IN THE
UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Docket No. 17-55901

CYNTHIA CARDARELLI PAINTER, an individual, and on behalf of other members of the general public similarly situated
Plaintiff-Appellant,

v.

BLUE DIAMOND GROWERS, a California Corporation,
Defendant-Appellee.

APPEAL FROM AN ORDER OF THE
UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
HON. STEVEN V. WILSON, PRESIDING
CASE NO. 2:17-CV-02235-SVW-AJW

APPELLANT'S OPENING BRIEF

CAPSTONE LAW APC
GLENN A. DANAS (SBN 270317)
BEVIN PIKE (SBN 221936)
KATHERINE W. KEHR (SBN 226559)
GLENN.DANAS@CAPSTONELAWYERS.COM
BEVIN.PIKE@CAPSTONELAWYERS.COM
KATHERINE.KEHR@CAPSTONELAWYERS.COM
1875 CENTURY PARK EAST, STE. 1000
LOS ANGELES, CALIFORNIA 90067
TELEPHONE: (310) 556-4811
FACSIMILE: (310) 943-0396

Attorneys for Plaintiff-Appellant
CYNTHIA CARDARELLI PAINTER

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

STATE CASES

FEDERAL STATUTES

STATE STATUTES

SECONDARY AUTHORITIES

JURISDICTIONAL STATEMENT

Pursuant to Ninth Circuit Rule 28-2.2, Plaintiff-Appellant Cynthia Cardarelli Painter submits the following statement of jurisdiction:

a. The United States District Court for the Central District of California exercised jurisdiction over this action after removal by Defendant-Appellee Blue Diamond Growers ("Defendant") on March 22, 2017, pursuant to the Class Action Fairness Act ("CAFA"), 28 U.S.C. §§ 1332(d), 1441, and 1446. (2 Excerpts of Record ["ER"] 96-103.)

b. On May 24, 2017, the district court granted Defendant's Motion to Dismiss with prejudice. (1 ER 1-5.) On the same day, the district court dismissed the action, concluding "Case Terminated." (2 ER 191 [Dkt. 21].)

c. Painter appeals the district court's order granting the Motion to Dismiss with prejudice and dismissing the case. The district court's order is final, and this Court has jurisdiction pursuant to 28 U.S.C. § 1291.

d. On June 23, 2017, Painter filed a Notice of Appeal the Order granting the Motion to Dismiss with prejudice and dismissing the case. (2 ER 6-12.) The Notice of Appeal is timely pursuant to 28 U.S.C. § 2107 and Federal Rule of Appellate Procedure 4(a). (Ninth Circuit Dkt. No. 14.)

ISSUES PRESENTED

1. Did the district court err in finding Painter's claims to be expressly

pre-empted based on two cases that considered only pre-emption of *other* statutory provisions and regulations not at issue here and despite the body of case law finding that the statutory authority forming the basis of Painter's claims is not pre-empted?

2. Did the district court err in concluding that Painter's "imitation" food allegations fail as a matter of law to satisfy the reasonable consumer test, despite: (a) the inapplicability of the reasonable consumer test to Painter's UCL claim based on the statute's "unlawful" prong; (b) conflating the at-issue "imitation" food product claims with other, inapposite cases' "standard of identity" claims; (c) misidentifying the harm or deception alleged; and (d) employing reasoning that contradicts Ninth Circuit authority and leads to the conclusion that "imitation" food violations could never satisfy the reasonable consumer test unless the defendant independently violates the separate statutory requirements for accurate back label "nutritional content" information?

3. Did the district court separately abuse its discretion by denying Painter leave to amend her complaint?

4. Should the action be stayed pending the FDA's resolution of this very issue on appeal?

STANDARD OF REVIEW

This Court reviews the order granting a motion to dismiss *de novo*.

Manzarek v. St. Paul Fire & Marine Ins. Co., 519 F.3d 1025, 1030 (9th Cir. 2008) (citing *Outdoor Media Group, Inc. v. City of Beaumont*, 506 F.3d 895, 899 (9th Cir. 2007). Further, "[d]enial of leave to amend is reviewed for an abuse of discretion." *Id*. at 1031 (citing *Gompper v. VISX, Inc*., 298 F.3d 893, 898 (9th Cir. 2002); *see also DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 185 (9th Cir. 1987). "Dismissal without leave to amend is improper unless it is clear, upon de novo review, that the complaint could not be saved by any amendment." *Manzarek*, 519 F.3d at 1031.

On a motion to dismiss, "[a]ll well-pleaded allegations of material fact in the complaint are accepted as true and are construed in the light most favorable to the non-moving party." *Faulkner v. ADT Sec. Servs., Inc*., 706 F.3d 1017, 1019 (9th Cir. 2013) (citations omitted). The complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Id*. (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Facial plausibility, in turn, exists where "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). In a motion brought under Federal Rules of Civil Procedure, Rule 12(b)(6), "the duty of a court is merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." *DiFolco v. MSNBC L.L.C.*, 622 F.3d 104, 113 (2d Cir.

2010) (citations and internal quotations omitted).

COMBINED STATEMENT OF THE CASE AND FACTUAL STATEMENT

I. PAINTER ALLEGES THAT DEFENDANT DECEPTIVELY MARKETS ITS ALMOND BEVERAGES AS NUTRITIONALLY EQUIVALENT OR SUPERIOR TO DAIRY MILK WHEN, IN FACT, ALMOND BEVERAGES ARE NUTRITIONALLY INFERIOR TO DAIRY MILK

This action arises out of Blue Diamond's marketing of the Almond Breeze Almond Milk beverages ("Almond Beverages") that it also manufactures, distributes, and sells. (2 ER 159, ¶1.) Painter alleges in her lawsuit that Defendant leads its customers to believe they are buying—at a premium—a nutritionally equivalent or superior alternative to dairy milk, as defined by the U.S. Food & Drug Administration ("FDA"). (*Id*., ¶2.) In fact, Almond Beverages lack many of the essential nutrients and vitamins dairy milk provides. (*Id*.)

