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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

GARY HOFMANN,

Plaintiff,

v.
FIFTH GENERATION, INC., a Texas
corporation; and DOES 1 through 100,
inclusive,

Defendants.

Case No.: 14cv2569 JM(JLB)
Related Case No: 14cv2990 JM(JLB)

**ORDER DENYING DEFENDANT
FIFTH GENERATION’S MOTION
FOR SUMMARY JUDGMENT**

This order addresses Defendant Fifth Generation, Inc.’s (“Fifth Generation’s”) motion for summary judgment filed on August 28, 2015. (Doc. No. 47). The matters were fully briefed and were found suitable for resolution without oral argument pursuant to Local Rule 7.1(d)(1).

For the reasons set forth below, the court denies Defendant’s motion for summary judgment.

BACKGROUND

Plaintiff Gary Hofmann (“Hofmann”) complains that the labeling of Fifth Generation’s product called Tito’s Handmade Vodka (“Tito’s”) is false because, in reality, the vodka is made by means of a “highly mechanized process that is devoid of human hands.” (Doc. No. 1, Exh. A ¶ 1). On September 15, 2014, he initiated this

1 lawsuit in San Diego Superior Court. (Doc. No. 1 at 2). On September 30, 2014, he filed
2 the operative First Amended Complaint (“FAC”) as a putative nationwide class action on
3 behalf of retail purchasers of Tito’s during the last four years. (Doc. No. 1, Exh. A ¶¶ 10,
4 19).

5 Plaintiff alleges that in August 2014, he purchased Tito’s at a BevMo! store in San
6 Diego, California. (Id. ¶ 15). It was prominently marked with the word “Handmade,”
7 and it was labeled as being “Crafted in an Old Fashioned Pot Still by America’s Original
8 Microdistillery.” (Id.) He claims that he saw the label, relied on it, and believed he was
9 buying a high-quality product made by human hands, not mass-produced in large
10 industrial vats. (Id. ¶¶ 16–17).

11 He claims that the Tito’s labeling is false and misleading because, in reality, the
12 vodka is mass-produced in large quantities from commercially manufactured neutral
13 grain spirits that are trucked and pumped into the Tito’s facility and distilled in modern,
14 technologically advanced stills. (Id. ¶¶ 1, 11). He quotes a 2013 Forbes magazine article
15 on Tito’s that described “massive buildings containing ten floor-to-ceiling stills and
16 bottling 500 cases an hour.” (Id. ¶ 11).

17 He alleges further that when Fifth Generation represented to the public that Tito’s
18 is “Handmade,” it concealed the highly automated nature of the manufacturing and
19 bottling process, and it concealed the fact that Tito’s is no longer made in an old-
20 fashioned pot still like the one pictured in the Forbes article, which was “cobbled from
21 two Dr. Pepper kegs and a turkey-frying rig.” (Id. ¶ 12). He contends that disclosure of
22 that information was necessary to make the Tito’s label truthful and not misleading
23 because most consumers are unaware of the probability that purportedly handmade
24 products are actually mass-produced, and many believe that a handmade product is
25 “made in small amounts [and] of inherently superior quality.” (Id. ¶¶ 12–13).

26 Consequently, Plaintiff claims, he and other consumers were fraudulently induced
27 to pay inflated prices for vodka they believed was genuinely handmade, when it was not.
28 (Id. ¶¶ 14, 18). “Essentially,” he says, “the Vodka is not worth the purchase price paid.”

1 (Id. ¶ 18). On that basis, he asserts four causes of action under California law:
2 (1) violation of California’s Unfair Competition Law (“UCL”), Business & Professions
3 Code § 17200 *et seq.*; (2) violation of California’s False Advertising Law (“FAL”),
4 Business & Professions Code § 17500 *et seq.*; (3) violation of California’s Consumers
5 Legal Remedies Act (“CLRA”), Civil Code § 1750 *et seq.*; and (4) negligent
6 misrepresentation. (Id. ¶¶ 37–79). He seeks restitution of the money class members paid
7 to buy the offending vodka and an injunction prohibiting continued violation of the UCL.
8 (Id. at 17–18).

