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PRACTICE TIP

How to Mediate a Product Liability Case

By Kevin Curry and Jennifer Bullard

"As a peacemaker the lawyer has a superior opportunity of being a good man. There will still be business enough." — Abraham Lincoln.

Mediation is a common feature of product liability practice. If done well, mediation earns you favor with your clients. They recognize that mediation is an opportunity to control the case outcome and save money. But before entering into mediation, preparation is crucial. Once at mediation, listen carefully to all parties present, including the mediator. If you prepare and listen, you increase the odds of a favorable result.

Build a Relationship With the Other Attorneys

Mediation, like politics, is the art of the possible. Building a good relationship with opposing counsel will pay dividends, and expand the scope of the possible. Discovery is the primary avenue to learn about the case. But frank pre-mediation discussions among counsel are also valuable. Use these discussions to ensure that all parties have the information necessary to evaluate the case. At the same time, use the discussions to

continued on page 7

I'll See You in the Agency!

'Primary Jurisdiction' Gains Ground As a Defense for Regulated Industries

By Cary Silverman

A barrage of lawsuits against food and other companies asserting that advertising or labeling of their products is misleading, even as government regulators have not challenged the representations, has led attorneys representing the companies increasingly to raise the "primary jurisdiction" doctrine as a defense. In essence, the doctrine provides that courts should not take jurisdiction of cases where the core issue raised by the plaintiff's claim is subject to the expertise of a federal agency.

This year, manufacturers used the primary jurisdiction doctrine to achieve several significant victories. This article briefly explores the underpinnings of the primary jurisdiction doctrine, highlights its use in product cases in 2012 and 2013, and considers the role primary jurisdiction may play in future consumer class action litigation and beyond.

The Primary Jurisdiction Doctrine

The primary jurisdiction doctrine should be of interest to any business, subject to the jurisdiction of a federal agency, that faces litigation challenging an aspect of a product, or its labeling or advertising. The flexibility of the doctrine may provide product makers with an additional, attractive public-policy-driven alternative to the more traditional federal preemption and compliance-with-standards defenses. Courts have applied the doctrine to dismiss cases where:

- An agency has adopted a formal regulation with which the company complied;
- An agency adopted an informal policy and may intervene through an enforcement or other action if it finds the practice at issue is unlawful in a specific instance;

continued on page 2

In This Issue

Primary Jurisdiction

continued from page 1

- An agency is considering adopting a policy on the practice at issue, even if the agency has not done so after several years of deliberation;
- An agency has effectively allowed the practice by not regulating it, even as it has issued regulations applicable to other specific aspects of the product; or
- There is an administrative petition pending before an agency involving the practice at issue.

Courts have recently shown an increasing acceptance of the primary jurisdiction doctrine in food and cosmetic cases. The principles of the doctrine, however, apply equally to cases involving other Food & Drug Administration (FDA)-regulated products, such as pharmaceuticals, or consideration of product issues by other agencies, such as the Consumer Product Safety Commission (CPSC) or National Highway Traffic Safety Administration (NHTSA).

General Principles

The primary jurisdiction doctrine is based on sound jurisprudence. It allows a court to decide not to hear a claim when it implicates technical or policy questions that are best addressed in the first instance by a government agency with regulatory authority over the product or service at issue rather than by the judicial branch. *See Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). While the primary jurisdiction doctrine has been around for over a century, it has newfound importance in suits alleging deceptive labeling or advertising.

The doctrine "applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues, which, under a regulatory scheme, have been placed within the special competence of an administrative body. ... " *CSX Transp. Co. v. Novolog Bucks County*, 502 F.3d 247, 253 (3d Cir. 2007) (quoting *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956)). The doctrine does not limit a court's authority, but "serve[s] as a means of coordinating administrative and judicial machinery and to promote uniformity and take advantage of the agencies' special expertise." *Id*. (citation omitted).

