

**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-Blue Diamond.

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 REPLY BRIEF

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I. INTRODUCTION

To decide whether Appellant Cynthia Painter’s complaint states a viable cause of action, the Court need not resolve whether Appellee Blue Diamond Growers’ (“Blue Diamond”) “almondmilk”¹ beverage is an imitation of dairy milk, whether it is a distinct product, or any other substantive issues as to whether the product is misbranded under section 403(c) of the Food, Drug, and Cosmetic Act (FDCA).² Instead, this Court need only determine whether the complaint states a “plausible” cause of action against Blue Diamond for failing to identify their almond beverage as “imitation” milk and, if so, whether the state law consumer claims based off that violation are preempted.

Painter has sufficiently pled that Blue Diamond’s “almondmilk” beverage is misbranded under the definition of “imitation” provided by the Food and Drug Administration (FDA) at 21 C.F.R. § 101.3(e)(1) because it “substitutes for and resembles” milk, which is a standardized food, and is “nutritionally inferior” to milk. Thus, the question becomes whether the claim is “plausible.” Blue Diamond argues that “no reasonable consumer can plausibly claim to be confused or misled about the nature of the product.” (Ans. Br., at 19.) However, members of both the

¹ “Almondmilk” is how Blue Diamond brands their almond beverage, however, the protologism “almondmilk” is not an actual English word.

² 21 U.S.C. §§ 301-399.

U.S. Senate³ and the U.S. House of Representatives⁴ agree that plant-based “milk” products mislead consumers. Indeed, Painter’s claims are not only plausible but are also issues of national concern.

There is no question that a misbranding violation of the FDCA can form the basis for a state law consumer claim 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 & Professions Code section 17500 (“FAL”). The only argument advanced by Blue Diamond regarding preemption is that two of the four prayers for injunctive relief, which are pled in the alternative, are preempted. (Ans. Br., at 42.) However, even if those two forms of injunctive relief are preempted, that still leaves two forms of injunctive relief from Painter’s operative complaint that are not preempted: the request that Blue Diamond be ordered to identify their product as an “imitation” of milk on the label and the request that Blue Diamond fortify

³ On January 12, 2017, Senator Tammy Baldwin of Wisconsin introduced the Defending Against Imitations and Replacements of Yogurt, Milk, and Cheese To Promote Regular Intake of Dairy Everyday Act (DAIRY PRIDE Act), with the stated purpose of “enforcement against misbranded milk alternatives.” S.130, 115th Cong. (2017).

⁴ See *Kelley v. WWF Operating Company*, No. 1:17-CV-117-LJO-BAM, 2017 WL 2445836, at *5 (E.D. Cal., June 6, 2017) (*citing* Los Angeles Times, Stop calling almond, soy and rice milks ‘milk,’ 25 members of Congress say, <http://www.latimes.com/business/la-fi-almond-milk-soy-milk-20161223-story.html>.)

their product so that it is no longer “nutritionally inferior” to dairy milk. To the extent that the other two requests are preempted, they can easily be stricken from the complaint or Painter could be given leave to amend. Preemption is not a valid ground for dismissal of Painter’s complaint.

Blue Diamond attempts to confuse the issues by requesting this Court find that “the imitation labeling requirement simply does not apply to Blue Diamond’s product” because “Blue Diamond makes real almondmilk, not imitation dairy milk.” (Ans. Br., at 49.) By advancing this argument, Blue Diamond is prematurely asking for a resolution on the merits that is not proper at the pleading stage.

Proposed amicus curiae Good Food Institute (GFI) seeks the same determination. However, there is not yet an adequate evidentiary record to make these rulings and their arguments should be rejected in this appeal as undeveloped.

Because the district court erred by dismissing Painter’s complaint with prejudice, this Court should reverse the district court’s ruling and remand the action. Painter respectfully requests that this Court instruct the district court to stay the action pending the determination of whether almond milk is an imitation of dairy milk, an issue which is pending before the FDA by request from Congress, the proposed amicus the Good Food Institute, the dairy industry, the almond industry, and the parties to this action.