9 On October 28, 2014, Fifth Generation removed the case to this court pursuant to
10 the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), asserting that Plaintiff is
11 a California citizen, Defendant is a Texas citizen, and the class claims place in
12 controversy more than \$5 million dollars. (Doc. No. 1 at 3–7). On December 18, 2014,
13 Fifth Generation filed a motion to dismiss the FAC or, alternatively, for a more definite
14 statement (Doc. No. 8), and a related request for judicial notice (Doc. No. 8-2). On
15 March 18, 2015, this Court denied that motion in part and granted it in part, and granted
16 Plaintiff leave to amend. (Doc. No. 15). On April 10, 2015, after Plaintiff amended the
17 operative complaint, Defendant answered. (Doc. No. 18).

18 On August 28, 2015, Fifth Generation filed a Motion for Summary Judgment.
19 (“Motion”) (Doc. No. 47). On October 5, 2015, Plaintiff filed an opposition to
20 Defendant’s motion. (“Opposition”) (Doc. No. 59). On October 9, 2015, Defendant filed
21 a reply in support of its motion. (Reply) (Doc. No. 63).

22 LEGAL STANDARD

23 A moving party is entitled to summary judgment where “there is no genuine issue
24 as to any material fact” Fed. R. Civ. P. 56(c); Prison Legal News v. Lehman, 397
25 F.3d 692, 698 (9th Cir. 2005). The court must examine the evidence in the light most
26 favorable to the non-moving party. United States v. Diebold, Inc., 369 U.S. 654, 655
27 (1962). While Rule 56 contains “no express or implied requirement . . . that the moving
28 party support its motion with affidavits or other similar materials negating the opponent’s

1 claim,” Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986), “the moving party bears the
2 burden of proof at trial, [and] it must come forward with evidence which would entitle it
3 to a directed verdict if the evidence were uncontroverted at trial.” Houghton v. South,
4 965 F.2d 1532, 1536 (9th Cir. 1992).

5 If the moving party meets its initial burden of production, the burden shifts to the
6 non-moving party to go beyond the pleadings by citing materials in the record to show a
7 genuine issue for trial. Celotex, 477 U.S. at 324 (citation omitted). The opposing party
8 also may not rely solely on conclusory allegations unsupported by factual data. Taylor v.
9 List, 880 F.2d 1040, 1045 (9th Cir. 1989). Nevertheless, the ultimate burden of persuasion
10 on the motion remains with the moving party. Nissan Fire & Marine Ins. Co., Ltd. v. Fritz
11 Cos., 210 F.3d 1099, 1102 (9th Cir. 2000). Doubt as to the existence of any issue of
12 material fact requires denial of the motion. Anderson v. Liberty Lobby, Inc., 477 U.S.
13 242, 255 (1986).

14 DISCUSSION

15 A. The Safe Harbor

16 Fifth Generation first raised its safe harbor argument in its motion to dismiss
17 Plaintiff’s statutory claims, where it argued that Plaintiff’s UCL and CLRA were barred
18 by the safe-harbor exception to California’s consumer-protection laws. (Doc. No. 8, p.
19 12-13).

20 In Cel-Tech Communications v. Los Angeles Cellular Telephone Co., 20 Cal. 4th
21 163 (1999), the California Supreme Court recognized a safe harbor under the UCL for
22 actions that the law actually bars, or for conduct the law “clearly permit[s].” Id. at 183.
23 The Court explained:

24 Although the unfair competition law’s scope is sweeping, it is not unlimited.
25 Courts may not simply impose their own notions of the day as to what is fair
26 or unfair. Specific legislation may limit the judiciary’s power to declare
27 conduct unfair. If the Legislature has permitted certain conduct or considered
a situation and concluded no action should lie, courts may not override that
determination.

28 Id. at 182. In short, “[a] plaintiff may . . . not plead around an absolute bar to relief

1 simply by recasting the cause of action as one for unfair competition.” Id. (internal
2 quotation marks omitted). The Ninth Circuit has recognized that the safe harbor applies
3 to claims brought under the CLRA. See Alvarez v. Chevron Corp., 656 F.3d 925, 933–
4 34 (9th Cir. 2011) (applying the safe harbor to a CLRA claim). The Ninth Circuit has
5 also recently extended the safe harbor to protect conduct authorized by regulation. See
6 Davis v. HSBC Bank Nevada, N.A., 691 F.3d 1152, 1169 & n.8 (9th Cir. 2012)
7 (“California intermediate courts agree with our conclusion that regulations can create safe
8 harbors.”).