A court 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 that (4) requires expertise or uniformity in administration." *Syntek v. Semiconductor Co., Ltd. v. Microchip Tech., Inc.*, 307 F.3d 775, 781 (9th Cir. 2002). When a core issue in a case meets this test, a court has discretion either to stay the case and retain jurisdiction, or dismiss the suit without prejudice. Since there is no formal mechanism for the court to refer the question at issue to the agency, the parties are responsible for initiating administrative proceedings themselves. *See id*. at 782 n.3.

The primary jurisdiction doctrine resembles other familiar principles. For example, similar to the doctrine of *forum non conveniens* as applied in most states, the primary jurisdiction doctrine permits a court to dismiss a case that is more appropriately heard in another venue. It also has some likeness to the political question doctrine, through which courts may decline to exercise jurisdiction over a public policy matter that is best decided by Congress through the political process. Under all three doctrines, prudential considerations prompt courts to decline to hear disputes where another body has greater institutional competence for resolving the issue in an effective and fair manner.

continued on page 3

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Primary Jurisdiction

continued from page 2

Over the years, courts have applied the primary jurisdiction doctrine to cases involving practices falling under the jurisdiction of various agencies, including cases raising environmental issues falling under the purview of the Environmental Protection Agency (EPA), conduct by telecommunication service providers subject to the Federal Communications Commission (FCC), and, as this article discusses, food and cosmetic representations falling under the jurisdiction of the FDA, U.S. Department of Agriculture (USDA), and Federal Trade Commission (FTC).

When issues raised in litigation are subject to the jurisdiction of state administrative agencies, similar principles apply through operation of the "*Burford* abstention doctrine," a federal law's commitment of the issue to state regulators, or state common law. *See, e.g., Burford v. Sun Oil Co.*, 319 U.S. 315 (1943) (providing that federal courts should avoid interfering with proceedings or orders of state administrative agencies on public policy issues that transcend the case before the court or where federal review of the issue would disrupt state efforts to establish a coherent policy with respect to a matter of substantial public concern); *Davies v. National Cooperative Refinery Ass'n*, 963 F. Supp. 990, 997-99 (D. Kan.1997) (dismissing citizen suit brought under Resource Conservation and Recovery Act as within specialized expertise of state environmental agency); *State ex. rel. Norvell v. Arizona Pub. Serv. Co.*, 510 P.2d 98, 103-04 (N.M. 1973) (applying the primary jurisdiction doctrine to state agencies as a matter of common law).

The Rise of Primary Jurisdiction in Product-Related Cases

Successful Use: Labeling of Juice Drinks, Yogurt, and Cosmetic Products

This past year's most high-profile win through use of the primary jurisdiction doctrine occurred in a commercial dispute, but the ruling is already having a significant impact in consumer class actions. In May 2012, the Ninth Circuit ruled in a case pinning Pom Wonderful, the manufacturer of pomegranate juice beverages, against Coca-Cola. Pom claimed that Coke's labeling of a competing product, Minute Maid "Pomegranate Blueberry," was deceptive because the product largely consisted of apple and grape juices. Pom sought to require Coke to place the phrase "Flavored Blend of Five Juices," which already appeared on the label, in a font of equal size and prominence to the product name.

A three-judge panel of the Ninth Circuit affirmed the district court's dismissal of the Latham Act claim, finding that when a plaintiff's claim requires a court to decide an issue committed to the FDA's expertise, dismissal in deference to the agency is the proper result. The court noted that FDA regulations govern statements that must appear on such labeling, and specify how prominently and conspicuously those statements must appear. "As best as we can tell," the court found, "FDA regulations authorize the name Coca-Cola has chosen" and the label abides by FDA requirements.

The court, however, made clear that it was not holding that the label was non-deceptive, distinguishing the primary jurisdiction doctrine from a regulatory compliance defense. Rather, it deferred to the FDA to take action if the agency believed the labeling would mislead consumers. "[U]nder our precedent, for a court to act when the FDA has not — despite regulating extensively in this area — would risk undercutting the FDA's expert judgments and authority," Circuit Court Judge Diarmuid F. O'Scannlain wrote. *See Pom Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1177-78 (9th Cir. 2012). Pom has filed a petition for a writ of certiorari and, on March 25, the U.S. Supreme Court asked the Solicitor General to weigh in on whether it should grant review.

