

24-15-cv

IN THE
United States Court of Appeals
FOR THE SECOND CIRCUIT

KAVASUTRA 6TH STREET, INC., KAVASUTRA 10TH STREET, INC.,
Plaintiffs-Appellants,

v.

ERIC ADAMS, AS MAYOR OF THE CITY OF NEW YORK, CITY OF NEW YORK,
COMMISSIONER ASHWIN VASAN, AS COMMISSIONER OF THE NEW YORK CITY
DEPARTMENT OF HEALTH AND MENTAL HYGIENE, NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE,
Defendants-Appellees.

*On Appeal from the United States District Court
for the Southern District of New York*

BRIEF FOR PLAINTIFFS-APPELLANTS

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CORPORATE DISCLOSURE STATEMENT
PURSUANT TO FRAP 26.1 (a)

Plaintiffs Kavasutra, 10th Street, Inc. and Kavasutra 6th Street, Inc. hereby certify that they are not owned by any parent corporation or any publicly held corporation that owns 10% or more of its stock.

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JURISDICTIONAL STATEMENT

The District Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1343(a)(3), 2201-2202. Under 28 U.S.C. § 1331, this action arises under the Constitution and the laws of the United States because defendants are improperly asserting violations against Plaintiffs by misapplying the Food and Drug Cosmetic Act (“FDCA”). *See Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 89 (1998); *see also Bensinger v. Denbury Res. Inc.*, 561 F.App’x 24, 25 (2d Cir. 2014)(explaining that the core of federal question jurisdiction is where the parties argue for different interpretations of a federal statute). Here, the question is whether Kava mixed with water constitutes a “food additive” as defined by the FDCA.

This Court has appellate jurisdiction under 28 U.S.C. §1292(a)(1) based on the district court's denial of Plaintiffs’ motion for a preliminary injunction.

Plaintiffs timely appealed the District Court order within 30 days, as required by Rule 4(a)(1) of the Federal Rules of Appellate Procedure. The District Court order denying Plaintiffs’ motion for a preliminary injunction was entered on December 8, 2023, and Plaintiffs served and filed a notice of appeal on December 28, 2023.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

1. Did the District Court abuse its discretion by denying Plaintiffs' motion for a preliminary injunction on the basis that Plaintiffs failed to show a likelihood of success on the merits?

Yes.

2. Did the District Court abuse its discretion by denying Plaintiffs' motion for a preliminary injunction on the basis that the public interest favored denial?

Yes.

STATEMENT OF THE CASE

A. The Parties

Plaintiffs Kavasutra, 10th Street, Inc. (“10th Street Location”) and Kavasutra 6th Street, Inc. (“First Street Location”) operate two New York City cafés that sell Kava mixed with water (A11). Kava is the root of a plant that is customarily mixed or brewed in water to produce a drink that is popular in Pacific Island cultures, including Hawaii and the American Samoa (A12). Kava has been a culturally significant and traditional beverage in the Pacific Islands for centuries and has been popular in the United States for decades (A12, A19-A20). Kava is the national drink of many Pacific Island countries and territories including American Samoa, a United States territory since 1900. The U.S. Mint produced a Quarter in U.S. Currency with American Samoa printed on the Quarter in 2009. The American Samoa quarter reverse design depicts the ava (kava) bowl. The ava (kava) ceremony is considered the most significant traditional event in Samoan culture. Kava is even featured on the American Samoa Quarter issued by the U.S. Mint (A12, A19-A20).

The New York City Department of Health and Mental Hygiene (“the Health Department”) enforces the New York City Health Code (“the Health Code”). See Health Code § 3.01(b). The Health Code authorizes the Department to embargo food under certain conditions (Health Code § 3.03(a)), such as when the

Department determines that the food is “adulterated” (Health Code § 3.03(a)(5)). A food can be “deemed adulterated” under any one of the 9 conditions identified in Section 71.05(c) of Health Code. Some of these conditions rely on New York State law. *See, e.g.*, Health Code § 71.05(c)(9)(referencing the New York State Agriculture and Markets Law). Other conditions import federal standards. *See, e.g.*, Health Code § 71.05(c)(3)(referencing FDCA and 21 U.S.C. § 346a, which relates to pesticides). The key provision here is Health Code § 71.05(c)(4), which deems a food adulterated when it contains a “food additive” that is “unsafe” within the meaning of the FDCA (21 U.S.C. § 348). Because the scope of the City’s authority under section 71.05(c)(4) of the Health Code depends on definitions found in the FDCA, an overview of key terms follows.

