FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

SKYE ASTIANA; TAMAR DAVIS LARSEN, on behalf of themselves and all others similarly situated, *Plaintiffs-Appellants*, v. THE HAIN CELESTIAL GROUP, INC., a Delaware corporation; JASON NATURAL PRODUCTS, INC., a California corporation, *Defendants-Appellees*.	No. 12-17596 D.C. No. 4:11-cv-06342-PJH OPINION

Appeal from the United States District Court
for the Northern District of California
Phyllis J. Hamilton, Chief District Judge, Presiding

Argued and Submitted
February 10, 2015—San Francisco, California

Filed April 10, 2015

Before: Sidney R. Thomas, Chief Judge and A. Wallace Tashima and M. Margaret McKeown, Circuit Judges.

Opinion by Judge McKeown

SUMMARY*

Preemption / Primary Jurisdiction / Food and Drug Administration

The panel reversed the district court's Fed. R. Civ. P. 12(b)(6) dismissal of a quasi-contract cause of action, and dismissal of California state law claims under the primary jurisdiction doctrine in a putative nationwide class action claiming that the class members were deceived into purchasing "natural" cosmetics.

Primary jurisdiction is a prudential doctrine that permits courts to determine whether a claim implicates technical and policy questions that should first be addressed by an agency with regulatory authority over the relevant industry.

The panel held that the Food, Drug, and Cosmetic Act did not expressly preempt California's state law causes of action that create consumer remedies for false or misleading cosmetics labels. The panel also held that although the district court properly invoked the primary jurisdiction doctrine, it erred by dismissing the case rather than issuing a stay pending potential agency action by the Food and Drug Administration. The panel indicated that on remand, the district court may consider whether events during the pendency of the appeal had changed the calculus on whether further FDA proceedings were necessary. Finally, the panel concluded that the district court erred in dismissing the

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

quasi-contract cause of action as duplicative of, or superfluous to, the putative class's other claims.

COUNSEL

Joseph N. Kravec, Jr. (argued) and Wyatt A. Lison, Feinstein Doyle Payne & Kravec, LLC, Pittsburgh, Pennsylvania; Michael D. Braun, Braun Law Group, P.C., Los Angeles, California; Janet Lindner Spielberg, Law Offices of Janet Lindner Spielberg, Los Angeles, California, for Plaintiffs-Appellants.

James M. Schurz (argued) and Lisa A. Wongchenko, Morrison & Foerster LLP, San Francisco, California, for Defendants-Appellees.

OPINION

McKEOWN, Circuit Judge:

A product labeled "all natural" or "pure natural" likely evokes images of ground herbs and earth extracts rather than chemicals such as "Polysorbate 20" or "Hydroxycitronellal." This class action alleges that false or misleading product labels duped consumers seeking natural cosmetics into purchasing products that were chock-full of artificial and synthetic ingredients. Although the underlying question of what constitutes a "natural" cosmetic poses a fascinating question, it is not the one we answer. Instead, this appeal requires us to decide whether federal preemption or the primary jurisdiction doctrine prevents the district court from

deciding when a "natural" label on cosmetic products is false or misleading.

We conclude that the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), does not expressly preempt California's state law causes of action that create consumer remedies for false or misleading cosmetics labels. Although the district court properly invoked the primary jurisdiction doctrine, it erred by dismissing the case rather than issuing a stay pending potential agency action by the Food and Drug Administration ("FDA"). On remand, the district court may consider whether events during the pendency of this appeal have changed the calculus on whether further FDA proceedings are necessary.

Background

The Hain Celestial Group and JĀSÖN Natural Products (collectively "Hain") make moisturizing lotion, deodorant, shampoo, conditioner and other cosmetics products. Hain labels these products "All Natural," "Pure Natural," or "Pure, Natural & Organic."

Skye Astiana, Tamar Davis Larsen, and Mary Littlehale (collectively "Astiana") filed a putative nationwide class action claiming that they were deceived into purchasing Hain's cosmetics, which contain allegedly synthetic and artificial ingredients ranging from benzyl alcohol to airplane anti-freeze. Astiana claims she likely would not have purchased—and certainly would not have paid the going price for—Hain's cosmetics had she been aware of their synthetic and artificial contents. Astiana sought injunctive relief and damages under the federal Magnuson-Moss Warranty Act,

California's unfair competition and false advertising laws, and common law theories of fraud and quasi-contract.