9 In its order granting in part and denying in part Fifth Generation’s motion to
10 dismiss (“Order”), this court remarked that the dispute with respect to the safe harbor
11 argument centered on what kind of government authorization was sufficient to invoke the
12 safe harbor doctrine. The court rejected Fifth Generation’s safe harbor argument for the
13 following reasons: (1) it did not cite any authority to show that the safe harbor extended
14 to information agency action of the type at issue in this case; (2) it did not meaningfully
15 address the distinctions raised by Plaintiff with respect to two relevant cases – Koenig v.
16 Snapple Beverage Corp., 713 F. Supp. 2d 1066 (E.D. Cal. 2010) and In re Celexa &
17 Lexapro Marketing & Sales Practices Litigation, 2014 WL 866571 (D. Mass. Mar 5,
18 2014); (3) its claims that TTB specifically investigated and approved of the “Handmade”
19 term were not properly before the court and could not be considered at that stage; and (4)
20 from the regulations it provided to the court and the apparent absence of any guidance
21 from TTB regarding the meaning of the word “Handmade,” it was not clear that such
22 representations were necessarily within TTB’s regulatory purview. (Doc. No. 15, p. 12).
23 This court also pointed out that the principles set out in Reid v. Johnson & Johnson, 780
24 F.3d 952 (9th Cir. 2015), which was decided after the briefing on this matter was
25 complete, were likely to be instructive going forward, since in that case the Ninth Circuit
26 joined the Third Circuit in holding that “[c]reation of federal law should demand at least
27 the same formality for purposes of preemption as it does for purposes of *Chevron*
28 deference.” Id. at 964. In doing so, the Ninth Circuit agreed with Fellner v. Tri-Union

1 Seafoods, L.L.C., 539 F.3d 237 (3d Cir. 2008), which Plaintiff’s case, Koenig, relied on
2 for its conclusion regarding the safe harbor, see 713 F. Supp. 2d. at 1074–75.

3 In this motion, Fifth Generation reasserts and more fully develops the safe harbor
4 argument. First, Fifth Generation argues that the safe harbor doctrine does not have the
5 same formality requirement as the federal preemption doctrine by attempting to make
6 distinctions between the two doctrines. Second, Fifth Generation contends that TTB’s
7 authorization of Tito’s label bars Plaintiff’s claims under the safe harbor doctrine because
8 (1) a certificate of label authorization (“COLA”) is a regulatory approval of a label’s
9 compliance with federal law; (2) the COLA for Tito’s “Handmade” vodka label triggers
10 the safe harbor doctrine as to any claims based on allegations that the label is misleading;
11 and (3) although not necessary, other evidence establishes that the COLA was issued
12 after TTB overcame any concerns about the word “Handmade.”

13 **1. The California Safe Harbor and the Federal Preemption Doctrines**

14 Fifth Generation argues that California’s safe harbor doctrine prohibits any claims
15 based on conduct that state or federal law has considered and permitted, and does so by
16 attempting to distinguish the California safe harbor from the federal preemption doctrine.
17 First, Fifth Generation argues that while the preemption doctrine is rooted in the
18 Supremacy Clause of the United States Constitution, see Fid. Fed. Sav. & Loan Ass’n v.
19 De La Cuesta, 458 U.S. 141, 152 (1982), the safe harbor doctrine was recognized by the
20 California Supreme Court when construing the meaning of “unfair competition” under
21 the UCL, see Cel-Tech, 20 Cal. 4th at 180-82. (Motion, p. 12). Second, while there is a
22 presumption against federal preemption in order to protect traditional state power, see
23 Wyeth v. Levine, 555 U.S. 555, 565 (2009), there is no presumption when applying the
24 safe harbor because it was created by the California Supreme Court based on its
25 conclusion that the legislature did not intend for court decisions about what constitutes
26 unfair competition to prohibit conduct that has been otherwise authorized by law, see
27 Cel-Tech, 20 Cal. 4th at 182. (Motion, pp. 12-13). Third, the Ninth Circuit’s refusal to
28 give preemptive effect to agency actions absent a showing of formality of that action is

1 rooted in the requirement of a showing that “Congress intended the agency’s
2 pronouncement to carry the binding and exclusive force of federal law,” Reid, 780 F.3d
3 at 964, while no such showing of Congressional intent of exclusivity is required in
4 applying the safe harbor, which has been recognized in a spirit of judicial deference to
5 prior state or federal legislative or regulatory action. (Motion, p. 13). Finally, at a later
6 point in the motion, Fifth Generation also argues that Koenig is inapposite to this case
7 “because the Food and Drug Administration has had nothing to do with regulating
8 alcohol beverages since 1976.” (Id. at 16).

