# CHAPTER 20

# DRONKERS v. KISS MY FACE LLC

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## I. Why It Made the List

*Dronkers v. Kiss My Face LLC*[1] adds to a growing body of case law regarding the scope of regulatory oversight on cosmetics and personal care products and confronts the implications of federal regulation on the labeling of organic products under the Organic Foods Production Act (OFPA). As consumer demand increases for food, cosmetics, and personal care products that are organic or made with organic ingredients, more consumers will likely file lawsuits relating to organic labeling and certification. The *Dronkers* decision may trigger additional regulations on the scope of federal oversight of organic products and may spark more widespread litigation in the future.

## II. Facts of Case

Defendant Kiss My Face LLC (KMF) is the manufacturer of a variety of personal care products, including soap, shampoo, moisturizer, and lip balm. The company describes itself as a leader in "natural body care" and emphasizes sustainable and plant-based

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* The views expressed in this chapter are the author's and do not necessarily reflect those of the Government of the District of Columbia, Department of Health.

1 Dronkers v. Kiss My Face, LLC, No. 12cv1151 JAH (S.D. Cal. Sept. 26, 2013).

ingredients. In keeping with its mission, the company advertises its use of "natural and organic" ingredients in its body care products.

Plaintiff Michael Dronkers filed a purported class action complaint against KMF in the United States District Court for the Southern District of California. Dronkers alleged that certain products sold by KMF were inappropriately labeled as "obsessively organic" when they did not qualify as organic under the criteria set by the U.S. Department of Agriculture's (USDA's) National Organic Program (NOP).[2] According to the complaint, the plaintiff and other consumers relied on KMF's misrepresentations that the products were organic and, as a result, paid for products that did not have the characteristics that were represented. The plaintiff asserted violations of California's False Advertising Law, Unfair Competition Laws, and Consumer Legal Remedies Act and sought to represent a class of all California residents who purchased any KMF product labeled as "organic" since 2008.

KMF moved to dismiss the case under Federal Rule of Civil Procedure 12(b)(6), arguing that all of the claims were preempted by the OFPA and NOP. Alternatively, KMF argued that the court should dismiss or suspend the case under the doctrine of primary jurisdiction or dismiss the claims for failure to sufficiently allege the requisite elements.

# III. Court Ruling

Judge John Houston denied KFM's motion to dismiss. The court found that the plaintiff's claims were not preempted by the OFPA, declined to apply the doctrine of primary jurisdiction, and concluded that the plaintiff sufficiently alleged his state law causes of action.

# IV. Rationale for Decision

## A. Organic Foods Production Act

KFM's challenges to the complaint centered on the application and scope of the OFPA. Enacted in 1990, the OFPA establishes the framework for producing and selling agricultural products as "organic." The objective of the OFPA is:

(1) to establish national standards governing the marketing of certain agricultural products as organically produced products;

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[2] 7 C.F.R. § 205.660(a).

(2) to assure consumers that organically produced products meet a consistent standard; and

(3) to facilitate interstate commerce in fresh and processed food that is organically produced.[3]

Under the OFPA, agricultural products that are to be sold or labeled as organically produced must have been produced and handled under certain standards set forth by USDA, and the producer must be certified by an agent accredited by USDA. USDA established the NOP to provide standards for the production of organic products and the process for accrediting certifying agents.[4] Specifically, under NOP regulations, anyone who produces or handles crops, livestock, livestock products, or other agricultural products intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic" ingredients must be certified by a USDA-accredited agent.[5] There are approximately 30,000 farms and processing facilities in the world that have been certified under the NOP.

Private or governmental entities may apply to USDA for accreditation as certifying agents. To become accredited, agents must meet certain requirements, including demonstrating expertise in organic production or handling techniques, conducting annual program reviews of their certification activities, and complying with NOP's recordkeeping guidelines.[6] So far, USDA has accredited approximately 100 certifying agents in the United States and worldwide.[7]

## B. Express Preemption

The doctrine of preemption is founded on the premise that "the Laws of the United States . . . shall be the supreme Law of the Land."[8] Accordingly, the United States Supreme Court has held that "state law that conflicts with federal law is without effect."[9] Preemptive intent may be "explicitly stated in the statute's language or implicitly contained in its structure and purpose."[10] If a federal statute contains an express preemption provision, the court

3 7 U.S.C. § 6501.

4 *See* 7 C.F.R. Part 205.

5 21 C.F.R. § 205.100(a).

6 USDA, National Organic Program, *available at* http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=NationalOrganicProgram&leftNav=NationalOrganicProgram&page=NOPAccreditationandCertification&description=Accreditation%20and%20Certification&acct=nopgeninfo (last accessed Dec. 20, 2013).

7 21 C.F.R. § 205.501.

