

For the Northern District of California **United States District Court**

("class products"). Docket No. 23, First Amended Complaint ("FAC") ¶ 3, Table 1. Plaintiffs allege that using the term ECJ violates Food and Drug Administration ("FDA") regulations which require food labels to reflect the common or usual name of an ingredient. FAC ¶¶ 16, 23, 44-49 (citing 21 C.F.R. §§ 101.4, 102.5). Plaintiffs allege that the common or usual name for ECJ is actually "sugar," and that defendant uses the term ECJ instead of sugar to make its products appear healthier to consumers. FAC ¶ 16, 21, 23, 40, 44. Plaintiffs further allege that defendant's failure to comply with these FDA regulations violates California's Sherman Law ("Sherman Law"), California Health and Safety Code 8 § 109875 et seq. Id. ¶¶ 8-10, 37-38, 61-65.

9 Based upon those alleged violations, plaintiffs filed a class action complaint against Santa Cruz 10 on September 16, 2013. Docket No. 1, Compl. On December 30, 2013, plaintiffs filed the FAC, 11 asserting causes of action under the following California consumer protection statutes: (1) the Unfair 12 Competition Law ("UCL") for unlawful business practices; (2) the UCL for unfair business practices; (3) the UCL for fraudulent business practices; (4) the False Advertising Law ("FAL") for misleading 13 and deceptive advertising (5) the FAL for untrue advertising; and (6) the Consumer Legal Remedies Act 14 15 ("CLRA") for unlawful sale of misbranded products and misrepresentations regarding those products. 16 Docket No. 23, FAC. Plaintiffs also allege causes of action for: (7) breach of express warranty; (8) 17 breach of implied warranty; (9) negligent misrepresentation; (10) negligence; (11) unjust enrichment; 18 (12) recovery in assumpsit; and (13) declaratory relief. Id. By the present motion, defendant moves to 19 dismiss plaintiffs' FAC. Docket No. 24, Def.'s Mot.

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DISCUSSION

22 Among other grounds, Santa Cruz moves to dismiss the FAC based upon the doctrine of primary jurisdiction. Santa Cruz argues that, because food labeling is within the special competence of the FDA, 23 24 and the FDA has not finalized it position on the term ECJ, the Court should apply the doctrine of primary jurisdiction, defer to the agency, and dismiss the action without prejudice. Docket No. 24, Motion to 25 Dismiss at 20-22. In response, plaintiffs contend that the doctrine of primary jurisdiction does not apply 26 in these circumstances because the FDA has "unwaveringly maintained since at least 2000 that the use 27 28 of ECJ on food ingredient lists is illegal." Docket No. 28, Pls' Opp. at 20.

I. Legal Standard

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"The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint 2 3 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). "[T]he doctrine is a 4 5 'prudential' one, under which a court determines that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority 6 7 over the relevant industry rather than by the judicial branch." *Id.* Although no fixed formula exists for 8 applying the doctrine, the Ninth Circuit has traditionally examined the following factors: "(1) [a] need 9 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 10 comprehensive regulatory authority that (4) requires expertise or uniformity in administration." Clark, 11 523 F.3d at 1115; see also Chabner v. United of Omaha Life Ins. Co., 225 F.3d 1042, 1051 (9th Cir. 12 2000) (in determining whether to apply doctrine of primary jurisdiction, court should consider "1) 13 whether application will enhance court decision-making and efficiency by allowing the court to take 14 15 advantage of administrative expertise; and 2) whether application will help assure uniform application 16 of regulatory laws.").