B. The Federal Food, Drug, And Cosmetic Act

The FDCA defines “food” broadly as “articles used for food or drink for man or other animals” and “articles used for components of any such article.” 21 U.S.C. § 321. Substances classified as “food” are presumed safe under the FDCA. *See U.S. v. Two Plastic Drums, More or Less of Food Labeled Black Currant Oil, (“Traco Labs”)*, 984 F.2d 814, 816 (7th Cir. 1993); *United States v. 29 Cartons of * * * An Article of Food (“Oakmont”)*, 987 F.2d 33, 35 (1st Cir. 1993). The Food and Drug Administration (“FDA”) can prevent the sale of a “food” only if it proves

by a preponderance of the evidence that the food is “injurious to health.” *Traco Labs.*, 984 F.2d at 816; *Oakmont*, 987 F.2d at 35.

Unlike “foods,” which are presumed to be safe, any substance that meets the FDCA’s definition of a “food additive” is presumed to be “unsafe” as a matter of law. *See Traco Labs*, 984 F.2d at 816; *Oakmont*, 987 F.2d at 35. The FDCA defines a “food additive” as

“any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food... if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use[.]”

21 U.S.C. § 321(s). If a substance is a food additive, the marketer has the burden of showing that the substance is generally recognized as safe (“GRAS”). *Traco Labs*, 984 F.2d at 816; *Oakmont*, 987 F.2d at 35.

C. Defendants’ Administrative Tyranny

Although Plaintiffs have operated for years, the Health Department has recently refused to allow Plaintiffs to sell or even possess Kava on the ground that it is an unsafe “food additive” under the FDCA. In November 2022, the Health Department inspected one of Plaintiffs’ locations and issued a summons, alleging that Plaintiffs violated Health Code § 71.05 by possessing, among other things,

“Kava in plastic containers” (A70-A71). The Health Department further alleged that Kava “is not Generally Recognized as Safe (GRAS) for use in food or is not an approved...food additive in accordance with the U.S. Food and Drug Administration (FDA)” (A71). Plaintiffs challenged the summons before the New York City Office of Administrative Trials and Hearings (“OATH”) (A70-A73).

On January 4, 2023, while the November 2022 summons was pending but before the OATH hearing had taken place, the Health Department issued another summons alleging again that Plaintiff’s supply of Kava violated Health Code § 71.05 because Kava was “not Generally Recognized as Safe (GRAS) for use in food or is not an approved...food additive in accordance with the U.S. Food and Drug Administration (FDA).” (A79-80, A170-A171). Likewise, on January 11, 2023, the Health Department issued an order preventing Plaintiffs from adding Kava “in any form to food or beverages or serve food or beverages” that contain Kava, on the grounds that Kava is “not a food as food additive within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act, or a substance “generally recognized as safe” (“GRAS”)[.]” (A187-A188).

In March 2023, the Health Department refused to appear for an OATH hearing on the November 2022 summons (A71). Plaintiffs appeared, and the administrative law judge (“ALJ”) found that “Kava is not being utilized as an additive or colorant” and “dismissed” the charge in March 2023 (A71).

Despite this decision from the ALJ holding that Plaintiffs were not using Kava as a food additive, the Health Department issued summonses on July 12, 2023 and July 13, 2023, again, alleging that Kava is “not an approved...food additive in accordance with the U.S. Food and Drug Administration (FDA)” and found Plaintiffs in violation of Health Code § 71.05 (A79-A80, A88, A191). Plaintiffs challenged the January 2023, July 12, 2023, and July 13, 2023 summonses at OATH hearings.

