No. 13–1379

IN THE

Supreme Court of the United States

ATHENA COSMETICS, INC.,

Petitioner,

v.

ALLERGAN, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONER

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RULE 29.6 STATEMENT

Pursuant to this Court's Rule 29.6, undersigned counsel state that no amendment is needed to the Rule 29.6 Statement in Athena Cosmetics, Inc.'s Petition for a Writ of Certiorari.

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REPLY BRIEF FOR PETITIONER

Allergan's opposition rests on the premise that its claim "depends entirely on state law." BIO 14. But this assertion is demonstrably incorrect.

Allergan sued under California's Unfair Competition Law ("UCL"), which provides a private right of action for the violation of any statute. Although Allergan did not use the UCL to enforce the FDCA's new-drug-approval requirement *directly*, the courts below nevertheless were required to—and did—apply that requirement. This is because Allergan's UCL claim "borrowed," as its predicate act, a violation of California's Sherman Food, Drug, and Cosmetic Law—which in turn requires new drugs to be approved by FDA "*under…the federal act*." Pet. 14.

By layering the UCL and Sherman Law on top of one another, Allergan constructed a state-law claim indistinguishable in effect from a lack-of-approval claim under the FDCA itself. The Federal Circuit's endorsement of such a claim cannot be squared with *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), which held that state-law claims—however pleaded—are impliedly preempted if they require a court to pass on the sufficiency of a manufacturer's "dealings with the FDA." *Id.* at 347.

The danger in the decision below is manifest. It gives private plaintiffs a roadmap to circumvent *Buckman*; override FDA's considered enforcement choices; and obtain rulings from lay judges and juries

on matters that Congress committed to FDA's "complete discretion." Pet. 12.

I. THE FEDERAL FDCA IS A CRITICAL ELEMENT OF ALLERGAN'S CLAIM.

In Allergan's telling, "[its] claim would…exist, and the outcome in this case would be the same, with or without the existence of the federal FDCA and its regulations." BIO 20. This is so, Allergan asserts, because the lower courts never applied federal law, and did not premise liability on Athena's lack of FDA approval. Allergan is wrong on both counts.

A. The Lower Courts Expressly Interpreted And Applied FDCA Requirements.

From the outset, the district court acknowledged that "[t]he alleged statutory violations" in Allergan's complaint "require that Athena's products be 'new drugs' *under the Federal Food, Drug, and Cosmetic Act*." Pet. 89a (emphasis added).

On summary judgment, the district court thus set out to "determine whether…RevitaLash products are drugs *for purposes of the FDCA*." Pet. 67a (emphasis added). Applying FDA's intended-use regulation, it expressly "f[ou]nd[]" that RevitaLash is a "drug[] *under the FDCA*…." Pet. 75a (emphasis added). And, because Athena "ha[d] not filed" a federal NDA, the district court held that "Athena violate[d] 21 U.S.C. § 355(a)"—the FDCA's new-drug section. Pet. 75a.

Allergan's premise is therefore belied by its own allegations and the district court's express findings.

The courts below interpreted FDCA regulations and found FDCA violations where FDA itself had not.

B. Allergan's Claim Is Premised On Lack Of Federal—Not State—Agency Approval.

Allergan observes that § 111550 of California's Sherman Law states that drugs must be approved *either* by FDA *or* by the California Department of Health Services ("CDHS"). BIO 9, 19-20. According to Allergan, the disjunctive wording of this provision means that "Allergan's claim d[id] not depend on [Athena's] failure to secure FDA approval." BIO 8.

But conflict preemption turns on "the relationship between [the relevant] state and federal laws *as they are…applied*, not merely as they are written." *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 526 (1977) (emphasis added). It is immaterial that a statute's text offers a "choice" between alternatives, if that "choice" is illusory in practice. *See, e.g.*, *Retail Indus. Leaders Ass'n* v. *Fielder*, 475 F.3d 180, 194-97 (4th Cir. 2007) (state statute preempted despite offering "choice" of modes of compliance, since the non-conflicting options were "not meaningful alternatives").