9 Plaintiff counters that the California safe harbor doctrine is inapplicable in this
10 case because it only applies to regulatory actions that merit Chevron deference.
11 Specifically, Plaintiff argues that the safe harbor primarily prohibits consumer fraud
12 actions where a state or federal statute “actually bar[s]” or “clearly permit[s] the conduct”
13 at issue. Loeffler v. Target Corp., 58 Cal. 4th 1081, 1125 (2014). Plaintiff contends that
14 a federal regulator’s actions create a safe harbor only under the same circumstances in
15 which a federal regulator’s actions amount to federal law for the purposes of
16 preemption—i.e., where the agency’s actions “were the result of a formal, deliberative
17 process akin to notice and comment rulemaking or an adjudicative enforcement action,”
18 and are therefore sufficiently formal to merit Chevron deference. Koenig, 713 F. Supp.
19 2d at 1076. See also Reid, 780 F.3d at 964 (“Creation of federal law should demand at
20 least the same formality for purposes of preemption as it does for purposes of *Chevron*
21 deference.”).

22 Additionally, Plaintiff argues that Fifth Generation’s attempt to distinguish Reid is
23 unavailing for the following reasons. First, while Fifth Generation attempts to distinguish
24 the safe harbor from the preemption doctrine based on their origins, it provides no
25 explanation as to why the fact that the two doctrines have differing origins means that
26 agency actions too informal to preempt state law should nonetheless trigger the California
27 safe harbor. (Opposition, p. 11). Second, Plaintiff contends that the presumption against
28 preemption has nothing to do with the question of whether a regulator’s action has

1 preemptive force, as the court in Reid explicitly refrained from “reach[ing] the question
2 of how ‘the presumption against preemption’ . . . might further guide [their] evaluation of
3 the preemptive effect of an action by the FDA implementing the [Food, Drug, and
4 Cosmetic Act (“FDCA”)].” (Id. at 12, citing Reid, 780 F.3d at n.7). Third, Plaintiff
5 responds to Fifth Generation’s Congressional intent of exclusivity argument by pointing
6 out that the purpose of the safe harbor is not to force California law to bend to the
7 informal determinations of a federal regulator, but it is to ensure that an action that is
8 clearly permitted by federal or state law is not the basis of a UCL or CLRA claim.
9 (Opposition, p. 12). Finally, Plaintiff argues that the fact that Koenig concerns an FDA
10 policy, not a TTB policy is “completely beside the point,” because both FDCA and
11 FAAA prohibit false or misleading labels. (Id. at 12).

12 In its reply, Fifth Generation responds to Plaintiff’s arguments by reiterating that
13 unlike the federal preemption doctrine, safe harbor does not require the same showing of
14 formality, and by arguing that the COLA procedures are significantly more formal than
15 the FDA statements in Koenig. (Reply, pp. 3-6).

16 While the issue of whether TTB’s COLA procedures are more formal than the
17 FDA statements in Koenig will be addressed in a later part of this order, Fifth
18 Generation’s argument that the alleged distinctions between the California safe harbor
19 and the preemption doctrines render the “formality” requirement discussed in Reid
20 irrelevant to the application of the safe harbor doctrine is unpersuasive. Moreover, Fifth
21 Generation failed to provide the court with any meaningful explanation as to why the
22 differing origins of the federal preemption and the safe harbor doctrines bear on the issue
23 of whether the formality requirement discussed in Koenig and Reid should be applied to
24 the safe harbor doctrine as well. The court is similarly not persuaded by Fifth
25 Generation’s arguments that the presumption against federal preemption and the
26 requirement of Congressional intent of exclusivity distinguish the federal preemption
27 from the safe harbor doctrine to the extent that the “formality” requirement is simply not
28 relevant to the application of the safe harbor doctrine.