In recent years—in particular, over the last decade—consumer demand for non-dairy milk substitutes has increased exponentially. (2 ER 159-60, ¶3.) The sales of almond-based substitutes for dairy milk in particular have increased approximately 40% between 2013 and 2014 alone. (*Id*.) Over this same period, sales for milk have steadily declined. By calling its Almond Beverages "milk"—a term used to define dairy milk—without specifying that the Almond Beverages are "imitation" milk, Defendant has capitalized on reasonable consumers'

understanding of the health benefits and essential nutrients that dairy milk provides. (2 ER 159-61, ¶¶ 3-6.) But Defendant's Almond Beverages do not provide the same health benefits and essential nutrients of dairy milk. (*Id.*) In fact, Defendant's Almond Beverages contain less of various essential nutrients present in a measurable amount in dairy milk and, therefore, the Almond Beverages are nutritionally inferior to dairy milk as defined by FDA regulation. *See* 21 C.F.R. § 101.3(e). Painter alleged that the Almond Beverages lack various essential vitamins and nutrients, as defined by the FDA, available in measurable amounts in 2% fat dairy milk, as follows:

ESSENTIAL VITAMIN/NUTRIENT	**2% FAT DAIRY MILK**	**ALMOND BREEZE ORIGINAL ALMONDMILK**
Protein	8.05g (16% DRV)	1g
Magnesium	27mg (6.8% RDI)	(4% RDI)
Phosphorus	224mg (22% RDI)	(2% RDI)
Potassium	342mg (9.7% DRV)	170mg (4% DRV)
Zinc	1.17mg (7.8% RDI)	0mg (0% RDI)
Riboflavin	.451mg (26% RDI)	(2% RDI)
Pantothenic Acid	.869mg (8.7% RDI)	.079mg (1% RDI)
Vitamin B6	.093ug (4.7% RDI)	.039mg (2% RDI)
Folate	12ug (3% RDI)	3ug (<1% RDI)

Vitamin D	120iu (30% RDI)	(25% RDI)

(2 ER 160-61, ¶ 4.)

II. PROCEDURAL HISTORY OF THE LAWSUIT

Painter filed a putative class action alleging that Defendant's marketing of Almond Beverages is false, misleading, and deceptive on January 23, 2017 in the Los Angeles Superior Court. (2 ER 112.) She then filed a First Amended Complaint ("FAC") on February 24, 2017. (2 ER 158-84.) She asserts three causes of action under California's Consumer Legal Remedies Act at Civil Code section 1750 ("CLRA"), the Unfair Competition Law at Business & Professions Code section 17200 ("UCL"), and the False Advertising Law at Business & Processions Code section 17500 ("FAL"). (*Id*.)

Painter further asserts in her FAC that Defendant's Almond Beverages are misbranded under the Food Drug & Cosmetic Act (the "FDCA") and the Sherman Food, Drug, and Cosmetic Law (the "Sherman Law"), which expressly incorporates the food labeling requirements set forth in the FDCA and provides that any food is misbranded if its labeling is false or misleading or does not conform to FDCA requirements. *See* Cal. Health & Safety Code §§ 110100(a), 110660-110805. (2 ER 163, ¶ 15.)

On March 22, 2017, Defendant removed this action to the United States

District Court for the Central District of California. (2 ER 96-103.) On March 23, 2017, the case was assigned to District Judge Stephen V. Wilson. (2 ER 190, Dkt. No. 4.)

Defendant filed a motion to dismiss the FAC on April 17, 2017, arguing that: (1) Painter failed to plead facts sufficient to state a cause of action as to each of her three causes of action; (2) Painter failed to plead each cause of action with requisite particularity under Rule 9(b); (3) federal law expressly pre-empts Painter's claims; (4) the primary jurisdiction doctrine bars Painter's claims; and (5) Painter lacks standing. (*See generally*, 2 ER 62-94.) After full briefing, the district court found the matter suitable for determination without oral argument and issued a written order on May 24, 2017. (1 ER 001; 2 ER 13, 33.)

The district court granted Defendant's motion to dismiss on two grounds. (1 ER 1-5.) First, the district court found Painter's claims to be pre-empted by federal law. Second, the district court found that the UCL, FAL, and CLRA claims are all governed by a reasonable consumer standard, and that Painter failed this test because she could not show plausible consumer confusion as a matter of law.

Painter expressly requested leave to amend in the event the district court was inclined to grant any part of the motion to dismiss. (2 ER 43:17-20.) The district court denied leave to amend on the basis that amendment would be futile. (1 ER 5.)

III. PAINTER TIMELY APPEALED THE DISTRICT COURT'S ORDER

On June 23, 2017, Painter timely filed a Notice of Appeal of the district court's May 24, 2017 Order Granting Motion to Dismiss with Prejudice and Dismissing the Case. (2 ER 6-12.) As the Order was issued without a hearing, Painter filed a notice on July 14, 2017 that no reporter's transcript would be filed. (2 ER 192, Dkt. No. 28; Ninth Circuit Dkt. No. 7.) On June 26, 2017, the Court set a deadline of November 30, 2017 for the filing of this Opening Brief. Painter then requested and received a streamlined extension until January 2, 2018 to file this Brief. (Ninth Circuit Dkt. No. 14.)

SUMMARY OF ARGUMENT

The district court dismissed Plaintiff-Appellant Cynthia Cardarelli Painter's action on two independent bases: on the ground that her claims are expressly pre-empted by federal law and on the ground that her UCL, FAL, and CLRA claims cannot satisfy the "reasonable consumer" test as a matter of law. The district court's Order is erroneous on both grounds.

Initially, the district court's entire order was affected by the court's repeated conflation of the claims at issue here and a type of claim that had been addressed in two prior district court cases the court relied on heavily: *Ang v. WhiteWave Foods Co.*, No. 13-CV-1953, 2013 WL 6492353 (N.D. Cal. Dec. 10, 2013) ("*Ang*") and *Gitson v. Trader Joe's Co.*, No. 13-CV-01333-VC, 2015 WL 9121232 (N.D. Cal.

Dec. 1, 2015) ("*Gitson*"). Painter's lawsuit alleges so-called "imitation" food product claims. Under the Food, Drug, & Cosmetic Act ("FDCA") and certain FDA regulations, which are incorporated verbatim into California state law, a food that substitutes for and resembles another food, but is nutritionally inferior to that food, must be labeled an "imitation" food. Defendant-Appellee Blue Diamond's Almond Beverages are, legally, "imitation" milk—they substitute for and resemble dairy milk, but are nutritionally inferior to dairy milk because they contain less of certain essential nutrients, including vitamins and minerals, that are measurably present in dairy milk.

Defendant could either fortify its product to make it nutritionally equivalent or superior to dairy milk, or it could label its product "imitation" milk. By doing neither, Defendant violates various federal statutory provisions and regulations as incorporated verbatim into California state law.

The *Ang* and *Gitson* cases on which the district court relied extensively address a different type of claim—rather than an "imitation food" claim, the orders issued in these two cases address a "standard of identity claim." Other than the superficial similarity that *Ang* and *Gitson* also involve claims about non-dairy milk products, the two types of claims are factually and legally distinct and are premised on violations of different provisions of the FDCA and the FDA regulations.

The concern animating "imitation food" claims is that consumers are

provided a substitute food that is nutritionally inferior to the food it is substituting without warning consumers of its nutritional inferiority. A "standard of identity" claim, in contrast, looks at whether the product's inclusion of a food product term in itself would mislead consumers. In *Ang* and *Gitson*, both "standard of identity" cases, the question was whether their soy products could use the words "milk" or "yogurt" at all. That is not the question here. Painter's case assumes the word "milk" can be used to describe almond milk, but asserts that it contains less of various essential nutrients and thus is nutritionally inferior to dairy milk. Consequently, it must be labeled "imitation" milk unless it is sufficiently fortified.