On July 12, 2023, the Health Department also ordered the 10th Street Location to close for failing to destroy its Kava inventory (A195). On July 13, 2023, the Health Department ordered the Sixth Street Location because the Health Code violations “were not or could not be corrected” (A94, A173-A174). On July 21, 2023, the Health Department inspected the First Street Location and issued a summons alleging that Plaintiff remained open despite the July 13, 2023 order to close and obstructed closing signs with potted plants (A198).

On July 26, 2023, while the OATH hearings for the January 2023, July 12, 2023, and the July 13, 2023 summonses were pending, the Health Department ordered Plaintiffs to “cease and desist from any and all food service operations” at the 10th Street and First Street locations because Plaintiffs allegedly violated Health Code § 71.05 by offering adulterated food to the public (A180-182).

D. Plaintiff's Complaint

While those administrative challenges were pending, Plaintiffs commenced this action for a declaration that Kava mixed with water is a food, not a food additive, under the FDCA. Plaintiffs alleged that “Kava, prepared as a single ingredient, mixed with water, with no other ingredients added, is a food under the FDCA” and therefore presumed to be safe until the FDA proves “by a preponderance of the evidence that Kava is injurious to health” (A102). Plaintiffs alleged that the FDA has made no such finding (A102).

Plaintiffs also allege that in November 2022 the Health Department inspected Plaintiff's First Street Location and issued a summons for possessing Kava, which the Health Department alleged was an unsafe food additive in violation of Health Code § 71.05 (A103). Plaintiffs successfully challenged that decision before an administrative law judge (“ALJ”), who found that Kava sold as a single ingredient mixed with water was not a food additive (A103).

Despite this finding from the ALJ, the Health Department continually issues Plaintiffs summonses alleging that Kava mixed with water is an unsafe food additive and the sale of Kava mixed with water violates Health Code § 71.05 (A103-A104). Indeed, following the ALJ decision the Health Department issued three violations of Health Code § 71.05 for the sale of Kava as an unsafe food additive (A103).

Because of the serial violations on the same baseless “food additive” ground, Plaintiffs started this action on July 21, 2023 (A100-A106), seeking a declaration that the Health Department cannot rely on the “food additive” ground to “restrict, interfere or prevent plaintiffs’ sale of Kava *as a food*” (A104)(emphasis added). Plaintiffs also asserted a claim for injunctive relief preventing Defendants from “restricting, interfering or preventing plaintiffs’ sale of Kava *as a food* under the FDCA” (A104)(emphasis added). Finally, Plaintiffs assert a claim under 42 U.S.C. § 1983, alleging that “despite the prior determination by an ALJ that Kava was a food and was legal to sell, defendants simply ignored the ALJ’s determination and closed plaintiffs’ locations for selling Kava, a legal product” (A105). Thus, Defendants violated “plaintiffs’ rights under the Fourteenth Amendment...under color of law in violation of 42 U.S.C. § 1983” (A105).

E. Plaintiff’s Preliminary Injunction Motion

Three days after filing the complaint, Plaintiffs moved by order to show cause for a preliminary injunction (A9). In support, Plaintiffs submitted the Declaration of Michael Klein, chief operating officer of Plaintiffs, (A11-A20), which annexed these exhibits: (1) Complaint, dated July 21, 2023 (A100-A105); (2) News article showing Kava featured on the American Samoa Quarter issued by the U.S. Mint (A18-A20); (3) World Health Organization Technical Report (A21-A68); (4) Office of Administrative Trials and Hearings (“OATH”) decision, summons No. 14372-

22F0, dated March 2, 2023 (A69-A72); (5) Notice and Order of Embargo, (A73-A83); (6) Renewal License as to Kavasutra 10th Street Inc. (A84-A85); (7) Summons and Closure Order issued July 13, 2023 (A86-A96). Plaintiff also submitted the declaration of Christopher Murray (A97-A98) and a memorandum of law (A106-120).

The Klein Declaration states that the Health Department ordered Plaintiffs to close the First Street and 10th Street locations, but Plaintiffs will have to continue paying monthly rent totaling \$9,950 per month (A14-A15). During the closure, Plaintiffs will be without income and will lose its customer base (A15).

