of the very issues that form the lynchpin of Plaintiff's claims, and inform the Court's analysis thereof, the Court applies the primary jurisdiction doctrine and stays the case pending the FDA's resolution of its ECJ guidance as contemplated in the 2014 FDA Notice.

CONCLUSION

Accordingly, the Court GRANTS IN PART Defendant's motion and STAYS the action pursuant to the doctrine of primary jurisdiction. A compliance hearing shall be held on **November 3, 2014** at **10:00 AM** to determine whether the case should remain stayed. A joint statement of no more than six pages updating the Court on the status of the FDA's action with respect to the ECJ guidance contemplated in the 2014 FDA Notice, and the parties' positions as to whether further briefing concerning whether the stay shall remain in effect, shall be due no later than **October 13, 2014**. The parties shall notify the Court through this joint statement should the FDA finalize its ECJ guidance before the scheduled compliance hearing.

IT IS SO ORDERED.

Dated: 05/05/14

THELTON E. HENDERSON
United States District Judge

United States District Court
Northern District of California