II. LEGAL ARGUMENT

A. Painter's Complaint States a Plausible Claim that Blue Diamond's "Almondmilk" is an "Imitation" of Dairy Milk Under the FDCA

Pursuant to Rule 12(b)(6), a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 570 (2007). A claim has "facial plausibility" if the plaintiff pleads facts that "allow [] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556). The Supreme Court has set forth a two-step process for determining whether a complaint states a cause of action sufficient to overcome a motion to dismiss under Rule 12(b). First, the court must accept all factual contentions as true but may ignore legal conclusions and threadbare recitals of the elements of a cause of action. *Iqbal*, *supra*, at 678. Second, the court must draw upon its "judicial experience and common sense" in determining whether a claim is plausible on its face. *Id.*

The FDA defines a food as an "imitation" if it "is a substitute for and resembles another food but is nutritionally inferior to that food." 21 C.F.R. § 101.3(e)(1). Therefore, there are three elements to an "imitation" claim: (1)

substitution, (2) resemblance, and (3) nutritional inferiority. In order for one food to be an imitation of another food, all three elements must be present. *See United States v. 651 Cases ... of Chil-Zert*, 114 F. Supp. 430, 432 (N.D.N.Y. 1953) (“*Chil-Zert*”). Whether Blue Diamond’s “almondmilk” is an imitation of dairy milk is a question of first impression. *Kelley v. WWF Operating Company*, No. 1:17-CV-117-LJO-BAM 2017 WL 2445836, at *6 (E.D. Cal., June 6, 2017). It is also a question of fact. *Id.*, at *5, fn. 4. “It is plain that no all-inclusive test of imitation can be prescribed” *Chil-Zert, supra*, at 432.

1. The Complaint Adequately Alleges That Blue Diamond’s “Almondmilk” is Used as “A Substitute For” Dairy Milk

Painter’s complaint alleges that consumers purchase “Blue Diamond Almond Beverages to substitute dairy milk.” (2 ER 116 ¶8.) Painter recognizes that whether Blue Diamond’s “almondmilk” beverage qualifies as “a substitute for” milk under the FDA’s definition of “imitation” is a legal conclusion that need not be accepted as true at the pleading stage. However, the allegation that Painter and other consumers actually purchased Blue Diamond’s “almondmilk” as a substitute for dairy milk is a factual statement that must be taken as true and construed in the light most favorable to her position. *Madison v. Graham*, 316 F.3d 867, 869 (9th Cir. 2002) (“Because this case was dismissed for failure to state a claim, all allegations of material fact in the complaint are taken as true and construed in the light most favorable to the appellants.”). When viewed in the light most favorable

to Painter, there is “more than a sheer possibility” that Blue Diamond’s “almondmilk” qualifies as a substitute for dairy milk.⁵

Blue Diamond attempts to establish as a matter of law that its “almondmilk” beverage is not a substitute for dairy milk by citing prior case law involving other products, by relying on comments from the Commissioner of Food and Drug (Commissioner) found in the Federal Register, by relying on dictionary definitions, and by adding a “consumer expectation” element to the FDA’s definition of “imitation.” Notwithstanding these arguments, it remains a question of fact as to whether Blue Diamond’s “almondmilk” beverage “substitutes” for dairy milk, and the issue cannot be resolved without an evidentiary record. Thus, none of Blue Diamond’s arguments support the dismissal of Painter’s complaint as a matter of law.