17 Primary jurisdiction may be invoked when an agency is addressing an issue through formal rulemaking procedures, as well as through adjudicative procedures. See, e.g., Clark, 523 F.3d at 1114-18 19 16; Kappelmann v. Delta Air Lines, Inc., 539 F.2d 165, 169 (D.C. Cir. 1976). Several courts within this 20 district have found application of the primary jurisdiction doctrine appropriate "where a determination" 21 of a plaintiff's claim would require a court to decide an issue committed to the FDA's expertise without 22 a clear indication of how the FDA would view the issue." Hood v. Wholesoy & Co, Modesto Wholesoy 23 *Co. LLC*, 12-CV-5550-YGR, 2013 WL 3553979, at *5 (N.D. Cal. July 12, 2013); see also, e.g., Reese 24 v. Odwalla, Inc., 13-CV-00947-YGR, 2014 U.S. Dist. LEXIS 40341, at *8 (N.D. Cal. March, 25, 2014); Ivie v. Kraft Foods Global, Inc., C-12-02554-RMW, 2013 WL 685372, at *7 (N.D. Cal. Feb. 25, 2013); 25 Astiana v. Hain Celestial, 905 F. Supp. 2d 1013, 1016-17 (N.D. Cal. 2012); Gordon v. Church & Dwight 26 Co., C 09-5585 PJH, 2010 WL 1341184, at *2 (N.D. Cal. Apr. 2, 2010). 27

1 II. Analysis

Food labeling is within the special competence of the FDA. *Morgan v. Wallaby Yogurt Co., Inc.,*13-CV-00296-WHO, 2013 WL 5514563, at *4 (N.D. Cal. Oct. 4, 2013); *Hood*, 2013 WL 3553979, at
*16. "The issue of proper declaration of ingredients on food labels is one as to which Congress vested
the FDA with comprehensive regulatory authority." *Reese*, 2014 U.S. Dist. LEXIS 40341, at *12 (citing
21 U.S.C. § 301 *et seq* and 21 U.S.C. § 341 *et seq*); *accord Astiana*, 905 F. Supp. 2d at 1015 ("[I]ssues
of beverage labeling have been entrusted by Congress to the FDA, pursuant to the FDCA (and its related
regulations)...").

9 Specific to the present case, FDA regulations 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). The 10 11 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). All of the claims in the FAC hinge on plaintiffs' 12 13 contention that ECJ is not the common or usual name of the ingredient at issue, thereby rendering defendant's products in violation of the above federal regulations and illegal under California's Sherman 14 15 Law. See generally FAC. Therefore, the issues raised by plaintiffs' complaint "fit[] squarely within" 16 Congress' delegation of authority to the FDA. *Clark*, 523 F.3d at 1115.

17 The parties dispute whether the FDA has resolved the issue of whether ECJ is the common or usual name of the ingredient at issue. Plaintiffs argue that the FDA has consistently maintained since at 18 19 least 2000 that the use of ECJ on food ingredient lists is false and misleading because ECJ is not the 20 common or usual name for that ingredient. Docket No. 28, Pls' Opp. at 20; see also FAC ¶¶ 45-53. The Court disagrees. In support of their contention, plaintiffs rely on a 2009 draft guidance issued by the 21 22 FDA and several warning letters. See id. In the 2009 draft guidance, the FDA states that it is advising 23 the regulated industry that the FDA's view is that "evaporated cane juice" is not the common or usual 24 name of any type of sweetener. Docket No. 25-1, Tansey Decl. Ex. A at 1-2. However, the 2009 draft 25 guidance further states: "This guidance is being distributed for comment purposes only" and "Draft - Not 26 for Implementation." Id. at 1. In addition, the guidance explains that it will only represent the FDA's current thinking on the topic once the guidance is finalized. Id. Therefore, it is apparent from the face 27 28 of the 2009 Draft Guidance that it only represents the FDA's preliminary view of the issue and not its

1 formal position.