The memorandum of law explained that Kava, when sold as a single ingredient mixed with water, is a food, not a food additive under the FDCA, yet the Health Department continues to penalize Plaintiffs for selling Kava on the grounds that it is an unsafe food additive (A115-A117). Plaintiffs also explained that the continuous flow of violations and closure orders will put them out of business (A110). Plaintiffs, therefore, urged the District Court to temporarily restrain defendants from interfering with Plaintiffs' sale of Kava by misclassifying Kava as a food additive (A120).

F. Defendants' Opposition And Cross Motion To Dismiss

Defendants opposed and cross-moved to dismiss the complaint. In support, Defendants submitted the declaration of Samtha Schonfeld (A136-A137), which

annexed the following exhibits: (a) Plaintiff's complaint (A100-A106); (b) FDA Memorandum entitled "Review of published literature pertaining to the safety of Kava for use in conventional foods" (A139-A168); (c) Embargo order, dated November 16, 2022 issued to Kavasutra 6th Street (A169-171); (d) Health Department Summons No. 143722F1, issued to Kavasutra 6th Street on July 13, 2023; (e) Order of the Commissioner, dated July 13, 2023 closing Kavasutra 6th Street (A172-A174); (f) Health Department Summons No. 09180-23F0, issued to Kavasutra 6th Street on July 21, 2023 (A175-176); (g) Health Department Order to Cease and Desist issued to Kavasutra 6th Street on July 26, 2023 (A177-A182); (h) Health Department Inspection report, dated September 17, 2018 (A183-185); (i) Health Department Summons No. 0009023F0, issued to Kavasutra 10th Street on January 4, 2023; (j) Order of the Commissioner, dated January 11, 2023 issued to Kavasutra 10th Street (A186-189); (k) Health Department Summons No. 0876623F0, issued to Kavasutra 10th Street on July 12, 2023 (A190-193); (l) Order of the Commissioner, dated July 12, 2023 closing Kavasutra 10th Street (A194-A196); (m) Health Department Summons No. 09177-23F0, issued to Kavasutra 10th Street on July 21, 2023 (A197-A198); and (n) Petition filed at the New York City OATH commencing revocation proceeding against Kavasutra 10th Street (A199-A205).

Defendants also submitted a memorandum of law, arguing that Plaintiffs failed to show a likelihood of success on the merits of its claim for declaratory relief.

Defendants insisted that “Kava is not a food, that Kava is not GRAS, and the Kava is an unapproved ‘food additive’ when it is mixed with food” (A221). Defendants also argued that the sale of “Kava ‘as a single ingredient food’ is undermined by the fact that: (1) the FDA classifies Kava as a ‘dietary supplement’ and not a food; (2) Kava is not ‘GRAS’ by the FDA; and (3) Kava is an unapproved food additive and therefore cannot be mixed with, or added to, food or beverages” (A225).

Perhaps recognizing the weakness of this argument, Defendants argued, in the alternative, that “[e]ven if Kava is classified as a ‘food,’ as Plaintiffs claim, Kava is still an unapproved ‘food additive’ under 21 U.S.C. § 321(s)” (A225)(citing *National Nutritional Foods Assoc. v. Kennedy*, 572 F.2d 377 (2d Cir. 1978)). Defendants concluded that “even if Plaintiffs were right that Kava is classified as a ‘food,’ as a dietary supplement it is an unapproved ‘food additive’ that cannot be added to, or mixed with, food or beverages because it is not GRAS by the FDA” (A222). On this same basis, Defendants sought to distinguish *Traco Labs* and *Oakmont*, arguing that black currant oil was a ‘food’ whereas Kava is a dietary supplement (A223). Defendants reasoned that “[a]s a dietary supplement, Kava must be GRAS for it to be combined with food. Kava is not GRAS and, therefore, it cannot be combined with food” (A223). Based on these arguments, Defendants claimed Plaintiffs failed to show a likelihood of success on the merits.