First, Blue Diamond examines how “courts have traditionally grappled with the word ‘imitation’ in the context of food” to determine what kind of foods generally qualify as a substitute. (Ans. Br., at 24.) In so doing, Blue Diamond concludes that foods qualify as a “substitute” when they “remove and replace” a natural ingredient with a cheaper, less nutritious ingredient. *Id.* From there, Blue Diamond argues that there are no allegations that “Blue Diamond’s almondmilk

⁵ Notably, JEC Consulting and Trading, Inc. filed a trademark application for “almondmilk” stating the term referred to an “almond-based food beverage as a milk *substitute*.” ALMONDMILK, U.S. Trademark Application Serial No. 85551704 (filed Feb. 24, 2012, abandoned Dec. 12, 2012) (emphasis added).

contains or is derived from any milk or dairy products.” (Ans. Br., at 26.) This is true; Painter has never contended that Blue Diamond’s “almondmilk” beverage is derived from dairy. Nor does it need to be to support Painter’s claims. The fact that the almond beverage is not derived from dairy does not excuse Blue Diamond from complying with the “imitation” provision of the FDCA. Had Congress wished for section 403(c) to apply only to food derivatives, Congress would have used the word “derivative” in the definition. *United States v. 62 Cases ... of Jam*, 340 U.S. 593, 601 (1951) (“*Jam*”). No such language was promulgated and no such requirement exists. Therefore, the fact that Blue Diamond’s “almondmilk” is not derivative of dairy milk is immaterial and certainly not dispositive.

Along the same lines, Blue Diamond argues that the Commissioner’s approval of the “opinions in the *Jam* and *Chil-Zert* cases” sets the standard for when a food qualifies as a substitute under the FDA’s “imitation” definition. (Ans. Br., at 26.) However, the Commissioner approved of these decisions because they “discussed factors of resemblance, substitution, and inferiority in concluding that the products involved were imitations.” *Imitation Foods; Application of the Term “Imitation,”* 38 Fed. Reg. 20702 (Aug. 2, 1973). Moreover, the Commissioner rejected the idea of adopting “objective standards” for substitution (and resemblance). *Id.* (“Other factors of comparison, such as taste, texture, origin and costs, are too subjective and uncertain to be appropriate for inclusion in this

regulation.”). Indeed, the *Chil-Zert* court found that “imitation is initially a question of fact” and “that no all-inclusive test of imitation can be prescribed.” *Chil-Zert, supra*, 114 F. Supp. at 432. Accordingly, neither the Commissioner’s comments nor the cases cited support applying an objective test to resolve whether a food is a “substitute for” another food on a motion to dismiss.

Blue Diamond also relies on the dictionary definition of “alternative” to classify its “almondmilk” beverage as an “alternative to” instead of a “substitute for” dairy milk, thus removing it from the FDA’s definition of an “imitation” food. (Ans. Br., at 27-28.) In advancing this argument, Blue Diamond relies only on the dictionary and provides no authority that if a product is an “alternative” then it cannot be “substitute” under the FDA’s definition.

Relying only on the dictionary, the terms “alternative” and “substitute” are synonymous and not mutually exclusive. Blue Diamond’s “almondmilk” beverage qualifies as *both* a “substitute” and an “alternative” to dairy milk. Under Blue Diamond’s dictionary definition of “substitute,” *i.e.* “one that takes the place of another,” any beverage that is put on cereal or consumed with cookies, *inter alia*, is a substitute for milk. The same circular analysis is true with Blue Diamond’s definition of “alternative,” *i.e.* “the choice between two mutually exclusive possibilities.” (Ans. Br., p. 28.) Take “imitationjam” as an example. *62 Cases ... Jam, supra*, 340 U.S. at 596. Under Blue Diamond’s dictionary definition,

imitationjam qualifies as an “alternative” for jam (you can either put jam or imitationjam on your toast). However, the Supreme Court found imitationjam was an “imitation” under the FDCA. *Id.* The main problem with Blue Diamond’s dictionary argument is that qualifying as an “alternative” based upon a dictionary definition alone does not foreclose being an “imitation.” *See generally id.* (“It was both within the right and the wisdom of Congress not to trust to the colloquial or the dictionary meaning of misbranding, but to write its own.”) Accordingly, Blue Diamond’s dictionary definitions do not support the dismissal of Painter’s claims.