In reality, CDHS has "*never*…approved" an NDA. C.A. App. 2208 (emphasis added). Allergan did not dispute that fact below and does not dispute it now. Thus, assuming RevitaLash is a "drug," Athena had no choice but to obtain *FDA* approval. In practice, therefore, liability turns solely on the *federal* approval status of RevitaLash.

Indeed, even if CDHS approval were not a dead letter, it would exist only for products that—unlike RevitaLash—are manufactured and sold exclusively within California.[1] As California's original new-drug statute makes explicit, the state legislature intended CDHS to approve drugs only when they are "not subject to the Federal Act" (*i.e.*, the FDCA). Cal. Stats. 1939, ch. 60 § 26288; *cf.* 21 U.S.C. 331 (articles subject to FDCA where they are "in interstate commerce"). In other words, the hypothetical CDHS-approval option is *for "local" drugs only*.[2]

Allergan has two rejoinders. First, it notes that the Sherman Law describes the "information" that an application for CDHS approval should contain. BIO 20. But this is irrelevant, because CDHS in fact does not *approve* such applications.

Second, Allergan cites the "admi[ssion]" of Athena's expert, BIO 20, that CDHS "accepted" (but did not approve) "a very few…NDA submissions relating to AIDS treating drugs in the 1980s." C.A. App. 2208. This only proves Athena's point: even at the height of the AIDS crisis—when California enacted emergency legislation to encourage prompt approval of AIDS

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[1] RevitaLash is manufactured in Idaho and distributed nationwide from Nevada. C.A. App. 3099-4000.

[2] This intent is less apparent from the face of the current statute, but there is little question it still holds true. *See* Cal. Stats. 1987, ch. 1316 § 2(b) (acknowledging that CDHS approval is limited to drugs "manufactured and used only within the state").

drugs, *see* Cal. Stats. 1987, ch. 1316 §§ 1-2, 5-6—no state NDAs were ever approved.

In sum, Allergan's argument that Athena could have obtained CDHS approval, and that Allergan's claim thus could have "exist[ed]…without the existence of the federal FDCA," BIO 20, is a fiction. This case necessarily implicates Athena's "dealings with the FDA," and the FDCA's existence "is a critical element in [Allergan's] case." *Buckman*, 531 U.S. at 347, 353.

II. THE DECISION BELOW IS CONTRARY TO *BUCKMAN*.[3]

A. The Fact That Allergan's Claim Uses A State-Law Vehicle Is Irrelevant.

Allergan insists that its complaint "did not assert the [FDCA] as an independent cause of action *or* as a predicate [statutory violation] for its UCL claim." BIO 4. But this is immaterial in the preemption analysis.

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[3] Allergan suggests that Athena's preemption argument was "untimely" because it was raised on a motion for reconsideration in the district court. BIO 6. But "it is irrelevant…*when* a Federal question was raised" below if "such question was actually considered and decided." *Orr* v. *Orr*, 440 U.S. 268, 274-75 (1979); *see also United States* v. *Williams*, 504 U.S. 36, 41-43 (1992) (any issue "passed upon" by a Court of Appeals is suitable for review by this Court). The preemption issue was fully briefed in, and squarely decided by, the Federal Circuit (and the district court before it). The issue is therefore preserved.

In *Buckman*, the plaintiffs did not assert a standalone claim under the FDCA, nor a state-law claim that "borrowed" an FDCA violation. Their claim was a pure *state common-law claim*. Pet. 24; *see also* Br. of United States as *Amicus Curiae* in *Warner-Lambert Co.* v. *Kent* ("*Kent* FDA Br."), 2007 U.S. S. Ct. Briefs LEXIS 1867, at *22 (Nov. 28, 2007) ("the claims in *Buckman* were…common-law tort claims").[4]

Nonetheless, this Court unanimously held that the claim was preempted. The Court's analysis did not turn on whether the claim "arose" under state or federal law. Nor did it look to whether the claim was "predicated expressly on" specific provisions of the FDCA. *Cf.* BIO 18-19. Had the Court taken either of those formalistic approaches, *Buckman* would have come out the other way.