Indeed, two cases have denied motions to dismiss in other "imitation" food cases involving almond milk products since the district court issued its Order. *Kelley v. WWF Operating Co.*, No. 1:17-CV-117-LJO-BAM, 2017 WL 2445836 (E.D. Cal. June 6, 2017) ("*Kelley*"); *Melissa Cuevas v. Topco Associates, LLC*, No. EDCV 17-0462-DOC (SPx), Dkt. No. 34 (July 18, 2017) ("*Cuevas*"). Both *Kelley* and *Cuevas* confirmed that reliance on *Ang* and *Gitson* is misplaced because the latter two cases involve "standard of identity" claims rather than "imitation" food claims.

In any event, both of the district court's central findings are erroneous. As to the first basis, Painter's "imitation" food claims are not expressly pre-empted. The relevant California law incorporates the relevant federal law verbatim and does not

add any requirements, and therefore the federal law does not pre-empt it. Numerous cases have recognized that the very type of claim asserted in this action is not expressly pre-empted. The district court's reliance on *Ang* and *Gitson* for support to the contrary is misplaced. Also, while the district court did not rule on this basis, Defendant contended below that Painter's requests for relief included various alternatives, one of which Defendant argued is pre-empted. While Painter disagrees, Painter could easily rectify the complaint by deleting that one alternative request for relief and thus eliminating Defendant's argument. If the district court relied on this argument, it was an abuse of discretion to deny Painter's request for leave to amend.

As to the district court's second basis for granting the motion, the district court erred in its application of the reasonable consumer standard to Painter's UCL, FAL, and CLRA claims. Initially, the reasonable consumer test does not apply at all to that portion of Painter's UCL claim that is based on the "unlawful" prong of the statute.

As to the other portions of Painter's UCL claim, as well as her FAL and CLRA claims, the district court's conclusion contradicts the FDA's own express reasons for passing the FDA regulations, which included potential consumer confusion. The district court's conclusion to the contrary is founded again on the inapposite *Ang* and *Gitson* cases, but the court's analysis conflates the at-issue

"imitation" food claims with "standard of identity" food claims, repeatedly stating that no reasonable consumer would be confused by Defendant's use of the word "milk" or would be confused as to whether almond milk is actually dairy milk. But that is only relevant in a "standard of identity" claim. Here, the question is distinct—whether Defendant is providing a type of "milk" that is nutritionally inferior to dairy milk without either labeling it an "imitation milk" or fortifying the product to ensure it provides a sufficient amount of certain essential vitamins and minerals as explicitly defined by the FDA.

The only other reason the district court enunciated for finding Painter's claims to fail the reasonable consumer test as a matter of law is that she does not allege the back-panel nutritional contents information to be inaccurate. But this finding does not support the district court's order for at least four reasons.

First, the district court's conclusion is contrary to established Ninth Circuit authority on disclaimers, holding generally that courts should not look beyond allegedly misleading statements in deciding a motion to dismiss.

Second, the notion that consumers could mitigate any harm in Defendant's violation of the "imitation" front-panel label requirements by looking at the back-panel nutritional contents is incorrect. The harm in an "imitation" food rule case is that the defendant is substituting a nutritionally superior food with a nutritionally inferior food without warning consumers of the substitute's nutritional inferiority.

To determine whether Defendant's products are "nutritionally inferior" as defined by federal law, the consumer would have to not only read the nutritional content label of the Almond Beverages, but would also have to take the information from the nutritional content label of dairy milk and then calculate the percentage differences in various essential vitamins and minerals. This is neither a simple task nor a step reasonable consumers could be expected to take. And at the very least, the district court erred in ruling to the contrary as a matter of law at the pleading stage.

Third, the district court's order ignores the well-understood principle that even a factually true statement can be misleading or deceptive to a reasonable consumer.

Finally, if allowed to stand, the district court's conclusion would mean that all "imitation" food claims would fail as a matter of law so long as the defendant is compliant with separate statutory provisions and regulations governing food product labeling. Such a rule would render § 101.3(e) (regulating "imitation" foods) unenforceable and cannot stand.

Alternatively, if the Court is not inclined to reverse the district court's Order, the matter should be remanded and stayed pending the FDA's resolution of the same issue raised in this appeal. In both *Kelley* and *Cuevas*, the district court stayed substantially similar actions alleging that certain almond beverages are

"imitation" milk and should be labelled as such and referred the question to the FDA.

LEGAL ARGUMENT

I. THE DISTRICT COURT ERRED IN FINDING THAT THE FDCA EXPRESSLY PREEMPTS PAINTER'S CHALLENGE TO DEFENDANT'S LABELING PRACTICES AND ABUSED ITS DISCRETION IN DENYING LEAVE TO AMEND

The district court erroneously held that the Federal Food, Drug, and Cosmetic Act ("FDCA") expressly pre-empts Painter's claims under the UCL, FAL, and CLRA.[1]

A. The Statutory Authority for Painter's Claims

Painter's claims are based primarily on Defendant's violation of FDA regulation 21 C.F.R. § 101.3(e), titled "Identity labeling of food in packaged form." This regulation provides, in relevant part, as follows:

> Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

21 C.F.R. § 101.3(e). The regulation further explains:

> A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is

[1] The district court found express pre-emption only, but not implied/conflict or field pre-emption, neither of which Defendant raised in its Motion to Dismiss.

> nutritionally inferior to that food.

21 C.F.R. § 101.3(e)(1). The regulation then sets forth criteria for determining if a food is nutritionally inferior to another food. "Nutritional inferiority includes… [a]ny reduction in the content of an essential nutrient that is present in a measurable amount," not including a reduction in caloric or fat content that complies with certain other sections not relevant here. 21 C.F.R. § 101.3(e)(4)(i).[2]

This regulation is incorporated verbatim into both California's Sherman Law (Cal. Health & Safety Code § 110100(a)) and the FDCA, 21 U.S.C. § 343(a) (which addresses "Misbranded Food"). The Sherman Law tracks the federal regulation perfectly, which provides that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food labeling regulations of this state." Section 343 provides that "[a] food shall be deemed to be misbranded… [i]f… its labeling is false or misleading in any particular." 21

[2] "For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the Daily Reference Value (DRV) of protein listed under §101.9(c)(7)(iii) and of potassium listed under § 101.9(c)(9) per reference amount customarily consumed and 2 percent or more of the Reference Daily Intake (RDI) of any vitamin or mineral listed under §101.9(c)(8)(iv) per reference amount customarily consumed, except that selenium, molybdenum, chromium, and chloride need not be considered." 21 C.F.R. § 101.3(e)(4)(ii); *see also* Guidance for Industry: A Food Labeling Guide, Food and Drug Administration (Jan. 2013) (citing 21 C.F.R. § 101.3(e) and stating that nutritional inferiority exists when "the new food contains less protein or a less amount of any essential vitamin or mineral.").