The primary jurisdiction doctrine was also a key factor when a federal district court in Minnesota dismissed a consumer class action challenging General Mill's labeling of Yoplait Greek yogurt in December 2012. In that case, the plaintiff alleged violations of Minnesota consumer protection law, claiming that the Yoplait Greek products are "neither Yogurt nor Greek, as those terms are used in the industry and defined by regulation." The plaintiff took particular issue with General Mill's use of Milk Protein Concentrate (MPC), a blend of dairy products, which is listed among the product's ingredients. MPC results in the thickness and protein content of typical Greek yogurt, but does not require the straining process traditionally used for producing Greek yogurt. In 1981, the FDA promulgated standards for yogurt, low-fat yogurt, and nonfat yogurt, but did not implement a provision regarding the use of "other optional ingredients." In 2009, the FDA proposed a rule updating its yogurt standard, which would recognize MPC as a permissible ingredient, but the rule remained on hold as the FDA did not schedule a public hearing "due to competing priorities and limited resources." Meanwhile, plaintiffs' lawyers filed several consumer class actions against the Greek yogurt makers.

U.S. District Court Judge Susan Richard relied on the primary jurisdiction doctrine to dismiss the suit without prejudice, concluding, "the FDA is in the best position to resolve any ambiguity about the standard of identity for yogurt — a matter requiring scientific and nutritional expertise." Judge Richard found it "imprudent for the Court, at this juncture, to substitute its judgment for that of the Agency's while revision of the standard of identity is pending." She recognized that FDA action would help ensure national uniformity in labeling, as contrasted with the flood of class action lawsuits on the issue, which may result in inconsistent rulings. Judge Richard dismissed the claim even as she acknowledged that the FDA's pronouncements on the issue

continued on page 4

Primary Jurisdiction

continued from page 3

"do not constitute a model of clarity." *Taradejna v. General Mills Inc.*, No. 12-993, 2012, 174264 WL 6113146, at *5 (D. Minn. Dec. 10, 2012). Thus, even if agency policy or practice does not definitively support the regulated party's position, and resolution of the issue involved in the litigation is not a high agency priority, Taradejna supports dismissal where the issue is within the agency's expertise.

Years earlier, General Mills and others were also successful in using the primary jurisdiction doctrine to persuade a court to dismiss a group's challenge to an advertising campaign promoting the weight loss benefits of consuming dairy products. Just before commencing litigation, the group had filed administrative petitions with the FTC and FDA, leading the district court to find those agencies better suited to consider the scientific basis of the representations and the probable impact on consumers. *Physicians Committee for Responsible Medicine v. General Mills, Inc.*, No. 05-cv-958, 2006 WL 3487651, at *6 (E.D. Va. Nov. 30, 2006), aff'd on other grounds, 283 Fed. Appx. 139 (4th Cir. 2008).

The primary jurisdiction doctrine, of course, applies to a wide range of products and services, not just food. For example, in November, Judge Phyllis J. Hamilton dismissed a consumer class action related to use of "natural" on lotions, deodorants, and other products. The court found that the plaintiffs could not argue that such claims were misleading due to artificial or synthetic ingredients in the cosmetics because, relying on *Pom Wonderful*, "Congress had entrusted the task of guarding against deception to the FDA," which had issued "remarkably specific" requirements for cosmetic labeling but that were silent on use of the term "natural." Private litigation, the court found, would "undercut the FDA's expert judgments and authority." Judge Hamilton concluded that "[i]n absence of any FDA rules or regulations (or even informal policy statements) regarding use of the word 'natural' on cosmetic labels, the court declines to make any independent determination of whether defendant's use of 'natural' was false of misleading." *Astiana v. Hain Celestrial Grp., Inc.*, No. 11-cv-6342-PJH, 2012 WL 5873585, at *3 (N.D. Cal. Nov. 19, 2012).