Defendants also argued that Plaintiffs will not suffer irreparable harm because the closure of their business resulted in “purely economic” harm (A230). Finally, Defendants argued that the equities tip in their favor because closing Plaintiffs’ businesses “promote[s] and protect[s] the health of New Yorkers” (A231).

G. Plaintiff’s Reply

In reply and in opposition to the cross motion, Plaintiffs refuted Defendants arguments that Plaintiffs must prove that Kava is GRAS because Kava is a dietary supplement (A223). Plaintiffs explained that 21 U.S.C. § 321(ff) provides that “a dietary supplement shall be deemed to be a food with the meaning of this chapter” (A241). In an event, the FDA does not require pre-approval for the sale of dietary supplements (A241). Instead, the FDA “regulates the labeling of dietary substances to as to prevent the misrepresentation of health benefits” and investigates complaints (A241).

H. District Court Order

The District Court denied Plaintiffs’ motion for a preliminary injunction in its entirety (A264-A265). The District Court held that “[b]ecause both sides made colorable arguments,” about safety of Kava consumption, “the Court cannot conclude at this stage on this record that plaintiffs are likely to succeed on the merits” (A261). The District Court acknowledged that “on a more complete record plaintiff may well prevail, but at the moment the positions of the parties are, at best from

plaintiff's position at equipoise" (A261). Although the District Court refused to consider whether Plaintiffs demonstrated irreparable harm, the District Court held that the equities tipped in favor of Defendants. The District Court reasoned that "defendants issued closing orders in the interest of public safety" (A261) and that since the FDA has issued memorandum that Kava may negatively affect human health, "it is not in the public interest for this court...to substitute my view of what is or is not safe for human consumption" (A262). This appeal ensued.

SUMMARY OF ARGUMENT

The District Court should have granted Plaintiff's motion for a preliminary injunction. Plaintiffs established a strong likelihood of success on its claim for a declaration that Kava mixed with water does not qualify as a "food additive" as defined by the FDCA. The First and Seventh Circuits held long ago that a single food mixed with an inactive substance does not qualify as a food additive.

The District Court tried to avoid the holdings of First and Seventh Circuits by holding that the parties submitted conflicting evidence about the safety of Kava (A260-A261). This was clear error. The Health Department misclassified Kava as a food additive that is unsafe. The District Court's analysis fixates on the word "unsafe," but ignores that Kava mixed with water does not qualify as a food additive in the first place. Because Kava mixed with water does not qualify as a "food additive" under the FDCA and the Health Code, the District Court's free-standing analysis about the safety of Kava was unnecessary and caused the Court to misperceive Plaintiffs' likelihood of success on the merits.

Plaintiffs also showed they would suffer irreparable harm without a preliminary injunction. Although the Health Department summonses include various violations, the Health Department – for strategic reasons – always includes the unsafe "food additive" ground of section 71.05(c)(4). The "food additive" violation is effectively incurable. As a practical matter, proving a substance is

GRAS requires considerable time and money to hire a panel of experts. The City's legal determination that Kava is a food additive when mixed with water will, thus, force Plaintiffs close their businesses, and the closure of Plaintiff's businesses is precisely the Health Department's aim.

The District Court also abused its discretion in holding that the public interest favors denial of the motion for a preliminary injunction. The public interest favors promoting health and avoiding the misapplication of the FDCA. The narrow injunction requested here seeks only to preclude the Health Department from preventing Plaintiffs from selling Kava mixed with water by misclassifying Kava as a "food additive" (*see* Health Code § 71.05(c)(4)), but it does not prevent the Health Department from enforcing any other provision of the Health Code. *See* Health Code § 71.05(c). The requested preliminary injunction balances Plaintiffs' legitimate interest in operating its business, the public's interest in avoiding wrongful enforcement of the law, and the Health Department's obligation to protect the public health. By contrast, denying the preliminary injunction adds nothing to Health Department's legitimate efforts to promote public health, and allows the Health Department's to put Plaintiffs out of business.