8 USDA, National Organic Program, *available at* http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=NationalOrganicProgram&leftNav=NationalOrganicProgram&page=NOPAccreditationandCertification&description=Accreditation%20and%20Certification&acct=nopgeninfo (last accessed Dec. 20, 2013).

9 Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992).

10 *Id.*

must still determine "the substance and scope of Congress' displacement of state law."[11] Furthermore, express preemption provisions are narrowly construed: "[W]hen the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'"[12]

While the Federal Food, Drug, and Cosmetic Act (FDCA) includes a provision that preempts state labeling and packaging laws that are different from or supplemental to federal law, the Food and Drug Administration (FDA) has never adopted comprehensive labeling requirements for cosmetics.[13] Thus, FDCA did not effectively preempt the claims asserted in *Dronkers*. Instead, KMF relied on the OFPA, which expressly preempts state law claims based on organic labeling. In support, KMF cited 7 U.S.C. § 6507, which prohibits states from adopting more restrictive organic certification requirements without USDA's approval.[14] According to KFM, this section displaced existing state organic labeling standards and established the exclusive manner in which states could impose future standards.[15] Other courts, however, have concluded otherwise. For example, the Eighth Circuit in *In re Aurora Dairy* determined that this provision preempted independent state certification requirements, but *did not* expressly preempt state law claims.[16]

At the outset, the plaintiff disputed the applicability of the OFPA to the personal care products at issue. The plaintiff argued that the OFPA, by its title and terms, applied to food, not cosmetics or personal care products. Thus, according to the plaintiff, the OFPA did not expressly preempt the claims at issue. The OFPA governs "agricultural products," which are defined as "any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock that is marketed in the United States for human or livestock consumption."[17] In addition, the stated purpose of the OFPA is to contemplate standards for "certain agricultural products" and the sales of "fresh and processed food."[18]

KMF argued that the NOP was intended to be a comprehensive regulatory framework to govern products that contained organic agricultural ingredients. It cited USDA's current position on the OFPA's application to personal care products. USDA's stance, however, has evolved over the years. In 2000, when USDA issued the final rule establishing the NOP, the agency responded to public comments asking that the NOP include

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11 Altria Group, Inc. v. Good, 555 U.S. 70, 77 (2008).

12 *Id*.

13 FDA has adopted limited requirements for cosmetics under the Fair Packaging and Labeling Act, which requires certain basic information on the appropriate label and a specific warning if the safety of the product has not been substantiated. *See* 21 C.F.R. Parts 701, 740.

14 7 U.S.C. § 6507.

15 *Dronkers*, Memorandum of Points and Authorities in Support of KFM's Motion to Dismiss, at 19.

16 *In re* Aurora Dairy Corp. Organic Milk Marketing & Sales Practices Litig., 621 F.3d 781 (8th Cir. 2010). *See also* Brown v. Hain Celestial Group, Inc., No. C 11-03082 LB, 2012 WL 3138013, *9 (N.D. Cal. Aug. 1, 2012).

17 7 U.S.C. § 6502(1); 7 C.F.R. § 205.2.

18 7 U.S.C. § 6501.

certification standards for cosmetics, body care products, and dietary supplements.[19] USDA concluded, however, that "[t]he ultimate labeling of cosmetics, body care products, and dietary supplements . . . is outside the scope of these regulations."[20] In 2002, the agency indicated that producers and handlers of cosmetics and personal care products were eligible to voluntarily seek certification under the NOP, but NOP labeling standards were not mandatory for such products.[21] By 2004, the agency reversed course through a Guidance Statement and determined that the OFPA does not extend to cosmetics and personal care products, and thus producers could not seek voluntary participation.[22] However, a year later, USDA issued a memorandum outlining its extant position—businesses that manufacture and distribute personal care products that contain organic agricultural products *may* be certified under the NOP as long as they meet NOP requirements.[23]

In 2009, NOP's standards board formally recommended that the regulations be revised to include personal care products; however, the agency has yet to implement any such changes.[24] Although the agency has expressed its views on the applicability of NOP requirements through the above statements and memoranda, it has not formally revised the regulations to include personal care products within the NOP.

While the parties briefed the motion to dismiss in *Dronkers*, the Northern District of California, analyzing a similar issue in *Brown v. Hain Celestial Group, Inc.*, determined that the OFPA was broad enough to cover cosmetics that contain agricultural products.[25] Under *Brown's* reasoning, the definition of "agricultural products" was not explicitly limited to food, instead including processed material.[26] The court acknowledged that "the phrase 'for human or livestock consumption' could be read as limited to agricultural products that are eaten or drunk"; however, the court adopted "a broader view that does not rely on the end use of the crops or livestock-derived products."[27]

The *Dronkers* court rejected the Northern District of California's broader view of the OFPA and concluded that cosmetics were not governed by the OFPA. Relying on a strict interpretation of the definition of "agricultural products," the court determined that the

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19 National Organic Program, 65 Fed. Reg. 80,548, 80,557 (Dec. 21, 2000) (to be codified at 7 C.F.R. pt. 205).