Hain filed two motions to dismiss the complaint. First, it moved to partially dismiss the suit under Federal Rule of Civil Procedure 12(b)(6). As relevant here, the district court dismissed the quasi-contract cause of action, noting that "while restitution is available as a remedy for plaintiffs' other causes of action, it is not a standalone cause of action in California and is nonsensical as pled in any event."[1]

In its second motion to dismiss, Hain asserted that Astiana's state law claims are preempted by the FDCA. In the alternative, Hain urged that the suit should be stayed or dismissed under the primary jurisdiction doctrine. The district court found the latter argument persuasive and dismissed Astiana's claims so the parties could seek expert guidance from the FDA.

Analysis

I. PREEMPTION

Hain argues that the FDCA expressly preempts Astiana's state law claims. Although the district court did not address this argument, Hain asks us to do so, citing our authority to "affirm on any grounds supported by the record." *Franklin v. Terr*, 201 F.3d 1098, 1100 n.2 (9th Cir. 2000). We accept this invitation because this purely legal question remains a threshold issue for resolution.

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[1] The district court also dismissed plaintiff Littlehale from the suit. Littlehale initially appealed this ruling, but voluntarily dismissed her appeal before oral argument.

In analyzing express preemption, we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). The FDCA proscribes any cosmetics labeling that is "false or misleading in any particular." 21 U.S.C. § 362(a). The more specific preemption language prohibits any state or local government from "establish[ing] or continu[ing] in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with" federal rules. 21 U.S.C. § 379s(a). Hain's argument that this language expressly preempts any state law claim that a cosmetic label is false or misleading does not square with Supreme Court precedent.

The preemption language of § 379s is virtually identical to the statutory text at issue in two Supreme Court cases: *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005). Like the statutes at issue in those cases, the FDCA bars states from imposing new or additional labeling "requirements," but is silent with regards to states' ability to provide remedies for violations of federal law. In light of this similarity, we have little difficulty concluding that the FDCA does not preempt state laws that allow consumers to sue cosmetics manufacturers that label or package their products in violation of federal standards.

In *Medtronic*, the Supreme Court considered whether the FDCA's prohibition on state medical device safety "requirements" that are "different from, or in addition to" federal requirements preempted state law product liability claims. 518 U.S. at 481 (quoting 21 U.S.C. § 360k(a)).

Looking to the text, the Court concluded that nothing in the statutory language "denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 495. Simply put, the availability of state law damages for violations of federal law "does not amount to [an] additional or different 'requirement.'" *Id.*

The Court reached a similar conclusion in *Bates*. There, chemical manufacturers argued that the labeling requirements of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*, preempted state law claims that their products failed to include adequate warnings. That statute mandates certain chemical labeling requirements and prohibits states from "impos[ing] or continu[ing] in effect any requirements for labeling or packaging in addition to or different from" federal requirements. 7 U.S.C. § 136v(b). The Court determined that this language is not an absolute bar to state law failure to warn claims, reasoning that FIFRA "does not . . . pre-empt any state rules that are fully consistent with federal requirements." *Bates*, 544 U.S. at 452. To the extent state law might be construed more broadly than federal law, the solution is not to prohibit state law suits altogether, but to "instruct the jury on the relevant [federal] standards, as well as any regulations that add content to those standards." *Id.* at 454.

Hain attempts to escape the dictates of the Supreme Court by arguing that Astiana's suit would create a "novel state labeling requirement" under California's Sherman Act, Health & Safety Code § 111730. This approach does not save the preemption argument. Astiana is not asking Hain to modify or enhance any aspect of its cosmetics labels that are required by federal law. Rather, she claims deception as a

result of advertising statements that contradicted the true ingredients listed on the FDA-mandated label. *See Williams v. Gerber Prods. Co.*, 552 F.3d 934, 939 (9th Cir. 2008) ("We do not think that the FDA requires an ingredient list so that manufacturers can mislead consumers and then rely on the ingredient list to correct those misinterpretations and provide a shield for liability for the deception."). FDA regulations do not require Hain to label its products as "All Natural" or "Pure Natural." If Astiana's suit ultimately requires Hain to remove these allegedly misleading advertising statements from its product labels, such a result does not run afoul of the FDCA, which prohibits "requirement[s]" that are "different from," "in addition to," or "not identical with" federal rules.

Hain also argues that the complaint's reference to the FDA's informal food labeling policy represents an attempt to create a state regulatory regime where no corresponding federal rules exist. This characterization does not ring true. Astiana referenced these regulations to demonstrate that Hain knew or should have known its products contained ingredients that would likely be considered synthetic and artificial. Notably, the complaint referenced Hain's correspondence with a non-profit organization for the same purpose.