U.S.C. § 343(a).

B. Painter's Claims Are Not Pre-Empted

Federal district courts in the Ninth Circuit routinely hold that UCL, FAL, and CLRA claims based on false or misleading labeling under 21 U.S.C. § 343(a) or for failure to follow federal labeling regulations such as 21 C.F.R. § 101.3(e), which are incorporated verbatim into the Sherman Law, are not pre-empted.

For example, in *Chavez v. Blue Sky Natural Beverage Co.*, 268 F.R.D. 365 (N.D. Cal. 2010), the court noted that section 343 "lists provisions of the FDCA that expressly pre-empt state law" and that these "do not include the relevant prohibition on 'false or misleading labeling set forth in 21 USC § 343(a)." *Id*. at 370. The *Chavez* court thus concluded that the "express pre-emption provision of the FDCA contained in section 343-1 therefore does not pre-empt the claims arising from false or misleading labels regulated by section 343(a)." *Id*. *See also Morgan v. Wallaby Yogurt Co., Inc.* 2013 WL 5514563, *6 (N.D. Cal. Oct. 4, 2013) ("Because the Sherman Law does not exceed the requirements of the FDCA, the plaintiff's claims are not expressly pre-empted."); *Clancy v. The Bromley Tea Co.*, 2013 WL 4081632, **8-9 (N.D. Cal. Aug. 9, 2013) ("Courts in this district 'have repeatedly refused to find pre-emption' where 'a requirement imposed by state law effectively parallels or mirrors the relevant sections of the [FDCA].'"); *Swearingen v. Yucatan Foods, L.P.*, 24 F. Supp. 3d 889, 896 (N.D. Cal. 2014)

(finding no pre-emption when the plaintiff "asserted a theory of liability that rested solely on seller's alleged failure to comply with nutritional labeling requirements of FDCA as incorporated into [the Sherman Law], and thus claims would rise or fall on seller's compliance with the FDCA"); *Wilson v. Frito-Lay N. Am., Inc.*, 12-CV-1568 SC, 2013 WL 1320468 (N.D. Cal. Apr. 1, 2013) (state law claims relying on statutes that explicitly incorporate federal law and regulations without modification are not pre-empted); *Brazil v. Dole Food Co., Inc.*, 935 F. Supp. 2d 947, 957-58 (N.D. Cal. Mar. 25, 2013) (finding no pre-emption in food labeling case based on identical Sherman Law and NLEA provisions); *Ivie v. Kraft Foods Global, Inc.*, 12-CV-02554 RMW, 2013 WL 685372, *8 (N.D. Cal. Feb. 25, 2013) (no pre-emption when plaintiff seeks to enforce clear FDA requirements via state law claims).

This is entirely consistent with Ninth Circuit case law that California state law claims under the UCL, FAL, and CLRA involving Sherman Act violations are not pre-empted where the Sherman Law essentially incorporates FDCA requirements. In *Ebner v. Fresh, Inc.*, 838 F.3d 958 (9th Cir. 2016), for example, the Ninth Circuit held that the FDCA did not pre-empt state law claims involving cosmetics labels. "The language in the Sherman Law is virtually identical to the language in the FDCA, which states that a 'cosmetic shall be deemed to be misbranded if its labeling is false or misleading in any particular.'" *Id.* at 965

(citing 21 U.S.C. § 362(a)). The Court explained that "the federal FDCA and California's Sherman Law prohibit the false or misleading labeling of a cosmetic" and that, therefore, the plaintiff was not requesting labeling requirements beyond what federal law already required. *Id*. "Rather, the state-law duty that Plaintiff seeks to enforce under the Sherman Law is identical to Fresh's federal duty under the FDCA." *Id*.

The *Ebner* opinion relies in part on *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753 (9th Cir. 2015), which also held that state law claims were not pre-empted by the FDCA. *Id*. at 759 (concluding that the plaintiff's "state law claims that Hain's products were labeled in a way that was 'false or misleading in any particular' may proceed"). The Court noted that "the FDCA bars states from imposing new or additional labeling 'requirements,' but is silent with regards to states' ability to provide remedies for violations of federal law. In light of this similarity, we have little difficulty concluding that the FDCA does not preempt state laws that allow consumers to sue cosmetics manufacturers that label or package their products in violation of federal standards." *Id*. at 757.

Painter alleges in her complaint, and Defendant admitted below, that Defendant "markets its Almond Beverages as a non-dairy alternative for consumers to purchase in lieu of dairy milk." (2 ER 89:9-10; 2 ER 159, ¶¶ 2-4.) The FAC further alleges that Defendant's marketing campaigns tout its Almond

Beverage products as being a substitute for dairy milk. (2 ER 159, ¶ 2.) Additionally, Painter's complaint sufficiently pleads in detail the nutritional inferiority of Defendant's Almond Beverages—putting her allegations squarely within the ambit of 21 C.F.R. § 101.3(e). (2 ER 160-61, 168-69, ¶¶ 4-5, 33-37.) Accordingly, Defendant's Almond Beverages are misbranded because they substitute for and resemble dairy milk, are nutritionally inferior to dairy milk, but fail to state that they are "imitation milk" on their labels as the FDA requires.[3]

Because Painter's UCL, FAL, and CLRA claims do no more than track the plain language of 21 C.F.R. § 101.3(e), as incorporated by the Sherman Law, they are not expressly pre-empted. Moreover, the express pre-emption provisions of the FDCA contained in 21 U.S.C. § 343-1 do not expressly pre-empt claims that arise, as Painter's do, under § 343(a). Accordingly, Painter's claims are not pre-empted.

C. To the Extent Any Individual Alternative Request for Relief is Pre-Empted, the District Court Abused Its Discretion By Denying Leave to Amend to Remove That One Allegation

Although the district court did not refer to this allegation, Defendant below noted that Painter's requests for relief include various measures stated in the alternative. One of those alternative forms of relief was an order that Defendant refrain from using "milk" in connection with its Almond Beverages, an issue

[3] 21 CFR 101.3(e)(2) and (3) only allow exceptions to this requirement if the substitute food is nutritionally equivalent to the food it substitutes for or resembles, or if the substitute food has an established standard of identity by regulation, neither of which applies to Defendant's Almond Beverages.

Defendant raised in its motion. (2 ER 89:23-25.)