A lawsuit brought by a competitor regarding whether Dr. Bronner's Magic Soaps qualified as "organic," as labeled suffered a similar fate. In that instance, the U.S. Department of Agriculture had repeatedly shifted its position on whether its organic standards applied to personal care products. The agency then indicated an interest in developing a comprehensive approach to such products with the FDA and FTC. While the USDA had struggled with this issue for over a decade, Judge Susan Illston found "[t]he fact that the USDA has not acted quickly enough, in the plaintiff's view, to develop and promulgate regulations regarding the labeling of personal care products does not mean that the Court may adjudicate plaintiff's Latham Act claim without impermissibly intruding on the USDA's jurisdiction." *See All One God Faith, Inc. v. Hain Celestrial Grp., Inc.*, No. 09-cv-3517, 2012 WL 3257660, at *10 (N.D. Cal. Aug. 8, 2012).

Not All Courts Have Applied the Primary Jurisdiction Doctrine

While defendants persuaded several courts to dismiss deceptive practices claims on primary jurisdiction grounds in a variety of circumstances, not all judges have applied it in food-related cases. For instance, ConAgra Foods raised the primary jurisdiction defense in a lawsuit challenging the labeling of Pam cooking spray, Hunt's tomato products, and Swiss Miss cocoa. The plaintiffs took issue with ConAgra's characterizing products as "100 natural" when they contained a propellant or preservatives, its touting of foods as "organic" when they contained certain allegedly disqualifying ingredients, and the company's antioxidant representations, among other claims, under California consumer protection laws. In rejecting ConAgra's argument that the FDA has primary jurisdiction over such matters, Judge Charles R. Breyer found instructive that the FDA has not issued a formal rule on use of the term "natural" on food labeling. The FDA's inaction, the court found, weighed against a need for uniformity in administration of labeling. Nor did the court regard the case as requiring the special expertise of the FDA. "[T]his case is far less about science than it is about whether a label is misleading," the court concluded. *Jones v. ConAgra Foods, Inc.*, No. 12-cv-1633, 2012 WL 6569393 (N.D. Cal. Dec. 17, 2012).

This Year's Primary Jurisdiction Rulings

Food makers are continuing to raise primary jurisdiction as a defense, a trend that we expect to continue in 2013 and expand to products regulated by other agencies.

For instance, on the heels of its successful use of the primary jurisdiction doctrine in the Minnesota Greek Yogurt class action, and bolstered by the *Pom Wonderful* and *Astiana* rulings, General Mills raised the doctrine as a defense in a class action over whether Nature Valley granola bars are "100% Natural" when they contain high-fructose corn syrup, high-maltose corn syrup, or the texturizer maltodextrin. General Mills' motion to dismiss acknowledges that the FDA has not adopted a formal regulation defining the term "natural" for food labeling, but notes that the agency has repeatedly issued guidance interpreting the term and routinely enforced this informal policy by issuing letters to manufacturers calling for corrective action to the label when it deems the label deceptive. If the FDA, in its expert judgment, believes more should be done to protect consumers, or that General Mill's advertising is deceptive, the agency can act. *Janney v. General Mills*, No. 12-cv-3919-PJH (N.D. Cal. motion filed Dec. 3, 2012).

continued on page 6

Primary Jurisdiction

continued from page 4

Campbell's Soup Co. is also among the companies facing lawsuits claiming that their products are not "100 Percent Natural" as labeled. A class action claims that Campbell's misrepresented seven of its soups as natural because they may contain genetically modified corn or soy ingredients. Campbell's moved to dismiss the case on the ground that the USDA, which has jurisdiction over the two chicken soup products that constituted the plaintiff's only purchases, inspected the labels and found them compliant with applicable regulations. USDA policy, Campbell's says, makes no distinction between ingredients developed through biotechnology and those resulting from research using conventional techniques. Campbell's also notes that USDA's informal policy allows products to be advertised as "natural" so long as they do not contain any artificial flavor, color, or chemical preservative, or any other artificial ingredient, and the product and its ingredients are not more than minimally processed. While the motion to dismiss largely focuses on preemption, Campbell's raises the primary jurisdiction doctrine as an alternative basis to dismiss the claim. *Barnes v. Campbell Soup Co.*, No. 12-cv-5185, at 8n.7 (N.D. Cal. motion filed Feb 13, 2013).