Instead, the Court's approach was functional: it looked to the *effect* of claims that pry into the defendant's "dealings with the FDA" on FDA's regulatory prerogatives and prosecutorial discretion. 531 U.S. at 347, 349-51; *see Kent* FDA Br. at *44 (in

[4] Allergan seizes on the *Buckman* Court's observation that the plaintiffs' claim existed "solely by virtue of the FDCA." BIO 18 (quoting 531 U.S. at 353). This did not mean that the plaintiffs were *suing under* the FDCA; rather, as the Court stated, their claim arose "under state tort law." 531 U.S. at 343. What mattered was that the FDCA's existence was a *condition precedent* for the plaintiffs' claims. The same is true here.

Buckman, "preemption resulted" not from the form of the claim, but "from the fact that liability turned on an inquiry that frustrated the federal scheme"); *cf. Northwest, Inc.* v. *Ginsberg*, 134 S. Ct. 1422, 1430 (2014) (preemption turns on the "real-world consequences" of a claim, not its "form").

In short, it simply does not matter that Allergan's complaint did not assert a freestanding cause of action under the FDCA, or a state-law claim that directly "borrowed" the FDCA. As detailed above, California's Sherman Law itself requires approval by FDA "under…the federal act." Thus, Allergan's claim "makes liability turn on the very same *determination*" that renders a standalone lack-of-FDA-approval claim so problematic. *Kent* FDA Br. at *17, *21 (emphasis added). Allergan's claim, therefore, necessarily results in "the same impermissible intrusion into FDA's oversight of the approval process and its exercise of enforcement discretion." *Kent* FDA Br. at *47.

This Court's "parallel claims" jurisprudence is not to the contrary. Some of the "parallel claims" cases that Allergan cites did not address *implied* preemption. Pet. 28-30. Moreover, all of them—unlike the claim in *Buckman* and Allergan's claim here—involved "traditional" state-law theories of liability (*e.g.*, fraud, negligence, failure to warn) that "predated the [FDCA]," *Buckman*, 531 U.S. at 352-53, and did not implicate the defendants' interactions with a federal agency. Pet. 35. And all of them were *damages* suits that "serve[d] a compensatory func-

tion distinct from federal regulation." *Wyeth* v. *Levine*, 555 U.S. 555, 563 (2009) (emphasis added). Pet. 33-34. Allergan's claim, in contrast, sought a flat-out ban on the sale of RevitaLash.

Allergan suggests that the Solicitor General agrees with its position on "parallel claims." BIO 12. In fact, the Solicitor General acknowledges that even "parallel" claims may be impliedly preempted if they fail to "appropriately account[] for FDA's role under the FDCA." Br. of United States as *Amicus Curiae* in *Mutual Pharm. Co.* v. *Bartlett*, 2013 U.S. S. Ct. Briefs LEXIS 450, at *41 (Jan. 22, 2013). Indeed, the Solicitor General has observed that "parallel" claims involving the FDA-approval process *are* impliedly preempted, even while arguing that other "parallel" claims are not. *See, e.g.*, Br. of United States as *Amicus Curiae* in *Bank of America, N.A.* v. *Rose*, 2014 U.S. S. Ct. Briefs LEXIS 2004, at *29-30 (May 27, 2014) ("Unlike…*Buckman*, respondents' suit does not involve…an agency's approval of a product"); Br. of United States as *Amicus Curiae* in *Albertson's, Inc.* v. *Kanter*, 2008 U.S. S. Ct. Briefs LEXIS 3763, at *32 (Dec. 5, 2008) (same). This is because "parallel" claims involving manufacturers' submissions (or non-submissions) to FDA would "influence the relationship between FDA and manufacturers" and "ask[ ] the finder of fact to speculate about the answers to questions…committed to FDA's discretion." Br. of United States as *Amicus Curiae* in *Medtronic, Inc.* v. *Stengel*, 2014 U.S. S. Ct.