20 *Id.*

21 USDA, Policy Statement on National Organic Scope (May 2, 2002), *available at* http://www.ota.com/pics/documents/Scope2002.pdf (last accessed Dec. 27, 2013).

22 USDA, Guidance Statement, National Organic Program Scope (Apr. 13, 2004), *available at* http://www.ota.com/pics/documents/ScopeGuidance041304.pdf (last accessed Dec. 27, 2013).

23 Memorandum from Barbara C. Robinson, Deputy Administrator, Transportation and Marketing Programs, Agricultural Marketing Service, to All USDA Accredited Certifying Agents (Aug. 23, 2005), *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5079488 (last accessed Dec. 27, 2013).

24 USDA NOSB recommendations (Dec. 10, 2009).

25 Brown v. Hain Celestial Group, Inc., No. C 11-03082 LB, 2012 WL 3138013 (N.D. Cal. Aug. 1, 2012).

26 *Id.* at *8.

27 *Id.* at *8.

OFPA applied to food—not cosmetics.[28] Because the OFPA was inapplicable to KMF's products, the court found that the claims were not expressly preempted.

## C. Implied Preemption

Alternatively, KMF argued that the plaintiff's claims should be dismissed based on implied conflict preemption. Under this doctrine, a state law will be preempted when an actual conflict between state and federal law exists, namely, when it becomes "impossible for a private party to comply with both state and federal requirements."[29] As with express preemption, courts begin with a presumption against preemption.[30]

According to KMF, allowing the plaintiff's claims to proceed would obstruct OFPA's purpose and objectives and subject KMF to challenges under the laws of all 50 states. KMF argued that it would be inappropriate for the court to adjudicate the plaintiff's state law claims based on its use of the term "organic," because doing so would lead to potentially conflicting standards under state and federal law.[31]

In rejecting KMF's implied preemption argument, the court relied heavily on the fact that USDA had not taken formal steps to include cosmetics and personal care products in the NOP.[32] Under USDA's current position, producers of cosmetics and personal care products *may* seek certification under the NOP, but the court concluded that the OFPA did not regulate the labeling of such products.[33] USDA's policy statement and its recommendations to include cosmetics and personal care products in the NOP were merely "informal agency actions lacking a rulemaking or adjudicatory process."[34] Thus, the agency actions lacked preemptive effect.

## D. Primary Jurisdiction

The court rejected KMF's alternative argument that the case should be dismissed or suspended under the doctrine of primary jurisdiction. Where a claim requires resolution of complex or specialized regulations, the doctrine of primary jurisdiction allows a court to defer to the applicable agency. This theory is intended to "promot[e] proper relationships between the courts and administrative agencies charged with particular

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28 *Dronkers*, Slip Op. at 6-7.

29 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2577 (2011).

30 *See* Wyeth v. Levine, 555 U.S. 555, 565 (2009), quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) ("[I]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . 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.'").

31 *Dronkers*, Memorandum of Points and Authorities in Support of KFM's Motion to Dismiss, at 22.

32 *Dronkers*, Slip Op. at 8.

33 *Dronkers*, Slip Op. at 8.

34 *Dronkers*, Slip Op. at 9.

regulatory duties."[35] Primary jurisdiction can be applied whenever enforcement of a claim "requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body."[36] In such a case, a court may refer the issues to the administrative agency.[37] This sort of referral "does not deprive the court of jurisdiction; it has discretion either to retain jurisdiction or, if the parties would not be unfairly disadvantaged, to dismiss the case without prejudice."[38]

When determining whether to apply the doctrine of primary jurisdiction, courts in the Ninth Circuit typically consider the following four factors: "(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."[39] Application of this doctrine is within the court's discretion.

KMF relied on the recent decision in *All One God Faith, Inc. v. Hain Celestial Group, Inc.*, which applied the primary jurisdiction doctrine to dismiss the plaintiff's organic labeling claims.[40] In *All One God Faith*, the plaintiff alleged that the defendant's personal care and cosmetics products falsely claimed to be "organic," when the products were not "organic" as consumers ordinarily understood that term.[41] Concluding that the case was within USDA's primary jurisdiction, the court initially stayed the case while the plaintiff pursued administrative review of the defendant's labeling through USDA. When USDA had not resolved the issue after nearly two years, the defendant moved to dismiss. The *All One God Faith* court explained that "Plaintiff's challenge to defendants' labeling would inevitably require the Court to interpret and apply federal organic standards, potentially create a conflict with those standards, and would intrude upon and undermine the USDA's authority to determine how organic products should be produced, handled, processed and labeled."[42]

The *Dronkers* court, however, declined to apply the doctrine of primary jurisdiction. It reasoned that "plaintiff's claims of improper labeling of defendant's products as 'organic' is not particularly complex [thus] requiring USDA expertise to resolve."[43] The court found nothing to indicate that USDA was currently involved in rulemaking procedures to address personal care products. Therefore, an agency decision or guidance was not imminent.[44] Consequently, the doctrine of primary jurisdiction was inapplicable.