Specifically, Painter alleged that Almond Beverages "cannot be legally manufactured, advertised, distributed, or sold in the United States as they are currently labeled." (2 ER 164, ¶16.) Therefore, Defendant must take any of four alternative steps. (*Id*.) Defendant could revise its labels to include the word "imitation" immediately before the word "milk" (¶16a); Defendant could revise its labels to state the percentages of characterizing ingredients or information regarding the presence or absence of ingredients that are part of the usual name of "milk" (¶16b); Defendant could fortify its Almond Beverages such that they are no longer nutritionally inferior to dairy milk (¶16c); "or" Defendant could stop using the word "milk" (¶16d). In other words, if Defendant is to continue using the word "milk," it must do so in a way that conforms with the law. If it is not willing to modify the label to state "imitation milk," or to specifically set out the nutritional differences between its product and dairy milk, or to change the product so that it is no longer nutritionally inferior to dairy milk, then Defendant may not use the term "milk." 21 C.F.R. 101.3(e).

Defendant argued this fourth alternative request (to stop using the term "milk") rendered her requested relief inconsistent with current FDCA regulations. (2 ER 89:23-25.) While Painter disagrees, this was just one of several alternative proposed requests for relief and, if the district court had found it pre-empted, it

could have struck that one allegation or Painter could have amended her complaint to omit that one allegation. Indeed, Painter specifically requested leave to amend in the event the district court was inclined to grant any part of the motion to dismiss, but the district court concluded amendment would be futile. (2 ER 43:17-21; 1 ER 5.) The district court's conclusion that amendment would be futile confirms that this argument formed no part of the district court's order. Dismissing the entire action without leave to amend to delete or amend that one alternative request would have been an abuse of discretion. *See, e.g., Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009), as amended (Feb. 10, 2009) ("dismiss[ing] the complaint without leave to amend… 'is improper unless it is clear that the complaint could not be saved by any amendment.'") (internal citations omitted).

D. The Authorities on Which the District Court Relied in Finding Pre-Emption Are Inapposite Because They Were "Standard of Identity" Cases, Which Are Based on Different Statutory Requirements and Different Factual Allegations Than the "Imitation Food" Claims at Issue Here

The district court based its pre-emption ruling on two district court cases that were themselves based on so-called "standard of identity" claims, rather than—as here—an imitation product claim. (1 ER 3 [relying on *Ang*, 2013 WL 6492353 and *Gitson*, 2015 WL 9121232].) In both *Ang* and *Gitson*, the courts found the claims to be pre-empted (or implausible, which Painter addresses separately, *infra*).

The district court's reliance on these two non-binding decisions was erroneous because the claims deemed to be pre-empted in *Ang* and *Gitson* differ materially from Painter's claims. Painter's claim is that Defendant's Almond Beverage products are actually, by law, imitation products. While Defendant labels and markets its products as "milk" products, legally they are imitation milk under 21 C.F.R. § 101.3(e) and must be labeled as such. Defendant's Almond Beverages legally qualify as imitation food because they "substitute for and resemble[] another food [milk] but [are] nutritionally inferior to that food." 21 C.F.R. § 101.3(e)(1).

Whether Painter's imitation food claims are pre-empted therefore depends on whether the state "imitation" statutes specifically track the relevant federal law. Because the Sherman Law incorporates verbatim the exact relevant provisions of the FDCA and FDA regulations (21 C.F.R. § 101.3(e) and 21 U.S.C. § 343(a)), the state law claims are not pre-empted. *See supra*, at 16-18; *see also Ebner*, 838 F.3d 958; *Astiana*, 783 F.3d 753; *Morgan*, 2013 WL 5514563, at *6; *Clancy*, 2013 WL 4081632, at **8-9; *Swearingen*, 24 F. Supp. 3d at 896.

Ang and *Gitson* do not affect this analysis, because they are based on other statutory provisions and evaluate whether these other state statutes are pre-empted by federal law. While Painter alleges violation of the imitation food laws, *Ang* and *Gitson* "addressed the issue of whether soy-based products' use of the term 'milk'

or 'yogurt' rendered them mislabeled as violating the 'standard of identity' for milk and yogurt, or whether they appropriately used their 'common and usual name.'" *Kelley*, 2017 WL 2445836, *10 (ruling on a motion to dismiss). Neither "of the[se] cases addressed whether those products are mislabeled because they are 'imitations' under § 101.3(e), like Plaintiff alleges here." *Id*. Indeed, in *Kelley*, the court concluded that it "is confident this is an issue of first impression." *Id*. The district court in *Cuevas* agreed in a ruling on a motion to dismiss or, in the alternative, to stay, concluding: "Ultimately, Defendant's reliance on *Ang* and *Gitson* is misplaced because neither *Gitson* nor *Ang* addressed the issue of whether plant-based products are imitations of cow milk under 21 C.F.R. § 101.3(e)." *Cuevas*, No. EDCV 17-0462, Dkt. No. 34, at *5 (citation omitted) The court then emphasized: "these cases only address the standard identity of 'milk' but did not resolve the issue of whether plant-based products are imitations of milk, and thus are not directly on point." *Id*. at **5-6.

Indeed, *Ang* and *Gitson* do not deal with claims arising under section 343(a) of the FDCA and section 101.3(e) of the FDA regulations (both of which deal with imitation foods), as do Painter's claims. Rather, these two cases deal with claims arising under sections 343(i) and 101.3(b), which set out the statutory requirements for identifying food "by its common or usual name" and for a food's "statement of identity" and 21 C.F.R. § 131.110, which describes "what 'milk' is." *Ang*, 2013

WL 6492353, *3; *Gitson*, 2015 WL 9121232, *2. The district courts in *Ang* and *Gitson* held in relevant part that the plaintiffs' claims in those two cases regarding the identity of milk are pre-empted. But that does not bear on whether Painter's claims—for different violations arising under different statutory authority—are pre-empted.

The district court, in finding Painter's claims to be pre-empted, relied entirely on the analyses of the district courts in *Ang* and *Gitson*, despite the fact that those cases involved different legal claims with different factual allegations based on violations of different statutory provisions. Painter's claims are not pre-empted, and *Ang* and *Gitson* do not support the district court's conclusion to the contrary.

II. THE DISTRICT COURT ERRED BY FINDING THAT PAINTER FAILED TO PLAUSIBLY ALLEGE THAT A REASONABLE CONSUMER IS LIKELY TO BE DECIEVED

A. The District Court Applied an Erroneous Legal Standard as To Painter's Claim for Violation of the UCL's Unlawful Prong

In finding Painter's claims to be implausible, the district court began broadly with the statement that UCL, FAL, and CLRA claims are all governed by the reasonable consumer standard that ultimately requires a showing that members of the public are likely to be deceived. (1 ER 3.) But the reasonable consumer test does not apply to Painter's UCL claim to the extent it is based on "unlawful" business practices.