2 Moreover, on March 5, 2014, the FDA issued a notice in the Federal Register reopening the comment period for the draft guidance on the use of the term ECJ.¹ Docket No. 32, Ex. 1. The notice 3 4 confirms that the 2009 draft guidance merely represents the FDA's "preliminary thinking regarding the 5 use of the term" ECJ, and the FDA has "not reached a final decision on the common or usual name of the ingredient." Id. The notice explains that the FDA is seeking additional information on ECJ's method 6 7 of production, the differences between ECJ and other sweeteners, and its basic characterizing properties. 8 *Id.* The notice also states that after reviewing the comments the FDA intends to revise the draft guidance, if appropriate, and issue it in final form. *Id.* The relevant federal regulations explain that "[g]uidance 9 10 documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the 11 agency's interpretation of or policy on a regulatory issue." 21 C.F.R. § 10.115(b)(1).

12 In light of the March 5, 2014 notice, the Court finds it appropriate to apply the doctrine of primary 13 jurisdiction. The notice states that the FDA has not resolved the issue of whether ECJ is the common or 14 usual name of the ingredient at issue and that the FDA is engaged in active rulemaking on the issue. 15 Further, the determination of whether ECJ is the common or usual name of the ingredient is best left to 16 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 17 between ECJ and other sweeteners, and its basic characterizing properties. Resolution of these issues 18 19 requires the expertise of the FDA. See also United States v. W. Pac. R. Co., 352 U.S. 59, 64 (1956) ("[I]n 20 cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter 21 should not be passed over."). Deferring to the FDA for resolution of these issues "will enhance decision-22 23 making and efficiency by allowing the court to take advantage of administrative expertise." See 24 Chabner, 225 F.3d at 1051.

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¹ The March 5, 2014 notice was first raised in defendant's reply brief. Docket No. 33, Def's Reply. Plaintiffs in this case have not responded to the arguments raised in the 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.

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Moreover, deferring to the FDA will allow for uniformity in administration on this issue. If the 1 2 Court were to proceed with this action and issue a decision that is contrary to the FDA's formal position 3 on ECJ, it would disrupt the uniform application of the FDA's regulatory rules. See United States v. 4 Philip Morris USA Inc., 686 F.3d 832, 837 (D.C. Cir. 2012) ("The primary jurisdiction doctrine rests 5 ... on a concern for uniform outcomes (which may be defeated if disparate courts resolve regulatory issues inconsistently)....'"). For this reason, courts find it particularly appropriate to defer to an agency 6 7 when, as is true here, the agency is in the process of making a determination on a key issue in the 8 litigation. See Clark, 523 F.3d at 1115 (explaining that application of the primary jurisdiction doctrine was appropriate because the "agency is actively considering how it will regulate VoIP services and [] the 9 agency's development of a uniform regulatory framework to confront this emerging technology is 10 important to federal telecommunications policy."); Gordon, 2010 WL 1341184, at *2 (applying primary 11 jurisdiction; "[because] this issue remains under review," "[i]t would be inappropriate for this court to 12 13 assume the FDA's regulatory role").

In sum, applying the doctrine of primary jurisdiction allows the Court to benefit from the FDA's
expertise on food labeling and will ensure uniformity in administration of the regulations.² See Reese,
2014 U.S. Dist. LEXIS 40341, at *16 ("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 . . . 'not

²Plaintiffs argue that the doctrine of primary jurisdiction is inapplicable where the agency cannot award a plaintiff the same relief as a court. Supp. Memorandum at 6. In support of this contention plaintiffs cite to *Rosado v. Wyman*, 397 U.S. 397, 406 (1970). However, the Supreme Court in *Rosado* merely held that the doctrine of primary jurisdiction is inapplicable where the agency does not allow the plaintiffs to "initiate or participate" in the administrative proceedings. *Id.* Here, the FDA has already initiated rulemaking procedures on the issue, and plaintiffs concede that they are allowed to participate in the proceedings by submitting comments. Supp. Memorandum at 6. Therefore, *Rosado* is inapplicable to the present circumstances.