ARGUMENT

THE DISTRICT COURT ABUSED ITS DISCRETION BY REFUSING TO GRANT PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

A. General Legal Principles

“This Court reviews the grant of a preliminary injunction for abuse of discretion.” *Citigroup Glob. Markets, Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d 30, 34 (2d Cir. 2010); *see also Almontaser v. N.Y. City Dep’t of Educ.*, 519 F.3d 505, 508 (2d Cir. 2008). “A district court abuses its discretion when it rests its decision on a clearly erroneous finding of fact or makes an error of law.” *Almontaser*, 519 F.3d at 508.

“A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). When “the government is a party to the suit, the final two factors merge.” *New York v. United States Dep’t of Homeland Sec.*, 969 F.3d 42, 58–59 (2d Cir. 2020). The public has an interest in preventing the wrongful enforcement of the law and in promoting correct enforcement of the law. *Nken v. Holder*, 556 U.S. 418, 436 (2009)(“Of course there is a public interest in preventing aliens from being wrongfully removed[,]” and “[t]here is always a public interest in prompt execution

of removal orders”). An administrative agency is not entitled to its “preferred policy” absent other circumstances, such as national security or the correction of a policy deemed unlawful. *See United States Dep't of Homeland Sec.*, 969 F.3d 42.

Irreparable harm is a “certain and imminent harm for which a monetary award does not adequately compensate.” *Wisdom Imp. Sales Co. v. Labatt Brewing Co.*, 339 F.3d 101, 113 (2d Cir. 2003) (citations omitted). Irreparable harm exists “where, but for the grant of equitable relief, there is a substantial chance that upon final resolution of the action the parties cannot be returned to the positions they previously occupied.” *Brenntag Int’l Chem., Inc. v. Bank of India*, 175 F.3d 245, 249-50 (2d Cir. 1999). This Court has held that when “the destruction of a business itself or indeterminate losses in other business” occurs, “the availability of money damages may be a hollow promise and a preliminary injunction appropriate.” *Tom Doherty Associates, Inc. v. Saban Entertainment, Inc.*, 60 F.3d 27, 38 (2d Cir. 1995). Thus, irreparable harm occurs when a plaintiff loses the ability to operate a business. *See Semmes Motors, Inc. v. Ford Motor Co.*, 429 F.2d 1197, 1205 (2d Cir. 1970).

For similar reasons, the loss of customer goodwill qualifies as irreparable harm. *See Reuters Ltd. v. United Press Int’l, Inc.*, 903 F.2d 904, 908 (2d Cir. 1990); *see also Tom Doherty Assocs., Inc.*, 60 F.3d 27, 38. In particular, irreparable harm is most evidence when the absence of an injunction would eliminate a company’s primary product. As this Court has explained:

“Where the availability of a product is essential to the life of the business or increases business of the plaintiff beyond sales of that product—for example, by attracting customers who make purchases of other goods while buying the product in question—the damages caused by loss of the product will be far more difficult to quantify than where sales of one of many products is the sole loss. In such cases, injunctive relief is appropriate.”

Tom Doherty Assocs., Inc., 60 F.3d 27, 38.

B. New York City Department Of Health Code & Federal Food, Drug, And Cosmetic Act (“FDCA”)

The Health Code authorizes the Health Department to embargo “adulterated” food. *See* Health Code § 3.03(a)(5). A food can be “deemed adulterated” when “the food is, bears or contains any food additive” and “is unsafe within the meaning of the [FDCA] (21 U.S.C. § 348).” *See* Health Code § 71.05(c)(4) (“the Food Additive Ground”). “To be a food additive, a substance must not only be added to food, but it must also have the purpose or effect of altering a food’s characteristics.” *Traco Labs*, 984 F.2d at 818; *see also Oakmont*, 987 F.2d at 37.

When distinguishing a “food” from a food additive, federal courts have held that when a food has “two or more active components...each component is a food additive.” *Traco Labs*, 984 F.2d at 818 (and cases cited). “But when there is only one active component, as is the case here, that single component does not affect the characteristics of the food in question—rather, it constitutes the food.” *Id.*; *see also*

id. at 820 (observing that every single court to consider this issue arrived at the same conclusion).

