

Recipe For Primary Jurisdiction Goes 'Natural'

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Law360, New York (November 21, 2016, 10:34 AM EST) -- Despite the number of products advertised as “all natural” or “natural,” the U.S. Food and Drug Administration has not provided much guidance to companies or consumers as to what the agency believes the term actually means. Inconsistency in industry’s use of the term and in court rulings has therefore created fertile ground for plaintiffs’ attorneys. For many years, the FDA’s only official reference to the definition of “natural” as used in food labeling was an informal “policy” regarding appropriate use of the word.

In November 2015, however, the FDA announced a formal request for comments from the public and industry to determine if “natural” should be formally defined and, if so, what that definition should be.[1] This change in the FDA’s position has led at least 11 courts to stay litigation involving the term “natural” until the agency completes its regulatory proceeding, and the trend is likely to continue.

Primary Jurisdiction

Primary jurisdiction is a common law doctrine that “comes into play whenever enforcement of [a cognizable] claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body[.]”[2] Under the doctrine, courts can stay or dismiss the implicated claims pending input from the administrative body.[3] Although the doctrine is permissive with no formulaic method for application, it is generally invoked when staying or dismissing the case would promote uniformity and provide the agency with an opportunity to offer input based on its expert and specialized knowledge of the issues.[4]

FDA Proceedings Regarding “Natural” Food

The FDA’s nonbinding guidance states that “natural” means “nothing artificial or synthetic (including colors 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.”[5] After receiving citizen petitions and requests for administrative



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determinations from courts, the FDA sought public comments regarding the use of the term “natural” on food labels.[6] Included in the request for comments is whether “natural” should apply to “foods that are genetically engineered or contain ingredients produced through the use of genetic engineering.”[7] The comment period closed on May 10, 2016.[8]

Because the FDA is reviewing the term, an increasing number of courts have stayed cases to allow the FDA to use its expertise and specialized knowledge to define “natural” as it applies to food, and to avoid inconsistency among different jurisdictions, which could ultimately require manufacturers to have different labels in different parts of the country. Due to the nature of the orders at issue, there could be other unreported decisions that are not discussed below. Based on the reported cases stayed thus far, however, any claim based on the presence of artificial or synthetic ingredients or genetically engineered ingredients should be evaluated to determine whether a stay is appropriate.

Applying Primary Jurisdiction in Light of FDA Proceedings

At this time, the Ninth Circuit and 10 district courts in California, Missouri, New Jersey and New York have determined the FDA’s proceedings require entry of a stay. In *Kane v. Chobani*, the plaintiffs appealed the dismissal by the district court under Federal Rule of Civil Procedure 12(b)(6) of their putative class action regarding use of the terms “natural” and “evaporated cane juice” on yogurt produced by Chobani.[9] On appeal, the Ninth Circuit concluded the dismissal was inappropriate, but that the case should be stayed under the primary jurisdiction doctrine because “[t]he delineation of the scope and permissible usage of the[se] terms ... in connection with food products ‘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.’”[10] Accordingly, the case was remanded and stayed pending resolution of the issues by the FDA.[11] Following the precedent of the Ninth Circuit, four California district courts also stayed cases based on “natural” food label claims, and a fifth case was stayed based on the parties’ stipulation.[12]

Despite the fairly clear decision that a stay was appropriate in *Kane*, which was decided in March 2016, the Ninth Circuit upheld a California district court’s decision not to stay a case under primary jurisdiction in September.[13] Because the district court’s decision is reviewed for abuse of discretion and the lower court had actually evaluated the argument, the fact that the Ninth Circuit was not inclined to reverse is not particularly surprising.[14] The Ninth Circuit’s independent evaluation of primary jurisdiction is a significant indication that entering a stay under primary jurisdiction is appropriate.

Genetically engineered or modified food is also affected by the FDA’s proceedings. In a case involving whether bioengineered corn could be labeled “all natural corn,” the New Jersey district court found that the FDA’s proceedings, which sought comments on genetically engineered foods, made staying the case the most prudent course of action.[15] Likewise, in New York, a case alleging the “natural” product improperly contained sugar derived from genetically modified organisms was stayed pending resolution of the FDA proceedings.[16]

Because the FDA’s decision was so recent, prior cases declining to stay or dismiss under primary jurisdiction are likely distinguishable. Although the Southern District of New York suggested a “split among courts” regarding whether the FDA’s technical expertise should be valued over the experience of judges, the cases cited predate the FDA proceedings.[17] Thus, the prior cases cited were evaluating FDA expertise that was unlikely to be offered. Despite this split, the court did ultimately find that a stay was prudent.[18] Two judges in the Eastern District of Missouri have also recently stayed cases.[19] In *George*, the court specifically noted that while previous claims regarding misbranding had been allowed

to proceed, the FDA's recent decision to reexamine the term "natural" made application of the primary jurisdiction doctrine appropriate.[20] Therefore, even if prior cases rejected application of the primary jurisdiction, courts are likely to reevaluate the issue based on the change in circumstances.