Finally, Blue Diamond argues that “a product is only a ‘substitute’ if there is some risk that a reasonable consumer will mistake it for the genuine article, which Painter has not demonstrated.” (Ans. Br., at 36.) Painter agrees that the section 403(c) “constitutes a valuable consumer protection measure by protecting against nutritionally inferior substitute foods.” *Imitation Foods; Application of the Term “Imitation,”* 38 Fed. Reg. 20702 (Aug. 2, 1973). However, Painter disagrees that consumer expectation is an element of section 403(c) of the FDCA. Regardless, even if consumer expectation were a requirement, Painter’s complaint sufficiently alleged that consumers rely upon and are misled by calling its almond beverage “milk.” (2 ER 162 ¶8). Considering there is a pending Senate Bill that specifically finds that “[p]lant-based products labeled as milk are misleading to consumers,” there is more than a “sheer possibility” that consumers are misled. S.130, 115th

Cong. (2017). Therefore, the district court should not have found that no reasonable consumer would be misled if he or she decided to substitute dairy milk with Blue Diamond's "almondmilk" beverage, as a matter of law on a motion to dismiss.

Blue Diamond fails to establish that it is entirely implausible that its "almondmilk" beverage qualifies as a substitute for dairy milk as a matter of law, and the complaint adequately pleaded the "substitute for" requirement of the FDA's "imitation" definition.

2. Blue Diamond Does Not Provide Sufficient Facts or Argument to Conclude at the Pleading Stage That Its "Almondmilk" Does Not Resemble Dairy Milk

Blue Diamond does not dispute that its "almondmilk" resembles dairy milk and, at one point, even concedes that "they 'resemble' each other" in making a counter-point about dairy milk being an imitation of their "almondmilk." (Ans. Br., p. 41.) Blue Diamond did not dispute the two products' resemblance in its underlining motion to dismiss. (*See* 2 ER 62.) Moreover, there are no facts before this Court to make a determination on the merits as to whether Blue Diamond's "almondmilk" beverage resembles dairy milk.

The only argument regarding "resemblance" is raised by GFI in their proposed amicus curiae brief. (GFI Br., at 16-17, ECF No. 25-2.) GFI groups the "substitute for and resembles" requirements together, noting that "the first two

elements are susceptible to varying interpretations; they may be read broadly or narrowly.” (*Id.*, at 16). GFI acknowledges that under a broad interpretation, “almond milk” resembles “cow’s milk because both are white liquids that can be poured over breakfast cereal.” (*Id.*, at 17). Thus, GFI indirectly admits there is more than a “sheer possibly” that Blue Diamond’s “almondmilk” beverage resembles dairy milk.

In determining whether one product resembles another, it must be remembered that “[i]mitation is a question of fact not tested by appearance alone but by many factors such as taste, smell, texture, consistency, melting points and use.” *Aeration Processes, Inc. v. Jacobsen*, 184 Cal.App. 2d 836, 841 (1960). “The test is not the presence or absence of any one element of similarity but the composite effect of all of them.” *Id.* (citing *Chil-Zert, supra*, at 432). As GFI points out, the Commissioner suggested an “evaluation of the overall impression conveyed by the food” is necessary to determine whether the “food is a substitute for and resembles another food.” (GFI Br., at 26.)