C. The District Court Committed Legal Error And Abused Its Discretion

1. Plaintiffs Showed A Strong Likelihood Of Success On The Merits

Here, Plaintiffs mix kava root with water and run it through a filter in the same way that coffee or tea is made. Plaintiffs established a strong likelihood of success on its claim for a declaration that Plaintiff’s primary product – Kava mixed with water – does not qualify as a “food additive” as defined by the FDCA and therefore cannot be “deemed adulterated” under the Food Additive Ground of the Health Code. *See* Health Code § 71.05(c)(4).

It has been well established for decades that a single food mixed with an inactive substance does not qualify as a “food additive.” *See Traco*, 984 F.2d at 816; *Oakmont*, 987 F.2d at 35. In *Traco Labs* and *Oakmont*, the claimants used “gelatin and glycerin” capsules to protect black currant oil (BCO) from rancidity and to aid in consumption. *Traco*, 984 F2d at 816; *Oakmont*, 987 F.2d at 35. In the same way, Plaintiffs here use water to deliver Kava for consumption. The Courts in *Traco* and *Oakmont* held that BCO remained a food despite its delivery through an inactive substance. *See Traco*, 984 F2d at 820; *Oakmont*, 987 F.2d at 39. Just as BCO is not

a food additive when consumed in a glycerin capsule, so too Kava is not a food additive when consumed in water.

The Seventh Circuit reasoned that the FDA’s broad definition of food additive that would “classify every component of food – even single active ingredients [such as coffee or tea] – as food additives” which would blur the Congressionally mandated distinction between food and food additives. *Traco*, 984 F.2d at 819. For example, the Seventh Circuit recognized that this interpretation would convert a food into a food additive when mixed with water and observed that the “only justification for this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme and shift to the processors the burden of proving the safety of a substance in all circumstances.” *Id.*

Despite the reasoning in *Traco*, the Health Department invites this Court on trip through the looking glass, arguing that a food (Kava) becomes a food additive when combined with an inactive substance (water) – the exact hypothetical the Seventh Circuit criticized as an Alice-in-Wonderland approach designed by administrative agencies to make an end run around the burden of proof established by the FDCA.

The District Court tried to avoid the mistake made by the FDA in *Traco Labs* and *Oakmont* by holding that the parties submitted conflicting evidence about the safety of Kava (A260-A261). The District Court concluded that the conflicting

evidence on safety was in equipoise, precluding Plaintiffs from showing a likelihood of success on the merits (A260-A261).

This was clear error. The Health Code authorizes the Health Department to deem a food adulterated when it contains a “food additive” that is “unsafe.” *See* Health Code § 71.05(c)(4). The Health Department repeatedly relied on this provision to issue Plaintiffs summonses and shutdown orders (A71) (alleging, in the November 2022 summons, that Kava “is not Generally Recognized as Safe (GRAS) for use in food or is not an approved...food additive in accordance with the U.S. Food and Drug Administration[.]”), (A79-80) (same in January 2023 summons), (A187-188)(same in January 2023 order).

The District Court’s analysis fixates on the word “unsafe,” but ignores that Kava mixed with water does not qualify as a food additive in the first place. *Traco Labs*, 984 F.2d at 816; *Oakmont*, 987 F.2d at 35. Because Kava mixed with water does not satisfy the definition of “food additive” the District Court did not need to determine whether Kava was an *unsafe* “food additive” to evaluate Plaintiffs’ likelihood of success on the merits. Whether the Health Department can rely on the “food additive” ground of the Health Code goes to the heart of Plaintiffs’ claim for a judgment declaring that Health Department must treat Kava mixed with water *as a food*, and not as a food additive, under the FDCA (A104, A120).

In sum, Kava mixed with water does not qualify as a “food additive” under the FDCA and the Health Code. Thus, the District Court’s free-standing analysis about the safety of Kava was unnecessary and caused the Court to misperceive Plaintiffs’ likelihood of success on the merits.