Hain finally points out that the FDA has never issued regulations regarding the use of "natural" on cosmetics labels. That is true, but Hain then argues that the FDA's failure to issue specific regulations on the subject is tantamount to a conscious decision by the agency to permit any use of this term a manufacturer sees fit. This argument proves too much. By this logic, a manufacturer could make any claim—wild, untruthful, or otherwise—about a product whose contents are not addressed by a specific regulation. The statute, however,

proscribes statements that are "false or misleading in any particular," not statements that are "prohibited by specific FDA regulations." Indeed, in a "Small Business Fact Sheet" published on its website, the FDA itself stated that while the agency "has not defined" the word natural, all cosmetics labels must still be "truthful and not misleading."[2] This statement is, of course, consistent with § 362(a)'s prohibition on "false or misleading" labeling and reinforces our conclusion that the FDA did not intend to permit indiscriminate use of the word "natural" on cosmetics labels.[3]

The FDCA does not expressly preempt state causes of action predicated on federal cosmetics labeling laws. Astiana's state law claims that Hain's products were labeled in a way that was "false or misleading in any particular" may proceed.

II. PRIMARY JURISDICTION

We next address whether the district court properly dismissed Astiana's claims under the primary jurisdiction doctrine. Before we reach the merits of the district court's decision, we consider two procedural points raised by Astiana.

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[2] *Small Business & Homemade Cosmetics: Fact Sheet*, U.S. FDA, http://www.fda.gov/Cosmetics/ResourcesForYou/Industry/ucm388736.htm (last updated Oct. 20, 2014).

[3] To the extent Hain claims that no consumer would be deceived by a cosmetics label that contains the phrase "All Natural" because every cosmetic necessarily contains artificial, synthetic, or manufactured materials, this argument goes to the merits of Astiana's assertion that she was deceived by the allegedly false or misleading label, not the question of federal preemption.

Astiana first urges that Hain waived its right to seek dismissal on primary jurisdiction grounds because this defense was asserted in a pleading titled: "Motion to dismiss for lack of subject matter jurisdiction, pursuant to Federal Rule of Civil Procedure 12(h)(3)." Strictly speaking, this title was inaccurate because "[p]rimary jurisdiction is not a doctrine that implicates the subject matter jurisdiction of the federal courts." *Syntek Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir. 2002). In Astiana's view, the erroneous caption on Hain's motion constitutes waiver of the primary jurisdiction defense.

Astiana's position reads too much into the caption. Just as one can't judge a book by its cover, a pleading caption is hardly dispositive of the nature of the pleading. Astiana also overlooks the reality of what occurred in the briefing of the motion. Both Hain and Astiana addressed the merits of the primary jurisdiction argument without reference to the caption. Far from waiver, Hain's motion put Astiana on notice of the defense, and Astiana responded to this argument.

Astiana also urges us to acknowledge that its correspondence with the FDA during the pendency of this appeal demonstrates that the agency declined to take primary jurisdiction over this case. In a motion for judicial notice, Astiana asserts that her counsel sent a letter to the FDA in December 2013, four weeks after the district court dismissed her claims. The letter, which was not sent to opposing counsel or the court at that time, asserted inaccurately that there had been a "Referral for 21 C.F.R. [§] 10.25(c) Administrative Determination" in the case. Although § 10.25(c) permits federal courts to refer matters to the FDA for administrative proceedings, the district court did not do so

in this case. Rather, the court had already dismissed the case when Astiana requested that "the FDA render an administrative determination on the meaning of 'natural' as applied to personal care products regulated under the FDCA, or advise that the agency declines to make such a determination." Astiana's letter did not comply with the FDA's requirements for initiating a citizen petition. 21 C.F.R. § 10.30. The inquiry was never assigned a docket number, and the FDA's response was neither posted to its website nor published in any other capacity. *Cf.* 21 C.F.R. § 10.65(a) (noting that "correspondence" with FDA employees does not constitute final agency action "subject to judicial review").

Hain's counsel learned of this missive nearly two months later and immediately wrote a letter to the FDA urging it not to respond to Astiana's request for administrative guidance. In March 2013, Dr. Linda M. Katz, the Director of the FDA's Office of Cosmetics and Colors, responded to Astiana's initial request and outlined the procedures for establishing the meaning of the term "natural," absent a pre-existing definition. The letter noted that "making the requested determination without adequate public participation would not be in keeping with FDA's commitment to the principles of openness and transparency." Dr. Katz further observed that "priority cosmetic public health and safety matters are currently fully occupying the resources that FDA has available for proceedings on cosmetics matters" and "proceedings to define 'natural' do not fit within [the agency's] current health and safety priorities."

The question is what do we do with this private correspondence on appeal? Our answer: nothing. Because any consideration as to the weight or the substantive

implications of the letter should be left to the district court on remand, we deny Astiana's motion for judicial notice.