The UCL forbids unfair competition, which the statute defines through three prongs: it covers actions that are unlawful, or unfair, or deceptive business practices. *See Walker v. Countrywide Home Loans, Inc.*, 98 Cal. App. 4th 1158, 1169 (2002) (the statute's disjunctive definition of "unfair competition has profound ramifications because 'a plaintiff may show that the acts or practices at issue are either unlawful *or* unfair *or* deceptive'"). Each prong of the UCL—unlawful, unfair, and deceptive (or fraudulent)—creates a separate and distinct basis for liability and one act can be alleged to violate any or all of the UCL's prongs. *Lozano v. AT&T Wireless Servs.*, 504 F.3d 718, 731 (9th Cir. 2007); *Planned Parenthood Federation of America, Inc. v. Center for Medical Progress*, 214 F. Supp. 3d 808, 836 (N.D. Cal. 2016); *Cornejo v. Ocwen Laon Servicing, LLC, et al.*, 151 F. Supp. 3d 1102, 1118 (E.D. Cal. 2015) (citing *Lozano*, 504 F.3d 718).

Painter's FAC alleges violations under the UCL as to all three prongs. In addition to alleging that Defendant's actions are unfair and deceptive, Painter also alleges specifically that Defendant's behavior constitutes "unlawful" business practices. (2 ER 178, ¶ 86 ("Defendant's acts, conduct and practices were unlawful, in that they constituted… c. Violations of California's Sherman Law; and d. violations of the Federal Food Drug & Cosmetic Act"); ¶ 87 ("By its conduct, Defendant has engaged in unfair competition and unlawful, unfair, and

fraudulent business practices").

As the Ninth Circuit recently explained, "[t]he UCL's unlawful prong 'borrows' predicate legal violations and treats them as independently actionable under the UCL." *Bruton v. Gerber Prod. Co*., 703 F. App'x 468, 471 (9th Cir. Jul. 17, 2017) (internal citation omitted). The Court explained: The best reading of California precedent is that the reasonable consumer test is a requirement under the UCL's unlawful prong only when it is an element of the predicate violation." *Id*. at 471-72 (citing and comparing *Consumer Advocates v. Echostar Satellite Corp*., 113 Cal. App. 4th 1351, 1354, 1360 (2003) (reasonable consumer test applied to a UCL claim where the predicate violations "both… require[d] meeting the reasonable consumer test") and *Los Angeles Mem'l Coliseum Comm'n v. Insomniac, Inc*., 233 Cal. App. 4th 803, 835 (2015) (not applying a reasonable consumer test "where the predicate violation was of federal tax law")). *See also Swearingen v. Late July Snacks LLC*, No. 13-CV-04324-EMC, 2017 WL 4641896, at *2-3 (N.D. Cal. Oct. 16, 2017) (explaining that "*Bruton* merely reiterates the uncontroversial proposition that 'the reasonable consumer test is a requirement under the UCL's unlawful prong only when it is an element of the predicate violation.'"); *Swearingen v. Yucutan Foods, L.P*., 24 F. Supp. 3d 889, 900 (N.D. Cal. 2014) (reconsidered on other grounds at 59 F. Supp. 3d 961 (May 20, 2014) ("[Defendant] argues plaintiffs fail to state a plausible claim for relief because they

fail to plead deception of the reasonable consumer or liability under the UCL. However, a plaintiff proceeding under the 'unlawful' prong need only plead facts to show it is plausible the defendant broke the law…").

In *Bruton*, the predicate violation alleged was of the Sherman Law, "which itself incorporates standards set by FDA regulations… [which] include no requirement that the public be likely to experience deception." *Id*. at 472. The Ninth Circuit therefore reversed the district court's grant of summary judgment as to the UCL claim based on the statute's unlawful prong. *Id*.

Here, the predicate violations for Painter's UCL "unlawful" prong claim include California's Sherman Law and the FDCA. The key allegation is that Defendant's Almond Beverages violate 21 C.F.R. 101.3(e) because they are required to be, but are not, labeled "imitation" milk. (2 ER 167-68, ¶¶ 32-35.) These regulations do not require any showing of public deception. Thus, Painter's UCL claim based on the "unlawful" prong of the statute should not have been subjected to the reasonable consumer test the district court imposed.

The case law the district court relied on is both inapposite and consistent with this rule. The district court relied indirectly on *Williams v. Gerber Prod. Co*., 552 F.3d 934 (9th Cir. 2008) for the purported rule that a reasonable consumer test governs UCL claims. But *Williams* was not an "unlawful prong" case. Not only is there nothing in the opinion to suggest the plaintiff was moving under the

"unlawful" prong of the UCL, the Ninth Circuit expressly stated that "nothing in Appellants' complaint suggested that they were attempting to directly enforce violations of the FDCA." *Id*. at 937. Whether the defendant's behavior had violated the "unlawful prong" of the UCL was not at issue and the case does not contradict Painter's authority that a reasonable consumer test does not apply here.

The district court erred in imposing a legal standard—the reasonable consumer test—to a claim to which that standard does not apply.

B. The District Court Erred in Finding Painter's Claims Implausible as a Matter of Law

As to Painter's CLRA and FAL claims and those portions of her UCL claim not based on the "unlawful" prong, the district court separately erred by finding Painter's claims implausible as a matter of law.

Initially, whether Painter's claims plausibly allege business practices that may mislead and deceive a reasonable consumer should not have been decided at the pleading stage. Federal courts are generally loath to resolve at the pleading stage whether a label or related advertising is deceptive. *See, e.g.*, *Williams*, 552 F.3d at 938 ("Federal courts 'have recognized that whether a business practice is deceptive will usually be a question of fact not appropriate for a decision on a [motion to dismiss]"). It is thus a "rare situation" where such a determination is appropriate at the pleading stage. *Id*. at 939.

Painter plausibly demonstrated that Defendant's business practices,

specifically, the marketing and labeling of its Almond Beverages, misled and deceived Painter and other reasonable consumers into believing they were buying, at a premium, a dairy-substitute that is nutritionally equivalent or superior to dairy milk. (2 ER 164-65, ¶¶ 19-20.) Painter alleged specific examples of Defendant's misleading and deceptive advertising and labeling, including its insistent nutritional comparison to dairy milk and its products' adequacy as a dairy milk substitute. (2 ER 159-61, 170, ¶¶ 3-4, 41-43.) Painter also alleged that she herself relied on the labeling and packaging of Defendant's Almond Beverages in believing that they contained *more* nutrients than dairy milk and were a suitable substitute. (2 ER 164-65, ¶¶ 17-20.)

In enacting the FDCA and the FDA regulations at § 101.3(e), Congress acted to ensure that the public would receive accurate information about the food products they buy. In speaking to "the regulations concerning 'imitation' food products," it is recognized that "[t]he FDA had two objectives." *Committee for Accurate Labeling and Marketing v. Brownback*, 665 F. Supp. 880, 883 (D. Kansas Jul. 8, 1987). These two objectives were first "to inform the public of the 'actual characteristics and properties of a new food product,'" and second "to encourage manufacturers to fortify their substitute food products to the level of nutritional equivalence." *Id*. It has also been recognized that "[t]he consumer, however, must be protected from unwitting purchase of a product which is different from what he

may reasonably expect. … This new regulation… will make certain that no food is labeled in a false or misleading way and thus fully implements the mandate given by Congress. *Imitation Foods*, 38 Fed. Reg. 2138 (Jan. 19, 1973).