As of the writing of this article, the Northern District of California had not ruled on General Mills' or Campbell's motions to dismiss. In February 2013, however, that court dismissed, on primary jurisdiction grounds, a claim that Kraft Foods had engaged in a deceptive practice by stating that the serving size of Dentyne breath mints is "one mint." This claim was predicated on an FDA regulation that, according to plaintiff, would have required a serving size of four mints. The FDA, however, proposed a smaller serving size for breath mints in 1997, solicited comments on the proposal in 2005, and placed the issue on its regulatory agenda for 2012. Since that the FDA was in the process of amending the serving size regulation, Judge Ronald M. Whyte "decline[d] to usurp the FDA's expertise in this area." With respect to state consumer protection claims challenging statements on several other product labels, Judge Whyte found the primary jurisdiction doctrine inapplicable because the alleged violations "mirror or are identical to the FDA provisions which require no original interpretation by this court." Where the court found clear compliance with federal labeling requirements, the court dismissed claims on preemption grounds. The court allowed various other claims, including those challenging "100% natural" representations on the labeling of granola and cheese products, to go forward. *See Ivie v. Kraft Foods Global, Inc.*, No. 12-2554 (N.D. Cal. Feb. 25, 2013).

The wide variation in court rulings applying the primary jurisdiction doctrine provides the U.S. Supreme Court with an opportunity in *Pom Wonderful* to provide helpful guidance on use of the doctrine in cases involving labeling regulated by federal agencies.

Practice Considerations

Primary jurisdiction should be considered an important defense for companies whose products or services are subject to federal regulation. In both consumer protection and product liability cases in which a government agency has regulated a product's design, labeling, or marketing, the flexibility of the primary jurisdiction doctrine may provide an additional, attractive public-policy driven alternative to the more traditional federal preemption and compliance with standards defenses.

Unlike federal preemption, a constitutional principle rooted in the Supremacy Clause, the primary jurisdiction doctrine does not require a conflict between a tort claim and a particular regulation or evidence that Congress sought to displace an entire regulatory field. *See* Victor E. Schwartz & Cary Silverman, Preemption of State Common Law by Federal Agency Action: Striking the Appropriate Balance that Protects Public Safety, 84 *Tulane L. Rev.* 1203 (2010). The primary jurisdiction doctrine allows the court to consider an agency's informal guidance, enforcement history, or even an agency's decision to further deliberate and not to act on a particular issue.

Nor does the primary jurisdiction doctrine require a finding that the manufacturer complied with a government standard that specifically regulates the product, practice, or representation at issue. Most state consumer protection laws provide a statutory regulatory compliance defense. *See* Victor E. Schwartz, Cary Silverman & Christopher E. Appel, "That's Unfair!" Says Who — The Government or Litigant?: Consumer Protection Claims Involving Regulated Conduct, 47 *Washburn L.J.* 93 (2007). The primary jurisdiction doctrine may provide an effective alternative where a state consumer protection law lacks such a provision, where state courts have narrowly interpreted the scope of the regulatory compliance defense, or where an agency has effectively authorized a practice by opting not to regulate it. The doctrine does not necessarily require compliance; it only requires finding that an agency, not a court, is in the best position to evaluate the lawfulness of the practice at issue.

Conclusion

In sum, primary jurisdiction has come to the forefront of food and cosmetic litigation because of the onslaught of consumer class actions challenging the advertising of products as "natural" or "organic." The history of, and public policy underlying, the doctrine shows that it has broader application in litigation involving a wide range of products. As courts become more familiar with a revitalized primary jurisdiction doctrine in the onslaught of food lawsuits, judges may become more receptive to such arguments in litigation involving other regulated products and industry conduct.

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