2. TTB's Authorization of Tito's Label

Fifth Generation next argues that because TTB specifically authorized Tito's label, Plaintiff's claims are barred under the safe harbor doctrine. Namely, Fifth Generation states that TTB has approved every single variation of the labels for Tito's Handmade Vodka, and has done so after questioning and examining the particular term "Handmade" on at least two separate occasions. (Motion, p. 13).

First, Fifth Generation contends that a COLA constitutes a regulatory approval of a label's compliance with federal law and that TTB's alcohol-label approval process is a "formal agency action that results in the creation of a property right in the regulated entity in the form of a COLA." (*Id.* at 14). Fifth Generation states that TTB's rule-making authority under the FAAA has been delegated from the Secretary of the Treasury, and relies on a district court case, Cruz v. Anheuser-Busch, LLC, for the proposition that it is this delegation that confers upon TTB's regulations, and specifically the COLA, "the exclusive effect of federal law." 2015 WL 3561536, at *4 (C.D. Cal. June 3, 2015) ("[t]he TTB has exclusive jurisdiction in regulating the labels on alcoholic beverages because Congress expressly granted exclusive authority to the Treasury Department who in turn delegated its duties to the TTB."). Fifth Generation further contends that under FAAA and TTB regulations, "no distilled spirit may be bottled or removed from a plant unless the TTB has first issued a COLA approving the bottle labels under the FAAA," and that TTB regulations provide specific administrative procedures for challenging an alcohol label that Plaintiff could have, but has not, pursued in lieu of this action. (Motion, p. 14).

Second, Fifth Generation argues that this case is exactly the type of situation for which the safe harbor exists. Fifth Generation relies on Cruz, where the court examined the effect of TTB's COLA, concluding that a COLA has the force of federal law and bars a claim that the approved label is misleading. 2015 WL 3561536, at *6. As in this case, the plaintiff in Cruz brought a UCL claim, alleging that the word "light" on the label for Anheuser-Busch's Rita products was misleading. *Id.* at *1. Fifth Generation argues that

1 as in Cruz, this court should find that the COLA here has the force of federal law and
2 bars Plaintiff's claims.

3 Plaintiff counters, arguing that TTB's approval of Tito's label is insufficiently
4 formal and therefore, does not trigger the application of the safe harbor doctrine.
5 (Opposition, p. 9). Plaintiff mainly relies on two cases, Koenig and United States v.
6 Mead, 533 U.S. 218 (2001), both to support its position and to argue that Cruz was
7 wrongly decided.

8 Mead, which is one of the seminal cases on Chevron deference, concerned
9 whether tariff classification rulings issued by the United States Customs Service
10 ("USCS") were entitled to Chevron deference. 533 U.S. at 221. The Court held that the
11 USCS rulings were not entitled to Chevron deference because the agency did not
12 "generally engage in notice-and-comment practice" when issuing its rulings, and the
13 rulings were not generally binding on third parties. Id. at 218-19. Plaintiff points out that
14 just as TTB's ability to issue COLAs stems from the Secretary of Treasury, which has in
15 turn been delegated authority from Congress, the USCS's tariff rulings in Mead were
16 similarly authorized by regulations promulgated by the Secretary of Treasury through
17 authority delegated by Congress. Id. at 222. According to Plaintiff, the Cruz court's
18 holding was based on the erroneous assumption that because the Secretary of Treasury
19 delegated authority to TTB to issue COLAs, those issuances must have the force of law
20 under Chevron. Opposition, n.9. Plaintiff submits that Mead demonstrates that this is not
21 so. Id.

22 Koenig, Plaintiff further argues, presents an analogous example of circumstances
23 where an agency's action was insufficiently formal to trigger the safe harbor. In that
24 case, the plaintiff argued that a beverage producer violated California's consumer
25 protection laws by falsely labeling its product as "natural." Koenig, 713 F. Supp. 2d at
26 1070-71. The defendant countered that the plaintiff's claim was barred by the California
27 safe harbor doctrine. Id. at 1073. The court in Koenig agreed with the Third Circuit's
28 approach (see Fellner v. Tri-Union Seafoods, LLC., 559 F.3d 237, 245 (3rd Cir. 2008))