The FDA clearly recognized the inherent deception involved when manufacturing a substitute food and failing to either fortify it with equal nutrients or label it as an imitation of a standardized food. It cannot reasonably be disputed that the FDA, in enacting 21 C.F.R. § 101.3(e), was concerned about consumer confusion when a nutritionally superior food product is substituted with a nutritionally inferior one without being fortified. Painter plausibly alleged deception under the reasonable consumer standard. The district court thus should have denied Defendant's motion to dismiss.

The district court's conclusion to the contrary was based on the findings in *Ang* and *Gitson*—which, as explained above, involve different claims and allegations—and those cases' conclusions that using the term "milk" at all on the label will not confuse consumers as to whether they actually are buying dairy milk. Indeed, as the district court acknowledged, the question in those cases was whether it was plausible "that the use of the word 'soymilk' misleads any consumer into believing the product comes from a cow." (1 ER 4, citing *Gitson* at *2.) And that is the question in a "standard of identity" case—whether the use of the word "milk" would confuse a reasonable consumer as to whether the product is in fact

dairy milk.

But that is not the question here, in an "imitation" food case. The question here is not whether Defendant can use the word "milk" at all, but whether Defendant violated other statutory provisions and regulations requiring that a milk substitute either be fortified to be as nutritious as dairy milk or be labeled an imitation product. By producing a product that is nutritionally inferior to dairy milk but failing to label it an "imitation" product, Defendant's product risks confusing the reasonable consumer **not** as to whether the product is actually dairy milk (as in a standard of identity case), but as to whether its product is as nutritious as dairy milk.

To the extent the district court at all addressed the relevant question—whether a reasonable consumer could be deceived as to whether the Almond Beverages are as nutritious as dairy milk—the court's conclusion cannot stand. The court held that the labeling cannot be deceptive because the nutritional information on the packaging is true. This conclusion, unexplained by any analysis, must be reversed for at least four reasons.

First, a court generally should not look beyond the allegedly misleading statement in deciding a motion to dismiss. *Williams*, 552 F.3d at 938 ("We disagree with the district court that reasonable consumers should be expected to look beyond misleading representations on the front of the box to discover the truth

from the ingredient list in small print on the side of the box.") "*Williams* stands for the proposition that where product packaging contains an affirmative misrepresentation, the manufacturer cannot rely on the small-print nutritional label to contradict and cure that misrepresentation." *Yumui v. Smart Balance, Inc.*, 733 F. Supp. 2d 1117, 1129 (C.D. Cal. 2010). "This binding authority therefore strongly suggests that courts cannot hold as a matter of law that disclaimers vitiate claims for misleading representations." *Mullins v. Premier Nutrition Corp.*, 178 F. Supp. 3d 867, 892 (N.D. Cal. 2016). Thus, the district court's reliance on the nutritional label contradicts binding Ninth Circuit authority.

Second, the district court's conclusion that a consumer can simply look at the nutritional content label to discern the nutritional content of Defendant's products is misplaced and addresses a problem that does not form part of Painter's lawsuit. The problem is not that the nutritional content is inaccurate—if it were, Painter would have sued under the statutes governing such information—rather, the problem is that consumers are not warned that Defendant's product is merely an "imitation" milk rather than a true, nutritionally-equal or -superior substitute for it. Looking at the nutritional contents on Defendant's products does not provide a comparison to dairy milk (as the word "imitation" would). In order to discern whether the Almond Beverages are nutritionally equivalent to dairy milk (through, for example, fortification with various vitamins and minerals), the consumer would

have to compare the content labels of Defendant's products and of dairy milk and then do the various calculations relevant to various types of nutrients to determine the percentage of difference between them. This is not reasonable.

Third, the fact that the separate nutritional facts label, whose content is governed by different FDA regulations, is not alleged to contain inaccurate statements does not preclude a claim under the FAL, UCL or CLRA. "The California Supreme Court has recognized 'that these laws prohibit 'not only advertising which is false, but also advertising which [,] although true, is either actually misleading or which has a capacity, likelihood or tendency to deceive or confuse the public.'" *Williams*, 552 F. 3d at 938. As such, "[a] perfectly true statement couched in such a manner that it is likely to mislead or deceive the consumer, such as by failure to disclose other relevant information, is actionable under the UCL[,]" FAL, and CLRA. *Id.* at 1255; *In re Ferrero Litigation,* 794 F. Supp. 2d 1107, 1115 (S.D. Cal. June 30, 2011) ("A statement may be deceptive and actionable under the UCL, FAL, and CLRA even though it is truthful.") Moreover, compliance with one FDA labeling regulation cannot impute compliance (or shield a defendant from noncompliance) with *all* FDA labeling regulations when assessing whether a label is deceptive. If that were the law, effectively no claims brought for violations of front-panel labeling requirements—as here—could succeed, so long as the nutritional facts panel (containing

information that is rarely verifiable at the pleading stage) is allegedly accurate.

Finally, under the district court's conclusion, no "imitation" product claim could ever meet the reasonable consumer standard unless the defendant also violates separate regulations that require nutritional information to include certain other facts (that is, other than whether the product is an "imitation") and to set them forth accurately.[4] But one of the very reasons animating the passage of the "imitation" statutory provisions and regulations in the first place was Congress's recognition of the potential for consumers to be misled when new, substitute products are developed that are nutritionally inferior to the existing products they substitute without warning consumers of that inferiority.

The district court failed to identify the actual harm and deception that reasonably may occur, failed to discern how to cure that harm or deception, and relied on case law addressing other types of harm based on violations of other statutory provisions. The district court erred in finding that the reasonable consumer test cannot be met as a matter of law.

[4] *See, e.g.*, 21 C.F.R. § 101.1 (principal display panel requirements); § 101.2 (information panel requirements); § 101.4 (ingredient designation requirements); § 101.5 (manufacturer information requirements); § 101.7 (declaration of net quantity requirements); § 101.9 (nutrition labeling); § 101.13 (nutrient content claims requirements); § 101.14 (health claims requirements); § 101.17 (warning, notice, and safe handling statements requirements)

III. IN THE ALTERNATIVE, THE MATTER SHOULD BE REMANDED TO THE DISTRICT COURT WITH INSTRUCTIONS TO STAY A RULING ON THE MOTION TO DISMISS PENDING THE FDA'S RESOLUTION OF THIS VERY ISSUE

In the less than two months following the district court's order below, two other courts declined to reach the merits of motions to dismiss in substantially similar cases pending the FDA's resolution of the issue—specifically, whether almond milk products must be labeled "imitation" under § 101.3(e). *See Kelley* 2017 WL 2445836; *see also Cuevas*, No. EDCV 17-0462, Dkt. No. 34.