Indeed, GFI provides a litany of organoleptic, chemical, and physical qualities that courts have examined while evaluating whether a food is an “imitation” of another food, including *Chil-Zert, supra* (Chil-Zert compared to ice cream in taste, appearance, color, body and melting qualities), *Aeration Processes, supra* (Instawhip Topping compared to whipped cream in consistency, color and

flavor), *Coffee-Rich, Inc. v. Kansas State Bd. of Health*, 388 P.2d 582, 587 (Kan. 1964)(Coffee-Rich compared to dairy creamer in color and flavor), *Midget Prod., Inc. v. Jacobsen*, 140 Cal.App. 2d 517, 522 (1956) (Mel-O-Dee Whip compared to whipped cream in color and heat tolerance), and *Baltimore Butterine Co. v. Talmadge*, 32 F.2d 904 (S.D. Ga. 1929) (Nutie compared to butter in melting point and taste). (*Id.*, at 19-20, 24-25). All of the cases cited by GFI support the proposition that evidence regarding the products themselves is needed to make the determination of whether a food is an “imitation” of another food. *See, e.g. Baltimore Butterine, supra*, at 909 (“The samples produced to the court (who is not an expert on food) were similar in appearance to much butter he has seen, though quite different in appearance from much other butter he has seen.”).

Although it is not suggested that the court needs to perform an actual taste test like the court in *Baltimore Butterine* conducted, there still has to be evidence in the record regarding the physical and chemical properties to determine whether the substitute food resembles the original food. Here, the record is bare because this case was dismissed at the pleading stage. Thus, it cannot be determined that Blue Diamond’s “almondmilk” beverage does not resemble dairy milk. Instead, because it is entirely “plausible” that Blue Diamond’s “almondmilk” beverage resembles dairy milk, the case must proceed so the parties can engage in discovery on this important issue.

3. It is Undisputed That Blue Diamond’s “Almondmilk” is Nutritionally Inferior to Dairy Milk in Several Categories

Finally, and perhaps most importantly, the substitute food must be “nutritionally inferior” to the original food. 21 C.F.R. § 101.3(e)(1). The complaint alleges that Blue Diamond’s “almondmilk” beverage is nutritionally inferior to dairy milk in several categories, including protein, Vitamin D, Vitamin B6, Magnesium, Phosphorus, Potassium, Zinc, *etc.* (2 ER 114-15.) This is undisputed.

However, Blue Diamond argues that its “almondmilk” product is nutritionally superior in other categories and therefore dairy milk should be labeled “imitation almondmilk.” (Ans. Br. 21.) This, of course, ignores the fact that “milk” is a standardized food with a statement of identity defined by the FDA whereas “almondmilk” beverage is not. 21 C.F.R. § 131.110. This also ignores that a substitute food is nutritionally inferior if there is “[a]ny reduction in the content of an essential nutrient that is present in a measurable amount...” 21 C.F.R. § 101.3(e)(4)(i). By definition, “nutritional inferiority” looks at what nutrients are in the original product and whether the substitute product has less, not vice versa. Blue Diamond’s claim that its almond beverage is superior in other nutritional categories is not applicable.

As advanced by the proposed DAIRY PRIDE Act, “[t]he Dietary Guidelines state that dairy foods are excellent sources of critical nutrients for human health, including vitamin D, calcium, and potassium, all of which are under consumed by

people of the United States.” S.130, 115th Cong. (2017). The only nutritional category where Blue Diamond’s “almondmilk” beverage meets the expectation of dairy milk is in calcium.⁶ Thus, per the FDA’s definition, Blue Diamond’s “almondmilk” beverage is nutritionally inferior to milk.

Since Painter pled sufficient facts to support a finding that Blue Growers’ “almondmilk” beverage lacks essential vitamins and minerals that normally occur in dairy milk, nothing else is required at this stage of the pleadings. The requirement that the “imitation” food be nutritionally inferior is met.