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

36 *Id.*

37 Clark v. Time Warner Cable, 523 F.3d 1110, 1114 (9th Cir. 2008).

38 Reiter v. Cooper, 507 U.S. 258, 268 (1993).

39 Syntek Semiconductor Co., Ltd. v. Microchip Technology, Inc., 307 F.3d 775, 781 (9th Cir. 2002).

40 All One Good Faith, Inc. v. Hain Celestial Group, Inc., No. C 09-3517 SI, 2012 WL 3257660 (N.D. Cal. Aug. 8, 2012).

41 *Id.* at *1.

42 *Id.* at *9.

43 *Dronkers,* Slip Op. at 10.

44 *Dronkers*, Slip Op. at 11.

Having resolved the challenges to the propriety of review, the court then considered the defendant's challenges to the sufficiency of the pleading. The court applied the heightened pleading standard under Federal Rule of Civil Procedure 9(b), but nonetheless concluded that each of the claims was pleaded with sufficient particularity. Accordingly, the court denied the defendant's motion to dismiss.

## V. Impact of Decision

The *Dronkers* decision highlights a significant gap in the regulation of cosmetics and personal care labeling. The decision affects organic labeling both from a regulatory and litigation perspective. First, the court's evaluation of preemption and primary jurisdiction exposes a need for further administrative clarification of the scope of the OFPA. The OFPA, through the NOP, sets forth a comprehensive regulatory scheme for organic labeling. Yet, cases like *Dronkers* demonstrate the perceived limitations of the current regulatory scheme with respect to organic non-food products. As organic non-food products grow in popularity, there is an increasing potential that NOP regulations will be interpreted and applied inconsistently. The uniformity in organic labeling that Congress believed the OFPA would provide may thus be jeopardized, as consumers and manufacturers will no longer be able to rely on a single set of standards.

Over the past decade, USDA has had the opportunity to consider the scope of the OFPA and NOP and their applicability to cosmetics and personal care products. Yet, despite issuing various informal statements, the agency has not engaged in formal rulemaking on the topic. As demonstrated by the lengthy procedural history of *All One God Faith*, which had been stayed for nearly two years while the parties and court awaited USDA advice, the lack of agency guidance also has the potential to delay the adjudication of claims based on allegedly deceptive labeling. However, as USDA defers formal action, courts may no longer find the need to wait for the agency's guidance. The *Dronkers* court, recognizing that guidance from USDA appeared "not imminent," declined to defer to the agency and allowed the case to proceed.[45] This decision sets the stage for inconsistent interpretations of organic labeling requirements.

Second, the decision opens the door for future claims involving cosmetics and personal care products. There have been relatively few decisions involving organic labeling of non-food products, and courts have reached differing conclusions about the scope of the OFPA.[46] As these types of claims become more prevalent, future courts confronting similar issues may find the *Dronkers* court's reasoning persuasive in evaluating the propriety of review of claims implicating the OFPA. Producers of organic cosmetics and personal care products may no longer be able to rely on a uniform set of standards to govern labeling.

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45 *Dronkers*, Slip Op. at 11.

46 *Compare Dronkers with Brown.*

Cosmetics and personal care products account for a significant portion of household spending. In 2010, Americans spent $33.3 billion on cosmetics and beauty products.[47] As more people look for healthier and sustainable alternatives, "organic" is no longer a term only found in the grocery store aisles. Legal challenges to the labeling and marketing of cosmetics and personal care products are becoming increasingly common in courts across the country. This trend may escalate unabated with decisions that, like *Dronkers*, may invite plaintiffs to test label statements under state-law theories.

## VI. Conclusion

*Dronkers* importantly illustrates a perceived gray area in the regulation of organic products. The decision highlights the risk that litigation hinging on the meaning of the term "organic" may lead to inconsistent interpretations impacting food, cosmetics, and personal care products alike. Courts confronting future claims involving the organic labeling of cosmetics and personal care products may rely on *Dronkers* in evaluating the propriety of challenges by consumers. Given the influx of claims based on deceptive or misleading labeling, manufacturers should remain vigilant of the potential implications and risks of organic labeling.

[47] Anna Maria Andriotis, Market Watch, 10 Things the Beauty Industry Won't Tell You, Apr. 20, 2011, available at http://www.marketwatch.com/story/10-things-the-beauty-industry-wont-tell-you-1303249279432 (last accessed Dec. 21, 2013).