1 and concluded that the FDA’s policy regarding the use of the term “natural” did not have
2 the force of law, because the statements set forth by the FDA regarding the use of the
3 term “natural” were not the result of a “formal, deliberative process akin to notice and
4 comment rulemaking or adjudicative enforcement action.” Koenig, 713 F. Supp. 2d at
5 1076. As pointed out in this court’s Order, the Ninth Circuit “joined the Third Circuit in
6 holding that ‘[c]reation of federal law should demand at least the same formality for
7 purposes of preemption as it does for purposes of *Chevron* Deference.’” (Doc. No. 15,
8 n.6) (quoting Reid, 780 F.3d at 964). Plaintiff argues that just as plaintiff’s claims in
9 Koenig were not barred by the California safe harbor doctrine, neither should his claims
10 be barred.

11 Plaintiff cites Walls v. United States, 582 F.3d 1358, 1377 (Fed. Cir. 2009) for the
12 proposition that “an agency adjudication is deemed formal under the [Administrative
13 Procedural Act] and subject to the requirements of [5 U.S.C.] §§ 556 and 557 only when
14 the agency’s authorizing statute requires a hearing with trial-type procedures,” and argues
15 that there is nothing in the record to indicate that TTB’s approval of Tito’s label
16 constitutes a formal adjudication for purposes of Chevron deference. (Opposition, n.6).
17 Additionally, relying on the Court’s statement in Mead that “[a]ny suggestion that rulings
18 intended to have the force of law are being churned out at a rate of 10,000 a year . . . is
19 simply self-refuting,” Plaintiff argues that the sheer number of TTB rulings undermine its
20 position that its rulings are entitled to Chevron deference. 533 U.S. at 223.

21 In its Reply, Fifth Generation counters that there is no question that TTB’s COLA
22 procedure is sufficiently formal by distinguishing it from the FDA statements in Koenig.
23 First, Fifth Generation argues that COLA procedures are significantly more formal than
24 the agency letters in Koenig because the issuance or denial of a COLA is the end result of
25 a formal regulatory procedure mandated by law before any label may be used in
26 commerce, and that a COLA, unlike an FDA interpretive letter, creates a property right.
27 (Reply, p. 5). Second, the FDA enforcement in Koenig was “purely discretionary –
28 taking into consideration available agency resources and other priorities,” while the

1 FAAA and TTB regulations “*require* the TTB to prohibit statements on labels that are
2 false or misleading.” (*Id.*) Additionally, as argued by Fifth Generation, in *Koenig*, “the
3 FDA’s prior refusal to act on the use of the word “natural” did not amount to a formal
4 approval of the word,” while the COLA procedure provided the type of a “deliberative
5 process akin to notice and comment rulemaking” (*Id.* at 11, citing *Koenig*, 713 F.
6 Supp. 2d at 1075-1076).

7 Having considered the parties’ arguments, the court finds that Fifth Generation has
8 not established that TTB’s COLA issued from a formal process sufficient to trigger the
9 California safe harbor doctrine. First, *Mead* illustrates that the Secretary of Treasury’s
10 delegation of authority to TTB is not dispositive of whether TTB’s COLAs have the force
11 of federal law, *Cruz* notwithstanding. While *Cruz* did not disagree with *Koenig* that safe
12 harbor applies only when a regulatory agency conducts a formal regulatory action under
13 *Chevron*, *Cruz* summarily held that the issuance of the COLA itself triggered the safe
14 harbor doctrine. This court does not find *Cruz* persuasive. As this court has already
15 indicated in its Order (Doc. No. 15), the principles announced in *Reid* are instructive and
16 stand for the proposition that a federal regulator’s actions create a safe harbor only under
17 the same circumstances required for preemption. Those circumstances exist when the
18 agency’s actions “[are] the result of a formal, deliberative process akin to notice and
19 comment rulemaking or an adjudicative enforcement action,” and are therefore
20 sufficiently formal to merit *Chevron* deference. *Koenig*, 713 F. Supp. 2d at 1076. *See*
21 *also Reid*, 780 F.3d at 964. Additionally, the court finds *Mead*’s concern that the sheer
22 number of rulings undermines entitlement to *Chevron* deference persuasive.

