UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ELIZABETH COX, individually and on behalf of all others similarly situated,

Plaintiffs,

vs.

GRUMA CORPORATION, *et al.*,

Defendant.

Case No.: 12-CV-6502 YGR

NOTICE OF TENTATIVE RULING FOR JUNE 11, 2013 HEARING

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD, PLEASE TAKE NOTICE OF AND BE PREPARED TO ADDRESS THE FOLLOWING TENTATIVE RULING AT THE HEARING SCHEDULED ON TUESDAY, JUNE 11, 2013, AT 2:00 P.M.:

The Court has reviewed the parties' papers and is inclined to order that this matter be stayed under the doctrine of primary jurisdiction pending review of the issues raised by the federal Food and Drug Administration (FDA). This is a *tentative* ruling and the parties still have an opportunity to present oral argument. Alternatively, if the parties JOINTLY stipulate in writing to entry of the tentative ruling, the hearing will be taken off calendar, and the tentative ruling will become the order of the Court.

The Court Plaintiff brings this putative class action alleging that the labels on certain of Gruma Corporation's food products, as well as its advertising and marketing, are false and misleading in violation of the California Unfair Competition Law, Bus. & Prof. Code section 17200 *et seq*. ("UCL"); the California False Advertising Law, Cal. Bus. & Prof. Code section 17500 ("FAL"); the Consumers Legal Remedies Act, Cal. Civ. Code section 1750 *et seq*.

("CLRA").[1] Plaintiff alleges that, because Defendant's Products contain genetically modified organisms ("GMOs") in the form of corn grown from bioengineered, genetically modified seeds, Defendant's labels indicating the Products are "All Natural" are false and misleading. (Plaintiff's Amended Class Action Complaint [Dkt. No. 33, "FAC"] ¶¶ 39-43.)

"The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency… and is to be used only if a claim involves an issue of first impression or a particularly complicated issue Congress has committed to a regulatory agency." *Clark v. Time Warner Cable*, 523 F. 3d 1110, 1114 (9th Cir. 2008). A court traditionally weighs four factors in deciding whether to apply the primary jurisdiction doctrine: "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek Semiconductor Co. v. Microchip Tech., Inc.*, 307 F.3d 775, 781 (9th Cir.2002) (amended).

The FDA has regulatory authority over food labeling. *See* 21 U.S.C. § 341 *et seq.* The Food, Drug, and Cosmetics Act (FDCA) establishes a uniform federal scheme of food regulation to ensure that food is labeled in a manner that does not mislead consumers. *See* 21 U.S.C. § 341 *et seq.* Food labeling enforcement is a matter that Congress has indicated requires the FDA's expertise and uniformity in administration. Congress amended the FDCA through the passage of the Nutrition Labeling and Education Act (NLEA) to "clarify and to strengthen" the FDA's "legal authority to require nutrition labeling on foods, and to establish the circumstances under which

[1] The FAC, while generally alleging false and misleading advertising and marketing, only recites facts concerning *labeling* of Defendant Gruma's Mission® Restaurant Style Tortilla Rounds, Mission® Restaurant Style Tortilla Strips and Mission® Restaurant Style Tortilla Triangles (hereinafter, "Defendant's Products"). (*See, e.g.*, FAC ¶¶ 9, 40, 43). In light of its intention to stay this action and refer the labeling issues to the FDA, the Court declines to rule on the question of whether Plaintiff's allegations sufficiently allege a claim for false advertising and marketing for reasons other than the labeling of Defendant's Products. Likewise, the Court reserves ruling on the standing and mootness issues raised in Defendant's Motion to Dismiss at this time.

claims may be made about nutrients in foods." H.R. Rep. No. 101-538, at 7, *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337. No state may "directly or indirectly establish. . . any requirement for the labeling of food that is not *identical* to the [FDCA]." 21 U.S.C. § 343-1(a) (emphasis supplied).

Focusing particularly on the issues alleged in the FAC, there are no FDA rules requiring that products containing GMO or bioengineered ingredients be labeled as such. The FDA has issued nonbinding industry guidance indicating that it "is not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed . . . . FDA is therefore reaffirming its decision to not require special labeling of all bioengineered foods." (Defendant's Request for Judicial Notice, Exh. A ["Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance," released for comment January 2001] at 2.) With respect to the use of the term "natural" on food labels, the agency has published non-binding guidance defining that term to mean that "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food." 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993). However, the parties appear to be in agreement that the FDA has not addressed, even informally, the question of whether foods containing GMO or bioengineered ingredients may be labeled "natural" or "all natural," or whether GMO or bioengineered ingredients would be considered "artificial or synthetic."

Thus, as Plaintiff concedes, "[t]he FAC identifies a gaping hole in the current regulatory landscape for 'natural' claims and GMOs, laying out how there is no direct regulation by the FDA of the term 'natural,' nor any requirement that a company disclose on a food product's label whether it contains GMOs." (Plaintiff's Memorandum of Points and Authorities in Opposition [Dkt. No. 47, "Oppo."] at 1:12-15, citing FAC at ¶¶ 20-25.) However, Plaintiff wrongly concludes that there is no agency charged with determining whether food labels may properly state that GMO products can be labeled "all natural." The FDCA and NLEA unquestionably and squarely give that authority to the FDA.

Under these circumstances, deference to the FDA's regulatory authority is the appropriate course. *Pom Wonderful, LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1176 (9th Cir. 2012); *Clark*, 523 F.3d at 1114. Otherwise, the Court would risk "usurp[ing] the FDA's interpretive authority[,]" and "undermining, through private litigation, the FDA's considered judgments." *Pom Wonderful,* 679 F.3d at 1176, 1178.

Based upon the foregoing, the Court is inclined to Order that:

(1) this Action be Stayed for a period of six months and referred to the United States Food and Drug Administration for determination of whether products containing GMO or bioengineered ingredients may properly be labeled "Natural" or "All Natural;

(2) counsel will confer and submit an agreed upon form of Order for Referral within ten days;

(3) the parties and counsel will cooperate in expediting the presentation of this question to the FDA, including assembling any materials or information required by the FDA;

(4) counsel will notify this Court promptly of any determination by the FDA; and

(5) Defendant's Motion (Dkt. No. 37) is granted with respect to the stay only and is otherwise denied without prejudice to re-filing upon an order dissolving the stay ordered herein.

No later than **5:00 p.m.** on **Monday, June 10, 2013**, the parties may JOINTLY stipulate in writing to entry of this tentative ruling. Otherwise, the hearing will take place as scheduled.

The parties should be prepared to address the issues above at the hearing. If the parties intend to rely on authorities not cited in their briefs, they must notify the Court and opposing counsel of these authorities reasonably in advance of the hearing by filing a statement of supplemental authorities, with pinpoint cites, and without argument or additional briefing. *Cf.* Civil L. R. 7-3(d). Copies of the cases should not be filed in the docket, but rather, Counsel should be prepared to provide copies of the supplemental authorities at the hearing. The parties will be given the opportunity at oral argument to explain their reliance on such authority.

IT IS SO ORDERED.

Date: June 7, 2013

YVONNE GONZALEZ ROGERS
UNITED STATES DISTRICT COURT JUDGE