Plaintiffs also cite to Rhoades v. Avon Products, Inc., 504 F.3d 1151 (9th Cir. 2007), but this 23 case is distinguishable. In *Rhodes*, the Ninth Circuit declined to apply primary jurisdiction because of the unique nature of the relevant agency. The court explained that unlike other agencies, the Patent and 24 Trademark Organization ("PTO") has not been designated by Congress as the exclusive expert in the field. Id. at 1164 ("Allowing the district court to decline a declaratory relief action on a primary 25 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."). Additionally, the 26 Ninth Circuit explained that "federal courts are particularly well-suited to handle the claims" at issue in that plaintiff's action. Id. In contrast, here, the issue of the proper labeling of food ingredients is one 27 as to which Congress has vested the FDA with comprehensive regulatory authority. See Reese, 2014 U.S. Dist. LEXIS 40341, at *12 (citing 21 U.S.C. § 301 et seq and 21 U.S.C. § 341 et seq). Moreover, 28 the present case requires the determination of issues that require the expertise of the FDA. See id. at *14; Hood, 2013 WL 3553979, at *5.

settled,' it is also under active consideration by the FDA. Any final pronouncement by the FDA in 1 2 connection with that process almost certainly would have an effect on the issues in litigation here."). All 3 of plaintiffs' claims hinge on their contention that ECJ is not the common and usual name for the ingredient found in defendant's products.³ Therefore, the Court finds it appropriate to dismiss the action 4 5 without prejudice pursuant to the doctrine of primary jurisdiction.⁴ See, e.g., Hood, 2013 WL 3553979, at *6 (dismissing without prejudice, among others, plaintiff's UCL, FAL, CLRA, and contract claims 6 7 under the doctrine of primary jurisdiction); Astiana, 905 F. Supp. 2d at 1017 (dismissing without 8 prejudice plaintiff's UCL, FAL, CLRA, and fraud claims under the doctrine of primary jurisdiction).

CONCLUSION

Accordingly, the Court GRANTS defendant's motion to dismiss and DISMISSES the action WITHOUT PREJUDICE, pursuant to the doctrine of primary jurisdiction. Docket No. 24.

IT IS SO ORDERED.

Dated: April 2, 2014

Suran Delaton

SUSAN ILLSTON UNITED STATES DISTRICT JUDGE

¹⁹ ³ Plaintiffs argue that it will not influence their lawsuit if the FDA issues guidance finding that ECJ is the common or usual name of the ingredient. Supp. Memorandum at 5. Specifically, plaintiffs argue that regardless of any future FDA action on the term ECJ, defendant will continue to be bound by the existing "sugar" statutes and regulations that require that the ingredient at issue be called "sugar." *Id.* (citing 21 C.F.R. §§ 101.4(a)(1), 101.4(b)(20), 102.5(d), 184.1854). However, elsewhere in the brief, plaintiffs concede that "[t]he FDA . . . does permit certain sweeteners derived from sugar cane to be referred to by slightly different names." *Id.* at 4. Therefore, 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."

⁴ In their supplemental brief in the *Amy's Kitchen* case, plaintiffs cite to the recent decision in *Swearingen v. Amazon Preservation Partners, Inc.*, 13-CV-04402-WHO, 2014 U.S. Dist. LEXIS 36830 (N.D. Cal. Mar. 18, 2014). In *Swearingen/Amazon*, the district court declined to apply the doctrine of primary jurisdiction, notwithstanding the FDA's issuance of the March, 5, 2014 notice, because "it remains unclear when or if the FDA will conclusively resolve the issue." *Id.* at *11 n.3. However, the March 5, 2014 notice explicitly states that after reviewing comments, the FDA intends to issue guidance in final form. Docket No. 32, Ex. 1. Therefore, the Court declines to follow *Swearingen/Amazon. See also Reese*, 2014 U.S. Dist. LEXIS 40341 at *10, 16 (applying the doctrine of primary jurisdiction based on the March 5, 2014 notice in part because the FDA stated it will issue final guidance on the use of the term ECJ).

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