As here, the plaintiff in *Kelley* alleged that the defendant's "Almondmilk products are 'misbranded under 21 C.F.R. § 101.3(e)." *Kelley*, 2017 WL 2445836, *2. As here, the *Kelley* plaintiff's core allegations were that the Almondmilk products "substitute for and resemble dairy milk, are nutritionally inferior to dairy milk, and fail to state 'imitation milk' on their labels as required." *Id*. In ruling on the defendant's motion to dismiss, the district court distinguished *Gitson* and *Ang* by noting that those cases addressed a different issue. Those cases looked at whether "soy-based products' use of the term 'milk' or 'yogurt' rendered them mislabeled as violating the 'standard of identity' for milk and yogurt, or whether they appropriately used their 'common and usual name.'" *Id*. But none of the cases addressed the issue in *Kelley*—and, indeed, here—specifically, "whether those products are mislabeled because they are 'imitations' under § 101.3(e)." *Id*.

The district court in *Kelley* also noted that "it appears the FDA is currently

considering whether to opine on a dispositive issue in this case." *Kelley*, 2017 WL 2445836, *10. In December 2016, members of Congress "explicitly ask[ed] the FDA to provide guidance on the issue." *Id*.

The district court in *Kelley* thus held: "this case is REFERRED to the FDA and STAYED pending a determination from the FDA on whether Defendant's products must be labeled 'imitation' under § 101.3(e), or when it appears the FDA does not intend to address the matter." *Kelley*, 2017 WL 2445836, *11-12. "The Court therefore need not address Defendant's multiple alternative arguments." *Id*., *11.

Shortly after the district court in *Kelley* referred the issue to the FDA, the district court in *Cuevas* decided a motion to dismiss or, in the alternative, to stay in a substantially similar lawsuit. As here and as in *Kelley*, the plaintiff in *Cuevas* alleged that the defendant "fails to accurately label Almondmilk beverages as 'imitation milk' as required by the [FDA, which] requires substitute products to be labeled as 'imitation' if there is any reduction of essential nutrients in a measurable amount from the product it is a substitute for." *Cuevas*, No. EDCV 17-0462, Dkt. No. 34, at *2. Like Defendant here and like the defendant in *Kelley*, the defendant in *Cuevas* relied on *Ang* and *Gitson*, which the district court found "misplaced because neither … addressed the issue of whether plant-based products are imitations of cow milk under 21 C.F.R. § 101.3(e). [] Indeed, there is no

controlling case on this issue and the FDA has not made any determination on this matter." *Id*. at p. 5.

The district court in *Cuevas* expressly agreed with *Kelley*'s conclusion that "whether Almondmilk should be deemed 'imitation' milk under § 101.3(e) 'involve[s] technical questions of fact uniquely within the expertise and experience of agency." *Cuevas*, No. EDCV 17-0462, Dkt. No. 34, at * 8 (citing *Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290, 314 (1976). "Because the FDA has not officially considered this issue and the Court's ruling can impair the uniformity of the FDA's regulation of food labels, the Court finds it would serve the interest of justice to stay this case pending the FDA's resolution of the *Kelley* referral." *Id*.

The district court therefore stayed the case "pending the FDA's resolution of the *Kelley* referral." *Cuevas*, No. EDCV 17-0462, Dkt. No. 34, at *3

Thus, if the Court is not inclined to reverse the district court order on its merits, Painter respectfully requests that the Court reverse and remand for further proceedings consistent with the FDA's resolution of the question whether almond milk should be labeled "imitation."

CONCLUSION

For these reasons, Appellant respectfully requests that the Court reverse the district court's order dismissing the FAC without leave to amend.

Dated: January 2, 2018

Respectfully submitted,

Capstone Law APC

By: / S / Glenn A. Danas
Glenn A. Danas
Bevin Pike
Katherine W. Kehr

Attorneys for Plaintiff-Appellant
Cynthia Cardarelli Painter

CERTIFICATE OF RELATED CASES

No other cases in this Court are deemed related to this case pursuant to Circuit Rule 28-2.6.

Dated: January 2, 2018

Respectfully submitted,

Capstone Law APC

By: / S / Glenn A. Danas
Glenn A. Danas
Bevin Pike
Katherine W. Kehr

Attorneys for Plaintiff-Appellant
Cynthia Cardarelli Painter

Form 8. Certificate of Compliance Pursuant to 9th Circuit Rules 28.1-1(f), 29-2(c)(2) and (3), 32-1, 32-2 or 32-4 for Case Number 17-55901

Note: This form must be signed by the attorney or unrepresented litigant *and attached to the end of the brief.*

I certify that (*check appropriate option*):

☐ This brief complies with the length limits permitted by Ninth Circuit Rule 28.1-1.
The brief is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

☒ This brief complies with the length limits permitted by Ninth Circuit Rule 32-1.
The brief is [8,751] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

☐ This brief complies with the length limits permitted by Ninth Circuit Rule 32-2(b).
The brief is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable, and is filed by (1) ☐ separately represented parties; (2) ☐ a party or parties filing a single brief in response to multiple briefs; or (3) ☐ a party or parties filing a single brief in response to a longer joint brief filed under Rule 32-2(b). The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

☐ This brief complies with the longer length limit authorized by court order dated [ ]
The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6). The brief is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable.

☐ This brief is accompanied by a motion for leave to file a longer brief pursuant to Ninth Circuit Rule 32-2 (a) and is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32 (f), if applicable. The brief's type size and type face comply with Fed. R .App. P. 32(a)(5) and (6).

☐ This brief is accompanied by a motion for leave to file a longer brief pursuant to Ninth Circuit Rule 29-2 (c)(2) or (3) and is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

☐ This brief complies with the length limits set forth at Ninth Circuit Rule 32-4.
The brief is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

Signature of Attorney or Unrepresented Litigant [/ S / Glenn A. Danas] Date [January 2, 2018]

("s/" plus typed name is acceptable for electronically-filed documents)

9th Circuit Case Number(s) 17-55901

NOTE: To secure your input, you should print the filled-in form to PDF (File > Print > *PDF Printer/Creator*).

****

CERTIFICATE OF SERVICE
When All Case Participants are Registered for the Appellate CM/ECF System

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on (date) January 2, 2018 .

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Signature (use "s/" format) / S / Patti A. Diroff

****

CERTIFICATE OF SERVICE
When Not All Case Participants are Registered for the Appellate CM/ECF System

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on (date) .

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

I further certify that some of the participants in the case are not registered CM/ECF users. I have mailed the foregoing document by First-Class Mail, postage prepaid, or have dispatched it to a third party commercial carrier for delivery within 3 calendar days to the following non-CM/ECF participants:

Signature (use "s/" format)