4. Painter’s Complaint Adequately Alleges a Plausible Claim That Blue Diamond Misbranded its “Almondmilk” By Not Complying with Section 403(c) of the FDCA

“Misbranding was one of the chief evils Congress sought to stop.” *Jam, supra*, 340 U.S. at 596. As explained above, Painter contends that whether Blue Diamond’s “almondmilk” is misbranded because it is an “imitation” of dairy milk is a question of fact that cannot be decided without an adequate evidentiary record. Since sufficient facts were pled to find that Blue Diamond’s “almondmilk” beverage resembles milk, acts as a substitute of milk, and is nutritionally inferior to milk, there are sufficient facts pled to allege that Blue Diamond’s “almondmilk” is misbranded under section 403(c) of the FDCA. Accordingly, the claim survives the

⁶ However, the calcium found in Blue Diamond’s almond beverage is calcium carbonate, an artificially added dietary supplement, the benefits of which are debatable. *See* United States Department of Agriculture Branded Food Products Database, <https://ndb.nal.usda.gov/ndb/foods/show/167142> (April 23, 2018).

threshold requirements to overcome a motion to dismiss.

B. The Consumer Causes of Action under California Law Based on the FDCA Misbranding Violation Are Not Preempted

There is no dispute that misbranding a food is a crime under sections 301(a) and 303(a) of the FDCA [21 U.S.C. §§ 331(a), 333(a)] and serves as a predicate violation of the California consumer laws as alleged in the complaint. (Ans. Br., at 35; *see also* GFI Br., at 14.) Blue Diamond also concedes that “Painter’s demands are not preempted to the extent it tracks exactly with the requirements of Section 101.3.” (Ans. Br., at 44; *see also* GFI Br., at 13.) Indeed, the main issue in this case is not preemption; it is whether Blue Diamond’s “almondmilk” is an imitation of dairy milk. (GFI Br., at 14 (“this case turns entirely on the question of whether the ‘imitation’ provision applies to distinct products like almond milk”)).

Blue Diamond and GFI point out that Painter’s complaint prays for relief that is arguably preempted or otherwise contrary to the FDCA. (Ans. Br., at 43; GFI Br., at 14.) Painter’s complaint seeks four forms of injunctive relief requiring Blue Diamond to: (1) place the words “imitation milk” on the label; (2) place a nutritional comparison of their product to nutritional values of milk; (3) fortify its almond beverage; or (4) cease using the term “milk.” (2 ER 133.) Critically, these suggested injunctions are pled in the alternative. Thus, if any are found to be preempted or otherwise contrary to law, they can easily be stricken.

Blue Diamond concedes that the first and the third requests “arguably align

with the requirements of the FDCA” and are, therefore, not preempted. (Ans. Br., at 43). GFI takes issue with the fourth request that Blue Diamond take the word “milk” out of the name of its product by suggesting that if Blue Diamond’s “almondmilk” beverage is found to be an imitation of dairy milk, it must include “imitation milk” on its label. (GFI Br., at 14). Painter agrees, in fact, GFI’s solution to Blue Diamond’s misbranding mirrors Painter’s first request for injunctive relief.

A motion to dismiss is only proper if the complaint fails to state a cause of action or is preempted. Fed. R. Civil. P. 12(b)(6). Here, both Blue Diamond and GFI agree that at least one claim for injunctive relief is not preempted. Thus, the complaint states a viable cause of action for injunctive relief and preemption cannot form a basis for dismissing the complaint.

C. Whether Blue Diamond’s “Almondmilk” is a Distinct Product is a Question of Fact That Cannot Be Resolved Without an Evidentiary Record

Blue Diamond insists throughout its answering brief that “Blue Diamond’s almondmilk is not an imitation food” but, instead, “[i]t is a distinct, alternative food with its own, distinct characteristics and nutritional qualities.” (Ans. Br., at 19). Blue Diamond also contends that it “sells real almondmilk, not imitation dairy milk, and its label is accordingly accurate and consistent with federal law.” *Id.* 23. However, whether a food is a “distinct” product is a factual defense to an

“imitation” claim under the FDCA. *Aeration Processes*, *supra*, 184 Cal.App. 2d at 843 (finding that “the subject product was not an imitation milk but a singular and distinctive food product [was] supported by substantial evidence”). This is not a motion for summary judgment on Blue Diamond’s affirmative defense. On the record before the court, there is no evidence, let alone substantial evidence, to support the finding that Blue Diamond’s “almondmilk” beverage is a distinct product.