Managing Cases Stayed Under the Primary Jurisdiction Doctrine

Although several courts have determined stays are appropriate regarding "natural" claims, the courts have not been uniform in their approach to managing cases while the stay is in place. In some cases, the courts ordered periodic status updates or requests for extension of the stay.[21] While this approach provides the court with updates, it also imposes a burden on the parties to prepare and submit those updates, which may state only that there has been no change in the FDA proceedings. Other courts have instead allowed the parties to simply inform the court when the FDA resolves the issue.[22] Because a stay under the primary jurisdiction doctrine should remain in effect until the agency completes its review of the issue, the most economical approach may be for the court to require the parties to contact the court upon resolution of the FDA proceedings.

Attorneys with pending litigation should evaluate whether the primary jurisdiction doctrine is implicated in their cases based on these new developments. Even if a motion to stay was previously unlikely to succeed, the recent FDA activity may make reevaluation of the issue fruitful.

DISCLOSURE: Shook Hardy & Bacon represents Pinnacle Foods Group in Thornton v. Pinnacle Foods Group LLC and Blue Diamond Growers, in George v. Blue Diamond Growers.

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[1] Use of the Term "Natural" in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69905 (Nov. 12, 2015).

[2] United States v. W. Pac. R. Co., 352 U.S. 59, 64 (1956).

[3] Id.

[4] Id.

[5] Food Labeling: Nutrient Content Claims, General Principals, Petitions, Definition of Terms, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

[6] Use of the Term "Natural" in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69905 (Nov. 12, 2015).

[7] Id.

[8] Docket information available at: <https://www.regulations.gov/document?D=FDA-2014-N-1207-1827>

[9] 645 F. App'x 593, 594 (9th Cir. 2016).

[10] *Id.* at 594 (quoting *Astiana v. Hain Celestial Grp. Inc.*, 783 F.3d 753, 760 (9th Cir. 2015)).

[11] *Id.* at 594-95.

[12] *Maxwell v. Unilever United States Inc.*, 2016 WL 5110498, at *1 (N.D. Cal. March 30, 2016); *Mains v. Whole Foods Market Inc.*, No. 12-cv-5652, 2016 WL 5791414 at 3 n.2 (N.D. Cal. April 18, 2016); *In re Hain Celestial Seasonings Products Consumer Litig.*, No. 8:13-cv-1757, 2016 WL 6302513 (C.D. Cal. May 10, 2016); *Viggiano v. Johnson & Johnson*, 2016 WL 5110500, at *2-3 (C.D. Cal. June 21, 2016); *Anderson v. The Hain Celestial Grp.*, No. 14-cv-03895, Dkt. 62 (N.D. Cal. April 8, 2016) (stayed by stipulation).

[13] *Brazil v. Dole Packaged Foods LLC.*, --- F. App'x ---, 2016 WL 5539863, at *1 (9th Cir. Sept. 30, 2016).

[14] *Id.*

[15] *In re Gen. Mills Inc. Kix Cereal Litig.*, 2016 WL 5110499, at *1 (June 13, 2016). In 2013, the district court referred the case to the FDA, but the FDA declined to make a determination. *Id.*

[16] *Forsher v. J.M. Smucker Co.*, No. CV 2015-7180 (RJD)(MDG), 2016 WL 5678567, at *1-2 (E.D.N.Y. Sept. 30, 2016).

[17] *In re KIND LLC Healthy & Nat. Litig.*, 2016 WL 4991471, at *4 (S.D.N.Y. Sept. 15, 2016) (citing *In re Frito-Lay N. Am., Inc. All Nat. Litig.*, 2013 WL 4647512, at *8 (E.D.N.Y. Aug. 29, 2013); *Ault v. J.M. Smucker Co.*, 2014 WL 1998235, at *5 (S.D.N.Y. May 15, 2014)).

[18] *In re KIND LLC Healthy & Nat. Litig.*, 2016 WL 4991471, at *6.

[19] See *George v. Blue Diamond Growers*, No. 4:15-cv-962, 2016 WL 1464644, at *3 (E.D. Mo. April 14, 2016); *Thornton v. Pinnacle Foods Grp. LLC*, No. 4:16-cv-00158, 2016 WL 5793193, at *2 (E.D. Mo. Sept. 30, 2016).

[20] *George*, 2016 WL 1464644, at *2-3.

[21] See, e.g., *Thornton*, 2016 WL 5793193, at *2; *In re Gen. Mills Inc. Kix Cereal Litig.*, 2016 WL 5110499 at *1; *In re KIND LLC Healthy & Natural Litig.*, 2016 WL 4991471, at *7.

[22] See, e.g., *George*, 2016 WL 1464644, at *3; *Viggiano*, 2016 WL 5110500, at *3.