We now consider the meat of Astiana's claim: whether the district court's decision to dismiss the case under the primary jurisdiction doctrine was error. Although the district court properly invoked primary jurisdiction, it erred by dismissing the case without prejudice rather than staying proceedings while the parties (or the district court) sought guidance from the FDA.

Primary jurisdiction is a prudential doctrine that permits courts to determine "that an otherwise cognizable claim 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." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). In evaluating primary jurisdiction, we consider "(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 to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek*, 307 F.3d at 781.

Not every case that implicates the expertise of federal agencies warrants invocation of primary jurisdiction. Rather, the doctrine is reserved for a "limited set of circumstances" that "requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Clark*, 523 F.3d at 1114 (quoting *Brown v. MCI WorldCom Network Servs.*, 277 F.3d 1166, 1172 (9th Cir. 2002)) (internal quotation marks omitted). Without doubt, defining what is "natural" for cosmetics

labeling is both an area within the FDA's expertise and a question not yet addressed by the agency.

Nonetheless, courts must also consider whether invoking primary jurisdiction would needlessly delay the resolution of claims. *Reid v. Johnson & Johnson*, No. 12-56726, 2015 WL 1089583, at *12 (9th Cir. 2015); *United States v. Philip Morris USA Inc.*, 686 F.3d 832, 838 (D.C. Cir. 2012) ("The primary jurisdiction doctrine is rooted in part in judicial efficiency."). Under our precedent, "efficiency" is the "deciding factor" in whether to invoke primary jurisdiction. *Rhoades v. Avon Prods., Inc.*, 504 F.3d 1151, 1165 (9th Cir. 2007).[4]

Common sense tells us that even when agency expertise would be helpful, a court should not invoke primary jurisdiction when the agency is aware of but has expressed no interest in the subject matter of the litigation. Similarly, primary jurisdiction is not required when a referral to the agency would significantly postpone a ruling that a court is otherwise competent to make. *See Amalgamated Meat Cutters & Butcher Workmen of N. Am.*, 381 U.S. at 686 ("[Primary jurisdiction] does not require resort to an expensive and merely delaying administrative proceeding

[4] Although the Supreme Court has never expressly held that courts should weigh efficiency concerns against other factors relevant to primary jurisdiction, *see Ellis v. Tribune Television Co.*, 443 F.3d 71, 90 (2d Cir. 2006), the Court has discussed judicial economy in several of its primary jurisdiction opinions. *See, e.g.*, *Reiter v. Cooper*, 507 U.S. 258, 270 (1993) (expressing concern that invoking primary jurisdiction "could produce substantial delay"); *Local Union No. 189, Amalgamated Meat Cutters & Butcher Workmen of N. Am. v. Jewel Tea Co.*, 381 U.S. 676, 686 (1965) ("[T]he doctrine of primary jurisdiction is not a doctrine of futility.").

when the case must eventually be decided on a controlling legal issue wholly unrelated to determinations for the ascertainment of which the proceeding was sent to the agency.") (internal quotation marks and citation omitted).

On the record before it, the district court did not err in invoking primary jurisdiction. Determining what chemical compounds may be advertised as natural on cosmetic product labels is "a particularly complicated issue that Congress has committed to" the FDA. *See* 21 C.F.R. § 700.3 *et seq.* Obtaining expert advice from that agency would help ensure uniformity in administration of the comprehensive regulatory regime established by the FDCA.

While the FDA had shown some reticence to define "natural," Judge Hamilton was not alone in thinking that new guidance would be forthcoming. In response to a flurry of litigation over *food* labeling, three other district courts invoked the agency's primary jurisdiction to see if the FDA intended to offer further regulations regarding the use of the term "natural."[5] Following these referrals, which occurred around the same time Hain sought to invoke primary jurisdiction in this case, the FDA outlined the complexities of the issue and responded to the courts that "priority food public health and safety matters are largely occupying the limited resources that FDA has to address food matters." Letter from Department of Health & Human Services, *In Re Gen. Mills*, No. CIV-A-12-249, at ECF No. 94. More

[5] These cases are: *In re Gen. Mills, Inc. Kix Cereal Litig.*, No. CIV-A-12-249 KM, 2013 WL 5943972 (D.N.J. Nov. 1, 2013), *Barnes v. Campbell Soup Co.*, No. C12-05185 JSW, 2013 WL 5530017 (N.D. Cal. July 25, 2013), *Cox v. Gruma Corp.*, No. 12-CV-6502 YGR, 2013 WL 3828800 (N.D. Cal. July 11, 2013).