Blue Diamond brings up an interesting side point, however, in arguing that calling its “almondmilk” beverage “‘imitation milk’ would be false and misleading and would suggest that it contains milk ingredients or is otherwise related to dairy products in a way that is entirely inaccurate.” (Ans. Br., at 34). As the Commissioner noted, “in some cases it may be necessary to include a standardized name in the name of a substitute food in order to provide the consumer with accurate descriptive, and fully informative labeling.” *Imitation Foods; Application of the Term “Imitation,”* 38 Fed. Reg. 20703 (Aug. 2, 1973). However, here, Blue Diamond’s “almondmilk” contains no milk whatsoever, so the labeling of their almond beverage is inaccurate even under their own theory.⁷ As the Supreme

⁷ The main ingredient in Blue Diamond’s “almondmilk” is filtered water. *See* United States Department of Agriculture Branded Food Products Database, <https://ndb.nal.usda.gov/ndb/foods/show/167142> (Accessed April 23, 2018). If Blue Diamond truly wanted to be accurate with its labeling, it would call their product “almondwater.”

Court pointed out a century ago, “The statute enjoins truth; this label exhales deceit.” *United States v. Schider*, 246 U.S. 519, 522 (1918). In *Schider*, the Supreme Court found that a compound labeled “Ess Grape” was an “imitation” under the FDCA because it did not contain any grapes. *Id.* “The obvious and undisputed purpose and effect of the label was to declare the bottled article ‘a compound essence of grape.’ In fact, it contained nothing from grapes and was a mere imitation.” *Id.* What was true 100 years ago for “Ess Grapes” is alleged now for Blue Diamond’s “almondmilk” beverage, *i.e.* it fails to contain the same nutrients as milk and is a mere imitation.

Finally, in resolving this motion, it is not necessary to speculate about the ramifications of requiring Blue Diamond’s “almondmilk” to comply with the section 403(c) of the FDCA. Both Blue Diamond and GFI suggest the results would be “absurd” by providing various examples of what foods might qualify as imitations of other foods. (Ans. Br., at 40-42; GFI Br., at 26-29). None of those issues are before this court. Finding that the complaint states a plausible claim that Blue Diamond’s “almondmilk” is an imitation of dairy milk will not open the floodgates to other imitation claims. Each of those foods would have to go through a fact-specific analysis as to whether they “substitute for and resembles another food but is nutritionally inferior to that food.” The issues raised on appeal are directly aimed at whether the pleadings support a finding that Blue Diamond’s

“almondmilk” violates section 403(c) of the FDCA and give rise to state law consumer remedies. Nothing in this appeal seeks to change substantive law.

A finding that Painter’s complaint states a plausible cause of action against Blue Diamond for mislabeling their “almondmilk” will simply result in the remand of this case back to the district court so that the parties (or the FDA) can develop the evidentiary record. Then and only then can this issue be determined. The court should not be persuaded by “absurd” hypothetical results that constitute a non sequitur to the issues presented in this appeal.

D. GFI’s Argument That Painter’s Application of the Imitation Provision is Unconstitutional is Misplaced

Proposed amicus GFI’s five-page pontification on First Amendment rights is misplaced. (GFI Br., at 35-40.) Indeed, GFI comes to the same conclusion by admitting that “the Court need not decide any of these weighty constitutional questions to resolve this case.” (GFI Br., at 41.) The reason this Court need not resolve any constitutional challenges is because this appeal does not present any constitutional challenges.⁸ Again, GFI admits this by stating that the constitutional issues are avoided by “preventing the law’s application to separate and distinct foods.” (GFI Br., at 42.) As stated above, whether Blue Diamond’s “almondmilk”