2. Plaintiffs Would Suffer Irreparable Harm Without A Preliminary Injunction

The District Court did not address Plaintiffs’ irreparable harm, but a discussion here is imperative. Although the Health Department summonses include various violations, the Health Department – for strategic reasons – always includes the unsafe “food additive” ground of section 71.05(c)(4). The “food additive” violation is effectively incurable. In theory, Plaintiffs could seek to have Kava registered as GRAS. See 21 C.F.R. § 170.30(b). But as a practical matter, proving a substance is GRAS requires considerable time and money to hire a panel of experts to prove that Kava is “generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use.” 21 U.S.C. 321(s); see 21 C.F.R. § 170.30(b). As a result, the City’s legal determination that Kava is a food additive when mixed with water disrupts the sale of Plaintiffs’ primary product. Indeed, disrupting the sale of Kava mixed with water and ultimately closing Plaintiff’s businesses is precisely the Health Department’s

aim. Thus, the existing violations for the sale of Kava mixed with water disrupt the sale of Plaintiffs' primary product, resulting in "indeterminate losses" and making "money damages...a hollow promise[.]" *Tom Doherty Associates, Inc.*, 60 F.3d 27, 38; *see Semmes Motors*, 429 F.2d 1197, 1205; *Reuters Ltd.*, 903 F.2d 904, 908. What's more, the Eleventh Amendment makes it far from clear that monetary damages will be available for the mistaken enforcement of the Health Code, highlighting the irreparable nature of the harm Plaintiffs will suffer. *See United States v. State of N.Y.*, 708 F.2d 92, 93 (2d Cir. 1983).

3. The Public Interest Favors An Injunction

The District Court abused its discretion in holding that the public interest favors denial of the motion for a preliminary injunction. The requested injunction would preserve the Health Department's ability to protect public health, while avoiding irreparable harm to the Plaintiffs and preventing the wrongful application of the FDCA.

Plaintiffs recognize the Health Department has an interest in promoting public health. *See generally Cent. Rabbinical Cong. of U.S. & Canada v. New York City Dep't of Health & Mental Hygiene*, 763 F.3d 183, 197 (2d Cir. 2014). But the public has an equally strong interest in avoiding the wrongful enforcement of the law. *See generally Nken*, 556 U.S. at 436 (weighing the public's interest in avoiding the wrongful removal of foreign nationals).

The narrow injunction requested here seeks only to preclude the Health Department from preventing Plaintiffs from selling Kava mixed with water by misclassifying it as a “food additive.” *See* Health Code § 71.05(c)(4). This injunction prevents the Health Department from issuing violations based on a flagrant misreading of the FDCA, but not from enforcing any other provision of the Health Code. *See* Health Code § 71.05(c).

If the Health Department were genuinely interested in protecting public safety, it would have issued violations for selling Kava with water under one of the other grounds identified in section 71.05(c) of the Health Code and supported that decision with evidence Kava is unsafe. It is unclear whether a lack of evidence, administrative expediency, or a personal vendetta has driven the Health Department to insist on using the food additive ground of section 71.05(c)(4), but whatever the motivation, the Health Department can promote public health without misinterpreting the FDCA. *See* Health Code § 71.05(c).

The Health Department’s preferred policy might be to apply the food additive ground to Kava mixed with water, but the policy preferences of an administrative agency are not dispositive. *See United States Dep’t of Homeland Sec.*, 969 F.3d 42, 87. For these reasons, a preliminary injunction balances Plaintiffs’ legitimate interest in operating its business, the public’s interest in avoiding wrongful enforcement of the law, and the Health Department’s obligation to protect the public

health. By contrast, denying the preliminary injunction adds nothing to Health Department's legitimate efforts to promote public health, and allows the Health Department's to put Plaintiffs out of business.

CONCLUSION

For these reasons, this Court should reverse, with costs; grant Plaintiffs a preliminary injunction preventing the Health Department from treating Kava or any other herbal products mixed with water as a "food additive" under the FDCA; and grant Plaintiffs any other relief that the Court deems just and proper.

Dated: April 3, 2024

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CERTIFICATE OF COMPLIANCE WITH FRAP 32(a)

This brief complies with the type-volume limitation of Fed. R. App. P. Rule 32(g)(1) because this brief contains **5,556** words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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