Briefs LEXIS 1868, at *15-16, 33-36 (May 20, 2014).[5]

B. This Is Not A "Health And Safety" Case.

Buckman contrasted "dealings-with-FDA" claims with non-preempted claims "implicating…the historic primacy of state regulation of matters of health and safety." 531 U.S. at 348. Allergan's attempts to shoehorn its claim into that category fail.

For example, Allergan stresses that the Sherman Law appears in California's "Health and Safety" Code. BIO 17-18. But preemption cannot turn on how states title their laws, or where they are codified. *Cf. Wisconsin Dep't of Indus., Labor & Human Rels.* v. *Gould, Inc.*, 475 U.S. 282, 287-89 (1986).

Allergan also conflates approval status with actual safety, arguing that unapproved drugs "are *by definition* unsafe." BIO 18. This is circular reasoning: under the FDCA, pre-approval is not required for cosmetics such as RevitaLash. One must accept that RevitaLash is a new drug—a determination committed to FDA's sole discretion—before one can even begin to apply Allergan's flawed tautology.

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[5] Allergan argues that this Court's denial of certiorari in *Stengel* counsels denial here. As the Solicitor General explained, however, the *Buckman* question was "academic" in *Stengel* because it arose only as a result of the Ninth Circuit's erroneous *express*-preemption ruling. 2014 U.S. S. Ct. Briefs LEXIS 1868, at *15-16, 33-36. No such bar to review exists here.

Moreover, "off-label" (*i.e.*, non-FDA-approved) uses of drugs and devices are often "essential to…optimal medical care." *Buckman*, 531 U.S. at 350-51 & n.5. Because lack of FDA approval, standing alone, "denotes nothing about health risks or benefits," it is "not possible to draw any conclusion about…safety" from an article's unapproved status. James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 84 (1998) (cited in *Buckman*).

In any event, *Buckman* teaches that, in classifying state-law claims as preempted "dealings-with-FDA" claims or non-preempted "health-and-safety" claims, the plaintiff's *actual theory of liability* controls. The *Buckman* plaintiffs were gravely injured by a device implanted in their spines (a use FDA had not approved). 531 U.S. at 346. Even so, the Court did not deem their claim a "health-and-safety" claim, because their *theory of liability* turned on alleged nondisclosures to FDA—not the substantive question of the device's safety. Pet. 24.

Here, by the same token, Allergan's *theory of liability* was not that RevitaLash is unsafe—it is not. Rather, as Allergan conceded below, its UCL claim arises "*purely as a result* of [Athena's] failure to obtain an approved new drug application." C.A. App. 500. Allergan's claim is therefore a preempted "dealings-with-FDA" claim, not a "health-and-safety" claim.

The same is true of Allergan's invocation of decisions such as *Farm Raised Salmon Cases*, 175 P.3d 1170, 1173 (Cal. 2008), *cert. denied sub nom. Albertson's Inc.* v. *Kanter*, 555 U.S. 1097 (2009), which involved the states' traditional power to prevent consumer deception. As Allergan admitted below, its *theory of liability* is "wholly independent of the veracity of the statements [Athena] made to consumers." C.A. App. 495.[6]

III. THE DECISION BELOW CREATES A SPLIT IN AUTHORITY.

Allergan argues that the Federal Circuit's decision does not create a true split of authority among the lower courts. Once again, Allergan is mistaken.