⁸ Neither party raised First Amendment issues in their briefs and an amicus generally cannot raise new issues on appeal. *See Tyler v. City of Manhattan*, 188 F.3d 1400, 1404. (10th Cir. 1997) (“Our review of the relevant case law demonstrates that it is truly the exceptional case when an appellate court will reach out to decide issues advanced not by the parties but instead by amicus.”)

is a separate and distinct product is an affirmative defense to a section 403(c) claim, a question of fact, and beyond the scope of this appeal. If Blue Diamond’s “almondmilk” or any other generic almond beverage is deemed a distinct product, it will be exempt from section 403(c). There is no threat of “serious” constitutional ramifications. The proposed amicus’ entire constitutional argument should be ignored.

E. The Case Should be Stayed Pending the FDA’s Resolution of Whether Almond Milk is a Nutritionally Inferior “Imitation” of Dairy Milk

As pointed out in Painter’s opening brief, “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.” (Appellant’s Opening Br., at 35 (*citing Kelley, supra, and Cuevas, infra*)). Specifically, *Kelley* found that the District Court “is not the appropriate forum to decide in the first instance whether almondmilk ‘substitutes for,’ is ‘nutritionally inferior’ to, and ‘resembles’ dairy milk such that it should be labeled ‘imitation’ milk under § 101.3(e)—an issue which forms the entire basis for Plaintiff’s case.” *Kelley, supra*, 2017 WL 2445836, at *5.

In *Kelley*, the court invoked the doctrine of primary jurisdiction, finding that this issue “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.” *Kelley*, *supra*, 2017 WL 2445836, at *5 (citing *Astiana v. Hain Celestial Group, Inc.*, 783 F.3d 753, 760 (9th Cir. 2015)). In doing so, the *Kelley* court referred the almond beverage issue to the FDA in June 2017 and stayed the action pending FDA’s response. The Central District did regarding the same issue in July 2017, citing *Kelley*’s referral to the FDA. *Cuevas v. Topco Associates, LLC*, No. 5:17-CV-00462-DOC-SP, ECF No. 34 (C.D. Cal., July 18, 2017).

Painter agrees that on remand the same referral would be appropriate. Blue Diamond argues that Painter should be judicially estopped from arguing this position since she opposed it in the district court.⁹ However, judicial estoppel does not apply when a party changes their position in response to a change in the law. *State of Ariz. v. Shamrock Foods Co.*, 729 F.2d 1208, 1215 (9th Cir. 1984). Moreover, “courts must balance a litigant’s need to react to economic change against the notions of fair play undergirding the equitable doctrine of judicial estoppel.” *Malaney v. UAL Corp.*, 552 F. App’x 698, 701 (9th Cir. 2014).

Although the decisions to refer this issue to the FDA in the *Kelley* and *Cuevas* cases are not controlling and technically not changes in the law, they are changes in the legal landscape. Furthermore, it would be judicially economical to stay this case pending a resolution of the issue by the FDA. Thus, Painter is not

⁹ The parties have switched positions on this issue. In the district court, Blue Diamond argued that this case should be referred to the FDA. (2 ER 90-91.)

playing “fast and loose” with the law by changing her position, she is doing so due to a change in the legal landscape and in the interest of judicial economy, both of which are legitimate reasons.¹⁰

Most importantly, however, is the fact that this Court need not reach a conclusion on this issue. This Court could reverse the dismissal of Painter’s complaint and remand this case to allow the district court below to decide whether a stay and referral to the FDA is appropriate.

III. CONCLUSION

For these reasons, Appellant respectfully requests that the Court reverse the district court’s order dismissing the First Amended Complaint.

Dated: April 23, 2018

Respectfully submitted,

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By: /s/ Glenn A. Danas

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¹⁰ Alternatively, Blue Diamond has changed their position regarding FDA referral for the sole purpose of trying to capitalize on an erroneous ruling by the district court below.

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

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