specifically, the agency "decline[d] to make a determination" at that time with respect to labeling genetically engineered ingredients as "natural." *Id.*

Once a district court determines that primary jurisdiction is appropriate, it may either stay proceedings or dismiss the case without prejudice. When the purpose of primary jurisdiction is for "parties [to] pursue their administrative remedies," a district court will "[n]ormally" dismiss the case without prejudice. *Syntek*, 307 F.3d at 782. However, when a court invokes primary jurisdiction "but further judicial proceedings are contemplated, then jurisdiction should be retained by a stay of proceedings, not relinquished by a dismissal." *N. Cal. Dist. Council of Hod Carriers v. Opinski*, 673 F.2d 1074, 1076 (9th Cir. 1982).[6] In either circumstance, the district court must be attuned to the potential prejudice arising from the dismissal of claims. Because the Ninth Circuit "has not clearly adopted the doctrine of equitable tolling in primary jurisdiction cases," prudence dictates that a court should stay proceedings rather than dismissing them when there is a "possibility" that the running of the statute of limitations during administrative proceedings could affect the parties' rights. *United States v. Dan Caputo Co.*, 152 F.3d 1060, 1062 (9th Cir. 1998) (per curiam).

[6] Indeed, this case demonstrates the mischief that can arise when a district court dismisses claims rather than staying them while awaiting agency action. Rather than seeking guidance from the FDA, Hain attempted to leverage the district court's dismissal on primary jurisdiction into an outright dismissal of some of Astiana's claims by arguing that she had forfeited her right to request a stay in proceedings. Enabling such "gotcha" litigation tactics is not the purpose of the primary jurisdiction doctrine.

In dismissing the case rather than staying it, the court did not consider whether the parties would be "unfairly disadvantaged." *Reiter*, 507 U.S. at 268. The purpose of referral to the FDA was not for the agency to adjudicate Astiana's claims, but to provide expert advice that would be useful to the court in considering this lawsuit. Plus, dismissing the case had the potential to prejudice members of the putative consumer class because of the running of the statute of limitations. In light of these considerations, we reverse the dismissal on primary jurisdiction grounds. On remand, the district court may consider whether events during the pendency of this appeal—including Astiana's informal letter, the FDA's website publication of a Small Business Fact Sheet regarding cosmetics labeling, and the FDA's response to the other courts—affect the need for further proceedings at the FDA or demonstrate that another referral to the agency would be futile.

III. QUASI-CONTRACT

The district court dismissed Astiana's quasi-contract cause of action, concluding that restitution "is not a standalone cause of action in California and is nonsensical as pled in any event." We part ways with the district court. Astiana's pleadings, though inartful, are better read as raising a valid quasi-contract claim seeking the remedy of restitution.

As the district court correctly noted, in California, there is not a standalone cause of action for "unjust enrichment," which is synonymous with "restitution." *Durell v. Sharp Healthcare*, 108 Cal. Rptr. 3d 682, 699 (Ct. App. 2010); *Jogani v. Superior Court*, 81 Cal. Rptr. 3d 503, 511 (Ct. App. 2008). However, unjust enrichment and restitution are not irrelevant in California law. Rather, they describe the theory

underlying a claim that a defendant has been unjustly conferred a benefit "through mistake, fraud, coercion, or request." 55 Cal. Jur. 3d Restitution § 2. The return of that benefit is the remedy "typically sought in a quasi-contract cause of action." *Id.*; *see Munoz v. MacMillan*, 124 Cal. Rptr. 3d 664, 675 (Ct. App. 2011) ("Common law principles of restitution require a party to return a benefit when the retention of such benefit would unjustly enrich the recipient; a typical cause of action involving such remedy is 'quasi-contract.'"). When a plaintiff alleges unjust enrichment, a court may "construe the cause of action as a quasi-contract claim seeking restitution." *Rutherford Holdings, LLC v. Plaza Del Rey*, 166 Cal. Rptr. 3d 864, 872 (Ct. App. 2014).

Astiana alleged in her First Amended Complaint that she was entitled to relief under a "quasi-contract" cause of action because Hain had "entic[ed]" plaintiffs to purchase their products through "false and misleading" labeling, and that Hain was "unjustly enriched" as a result. This straightforward statement is sufficient to state a quasi-contract cause of action. To the extent the district court concluded that the cause of action was nonsensical because it was duplicative of or superfluous to Astiana's other claims, this is not grounds for dismissal. Fed. R. Civ. P. 8(d)(2) ("A party may set out 2 or more statements of a claim or defense alternatively or hypothetically, either in a single count or defense or in separate ones.").

REVERSED and REMANDED.