23 Second, while mindful of Fifth Generation’s arguments differentiating TTB’s
24 COLAs from the FDA statements in *Koenig*, these are differences of degree and only
25 establish that COLA procedures are *more* formal than the agency letters in *Koenig*. The
26 COLA procedures remain less formal than those required “of a formal, deliberative
27 process akin to notice and comment rulemaking or an adjudicative enforcement action.”
28 *See id.* In sum, TTB’s action related to its examination and approval of the term

1 “Handmade” on Tito’s label, including the COLA it issued, is insufficient to trigger the
2 safe harbor doctrine at this juncture in the case.

3 **3. TTB’s Determination that “Handmade” is Not Misleading**

4 Fifth Generation argues that while not necessary, the evidence in this case
5 establishes that the COLA was issued after TTB overcame any concerns about the word
6 “Handmade” because (1) TTB specifically raised questions about the word “Handmade”;
7 (2) it thoroughly inspected Fifth Generation’s facilities as to every aspect of its
8 operations; and (3) it satisfied itself that the labels were in compliance with its labeling
9 regulations and not misleading. (Motion, p. 17). Thus, Fifth Generation submits that
10 “there is no question that the TTB thoroughly reviewed Fifth Generation’s facility,
11 distillation process, and essentially every part of its business and concluded multiple
12 times that the labels for Tito’s Handmade Vodka – and in particular, the term
13 ‘Handmade’ – were not misleading.” (Reply, p. 8).

14 Fifth Generation further details the circumstances under which the COLA was
15 issued in this case, which include TTB’s confirmation that it had “[r]eviewed [and]
16 considered all the various information and explanations provided by Mr. Beveridge,”
17 including the label in its totality, and after considering all the information, it concluded
18 that the reference to the word “Handmade” was in compliance with the labeling
19 regulations and not misleading. (Beveridge Decl., Exh. 4). These circumstances, Fifth
20 Generation argues, demonstrate that “the labels for Tito’s Handmade Vodka were
21 approved after a rigorous review by officials in the upper echelon of the responsible to
22 federal agency, *not mere self-reporting*.” (Motion, p. 17).

23 Plaintiff counters that Fifth Generation’s argument appears to be based
24 predominantly on a letter sent by Karen Frelove, the then Director of Advertising,
25 Labeling and Formulation, to Mary Ryan, another TTB official, which states that TTB
26 has determined the reference to “Handmade” is in compliance with TTB’s regulations
27 and is not misleading. (Motion, p. 18). Plaintiff argues that the declaration of Janet
28 Scalese, the representative of TTB designated to provide sworn testimony in this

1 litigation, “tells a different story.” (*Id.*). According to Scalese, TTB determined that the
2 term “Handmade” constituted “information that was not required” under 27 C.F.R.
3 5.33(f), and further explained that it was “the responsibility of the submitter who signs
4 the Certificate of Label Approval Application under the penalty of perjury....” (Exh. 10,
5 p. 44). The relevant portion of the Scalese declaration, as set forth by Plaintiff, is as
6 follows:

7 There are no standards or regulations that specifically address the use of the
8 term ‘handmade.’ TTB’s labeling specialists do not verify claims such as
9 ‘handmade’ when they review alcohol beverage labels. These terms are
10 considered additional information, or ‘puffery,’ covered under 27 CFR
11 5.33(f). The burden of accuracy of such terms falls on the submitter who is
12 required, under penalty of perjury, to sign the Certificate of Label Approval
13 application. . . . TTB does not have standards or a method to verify
14 statements such as these. They are assumed to be true and correct.

15 *Id.* at 45.

16 Fifth Generation objects to Plaintiff’s use of this declaration by stating that Ms.
17 Scalese “makes no claim to have personal knowledge regarding the Tito’s Handmade
18 Vodka label approvals,” and that her declaration goes on to state that TTB had
19 determined “as a matter of policy, the term ‘Handmade’ ha[d] no definition in the TTB
20 regulations, nor any industry standard and *as such*, constituted puffery, and did not
21 conflict with or qualify any of the mandatory statements on the label.” *Id.* (emphasis
22 added). Given Ms. Scarlese’s position with TTB, her declaration illuminates TTB’s
23 verification practice, or lack thereof, relating to terms such as “Handmade.”