First, Allergan mischaracterizes the appellate decisions cited in Athena's Petition. Contrary to Allergan's assertion, *PDK Labs, Inc.* v. *Friedlander*, 103 F.3d 1105 (2d Cir. 1997), and *PhotoMedex, Inc.* v. *Irwin*, 601 F.3d 919 (9th Cir. 2010), were not exclusively about "use [of] the [*federal*] Lanham Act as a vehicle…to enforce the FDCA." BIO 13-14. The plaintiffs in both cases also asserted *state-law* claims premised

[6] Indeed, Allergan's claim in the district court was that RevitaLash promises to, and does in fact, cause eyelashes to grow. In other words, according to Allergan, Athena broke the law by telling the truth about RevitaLash. Consumer deception was never at issue below, and it is not at issue here. Allergan's disparaging reference to RevitaLash as "snake oil" (BIO 22) is both false and unsupported by any evidence in the record.

on lack of FDA approval. *See Friedlander*, 103 F.3d at 1107, 1113; *PhotoMedex*, 601 F.3d at 921, 923 & n.7. The Lanham Act claims may have received more discussion, but the courts clearly found the plaintiffs' state-law claims barred by the FDCA. Meanwhile, both *Loreto* v. *P&G*, 515 F. App'x 576 (6th Cir. 2013), and *Perez* v. *Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013)—the latter of which Allergan entirely ignores—involved *only* state-law claims.

Second, Allergan argues that the cases in Athena's Petition involved state statutory claims "predicated expressly" on noncompliance with the FDCA, whereas Allergan's UCL claim is "predicated" on California's Sherman Law. BIO 14. As already discussed, this is a distinction without a difference, because the Sherman Law itself requires approval "*under…the federal act*."

Thus, like each of the cases in Athena's Petition, the question on which liability ultimately turns here is the sufficiency of Athena's *federal* approval status. As in all of those cases, "were it not for the federal regulatory scheme the FDCA created," Allergan's state-law theory of liability would collapse. *Loreto*, 515 F. App'x at 579. That Allergan chose to coat the dispositive federal inquiry in *two* layers of state-law veneer, rather than just one, is not a meaningful distinction.

IV. ATHENA DOES NOT CONCEDE THAT REVITALASH IS A "DRUG."

Allergan claims that Athena "does not dispute in this Court that RevitaLash is a drug." BIO 8, 22. That is not true. Athena's Petition repeatedly denies that RevitaLash is a "drug." *See, e.g.*, Pet. 2 (district court's "drug" holding "was directly contrary to FDA's position"), 5 (RevitaLash products are "cosmetics and not 'drugs'"), 10 ("FDA *does not* consider products such as RevitaLash…to be 'drugs'").[7]

Athena does not *ask this Court* to review and decide the drug-or-cosmetic question. But that is not because the lower courts were correct—it is because this is a "decision[ ] Congress entrusted to FDA alone." Pet. 2-3. As Allergan itself asserted just weeks ago, in a case in which *Allergan's* products are alleged to be unapproved "drugs" under California law, "*FDA…has primary jurisdiction to determine* whether a product is a 'drug.'" Mot. to Dismiss (Doc. 20-1) at 19, *Ruhnke* v. *Allergan, Inc.*, No. 8:14-cv-420 (C.D. Cal. June 23, 2014). That is the issue squarely presented here: who should decide, in the first in-

[7] Allergan is wrong that FDA regulations require "all hair growth *products*" to have an approved NDA. BIO 1 (citing 21 C.F.R. 310.527(b)) (emphasis added). That regulation applies only to articles that FDA has already determined to be "*drug* product[s]." 21 C.F.R. 310.527(b) (emphasis added). Indeed, in response to Allergan's lobbying efforts, FDA has expressly stated that it must decide the "drug" status of eyelash conditioners "on a product by product basis." Pet. 11-12; C.A. App. 2879, 2834.

stance, whether products in interstate commerce are drugs or cosmetics—FDA, or judges and juries acting under state law?

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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August 5, 2014