24 Even assuming that TTB did not rely on the truthfulness of the submitter but
25 determined the meaning of “Handmade” on its own, the fact that the term “Handmade”
26 has no definition in TTB regulations, nor any industry standard is significant. Because
27 TTB considers a term such as “Handmade” to be additional information and/or puffery to
28 be verified by a submitter outside the reach of TTB standards or regulations, it appears
that a COLA does not sanction such a term, whether it is to be considered as additional
information or puffery. This raises a genuine issue as to whether TTB determined
“Handmade” not to be misleading, and, if so, whether it was the kind of regulatory action
that “actually bars” or “clearly permit[s] conduct,” see *Cel-Tech Communications*, 20

1 Cal. 4th at 183. Therefore, at this juncture, given the tension between the Freelove letter
2 and the Scarlese declaration, Fifth Generation has not established that any TTB
3 “approval” of the term “Handmade” should be given the force of federal law, triggering
4 the California safe harbor doctrine.¹ Further development of the factual record may be
5 helpful in clarifying and resolving this tension.

6 **B. Negligent Misrepresentation Claim**

7 In addition to the safe harbor argument, Fifth Generation also argues that
8 Plaintiff’s negligent misrepresentation claim is barred by the economic loss doctrine. As
9 correctly pointed out by Plaintiff, this argument exceeds the scope of Judge Burkhardt’s
10 amended scheduling order, which provides that “Defendant’s anticipated motion for
11 summary judgment *on the safe harbor issue* shall be filed on or before August 28, 2015.”
12 (Doc. No. 40) (emphasis added). In its Reply, Fifth Generation contends that this
13 argument does not exceed the scope of the scheduling order, as the determination of its
14 safe harbor argument would be dispositive to the negligent misrepresentation claim as
15 well. (Reply, n.10).

16 If that is in fact the case, Fifth Generation failed to make that argument in its
17 Motion, and instead based its argument on the economic loss doctrine. (Motion, p. 19).
18 Only in its Reply did Fifth Generation attempt to connect the negligent misrepresentation
19 claim to the safe harbor argument, erroneously relying on Kallita Air v. Cent. Tx.
20 Airborne Sys., Inc., 2009 WL 1636036, at *5-8 (N.D. Cal. June 8, 2009) for the
21 proposition that “the economic loss doctrine applies unless there are facts that create a
22 special relationship between the buyer and a seller,” and that because TTB defined, as a
23 matter of law, what the labels for Tito’s Handmade Vodka can say, “that decision
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25
26 ¹ In his Opposition, Plaintiff also brings forth the argument that because FAAA is a floor rather than a
27 ceiling, the COLA approval does not constitute “clear permission” to use the label. (Opposition, p. 14).
28 Because the court has already concluded that Fifth Generation has not established that TTB’s approval
of the term “Handmade” triggers the application of the safe harbor doctrine, this additional argument by
Plaintiff need not be addressed in this order.

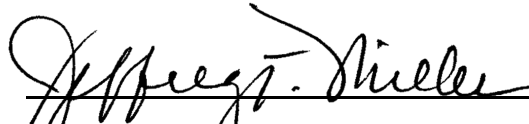
1 effectively precludes any ‘special relationship’ that would be required for the negligent
2 misrepresentation claim to proceed.” (Reply, n.10).

3 Fifth Generation cites Kallita for the wrong proposition, since Kallita’s holding as
4 to the special relationship test concerned negligence claims, not negligent
5 misrepresentation claims. 2009 WL 1636036, at *5. In fact, as pointed out by Plaintiff in
6 his Opposition and unaddressed by Fifth Generation in its Reply, Kallita specifically
7 notes that “the economic loss doctrine did not apply to Kallita’s negligent
8 misrepresentation claim and thus that claim was not barred.” Id. at *2. Accordingly, the
9 court rejects Fifth Generation’s attempt to connect the negligent misrepresentation claim
10 to the safe harbor doctrine as it lies outside the scope of Judge Burkhardt’s order
11 permitting the motion for summary judgment to be brought on the safe harbor issue only
12 (Doc. No. 40).

13 Fifth Generation’s motion for summary judgment on the safe harbor issue is
14 denied, and its motion for summary judgment on the negligent misrepresentation claim is
15 stricken without prejudice.

16 IT IS SO ORDERED.

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18 DATED: November 20, 2015

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20 JEFFREY T. MILLER
21 United States District Judge
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