No. 13-1379

IN THE
Supreme Court of the United States

ATHENA COSMETICS, INC.,

Petitioner,

v.

ALLERGAN, INC.,

Respondent.

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

SUPPLEMENTAL BRIEF FOR RESPONDENT

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RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondent Allergan, Inc. discloses that its parent corporation is Actavis plc, which is a publicly traded company. No other publicly held corporations own 10% or more of Allergan, Inc.'s stock.

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SUPPLEMENTAL BRIEF FOR RESPONDENT

The Solicitor General has confirmed that "parallel state-law claims are not impliedly preempted unless they conflict with FDA's administration of the FDCA" and that "the court of appeals' determination that RevitaLash is a 'drug' under [California law] poses no conflict with federal law or with any decision of FDA." U.S. Br. 9–10.

In response, petitioner Athena Cosmetics, Inc. now contends that outside the realm of "fraud, negligence, [or] failure to warn" claims, *all* state statutes regulating the marketing or sale of unapproved drugs are impliedly preempted by Section 337 of the FDCA—even where there is no conflict between the demands of federal and state law. Pet. Supp. Br. 1. That contention does not warrant review.

I. The FDCA Does Not Preempt All State Drug Regulation

According to Athena, the Solicitor General's conclusion that Allergan's state-law claim is not preempted by the FDCA is "wrong" for three reasons (Pet. Supp. Br. 3), each of which boils down to the notion that there is no role for parallel state regulation of drugs. But both Congress and this Court have already rejected that position. Drug Efficacy Amendment of 1962, Pub. L. No. 87-781, § 201, 76 Stat. 780, 793; *Wyeth v. Levine*, 555 U.S. 555, 573, 578 (2009).

1. This Court has repeatedly explained that the FDCA does not preempt "parallel" state laws. *See*, *e.g.*, *Wyeth*, 555 U.S. at 574; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001). Athena does not deny that the California law at issue

here is parallel to federal law (indeed, it is identical); instead, Athena argues that such a law is saved from preemption only if "judges and juries will *apply* [it] in the same manner FDA would." Pet. Supp. Br. 3. Athena fundamentally misapprehends the nature of "parallel" state-federal regulation.

Under both federal and California law, whether a product is a "drug" is a question that "hinges on an article's 'intended use.'" Pet. Supp. Br. 4. Courts regularly decide the intended use of products in this context. *See*, *e.g.*, *United States v. Article of Drug … Bacto-Unidisk*, 394 U.S. 784, 798 (1969); *United States v. Storage Spaces Designated Nos. "8" & "49"*, 777 F.2d 1363, 1366 (9th Cir. 1985); *United States v. Millpax, Inc.*, 313 F.2d 152, 154 (7th Cir. 1963); *United States v. 47 Bottles, More or Less*, 320 F.2d 564, 567 (3d Cir. 1963). Moreover, in this case that question is specifically governed by an on-point regulation, applicable identically under both federal and California law, providing that all externally applied hair growth products are "new drugs." *See* Cal. Health & Safety Code § 110110; 21 C.F.R. § 310.527. There is thus little danger that state law will be applied in this context in a way that conflicts with federal law.

And it is clear that state law has *not* been applied in this case in a way that conflicts with federal law: The government's brief leaves no doubt that FDA does not disagree with the judgment of the courts below that RevitaLash is a drug. As the government's brief explains, Allergan's "claim thus does not supplant any regulatory determination by FDA regarding the product's status as a cosmetic or a new drug. No conflict is presented between the federal and state standards in this regard or in the application of those standards to petitioner and

RevitaLash." U.S. Br. 11. That should be the end of the implied conflict preemption inquiry.

2. Athena next argues that the state-law claim here is preempted under *Buckman*. Pet. Supp. Br. 5. The entire rationale of *Buckman* is inapplicable here, however, because Athena never filed any application with FDA, fraudulent or otherwise, to sell its RevitaLash drug products. Allergan did not accuse Athena of defrauding FDA, but rather of selling a new drug without securing the requisite regulatory approval.*

Athena could have filed a new drug application *after* Allergan filed its lawsuit or *after* the district court held that the sale and promotion of RevitaLash was unlawful. But instead, Athena stipulated to the entry of an injunction barring the promotion and sale of RevitaLash in California pursuant to the very California Health and Safety Code statute that it

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* Although the government correctly observes that the availability of state-level approval is ultimately irrelevant (U.S. Br. 11 n.3), Athena continues to insist that such approval is "fanciful." Pet. Supp. Br. 1 n.1. California legislative and executive materials, however, clearly describe a mechanism for submitting and obtaining approval of new drug applications. *See* Cal. Health & Safety Code §§ 111550, 111555, 111560, 111575 (describing the process and bases for submitting, approving, and denying new drug applications); 61 Ops. Cal. Att'y Gen. 192 (1978) (discussing limits on "advertising which has been approved subsequent to the submission of an appropriate federal or state new drug application"). California courts have enforced these procedures. *See People v. Sanjuan*, No. BC420860, 2009 WL 8747808, at *2 (Cal. Super. Ct. Oct. 1, 2009) (enjoining defendant from "[s]elling … any new drug … unless in compliance with Health and Safety Code section 111550 *et seq.*"). And, of course, Athena never even submitted a state-level application, so it has no basis to assert that such an application would not have been considered.

argues is preempted. *See* Letter from M. Perry to Supreme Court of the United States (Sept. 9, 2014) (enclosing Order Granting Joint Motion for Entry of Modified Permanent Injunction, No. 8:07-01316-JVS-RNB at Dkt. No. 1087 (C.D. Cal. Sept. 4, 2014)). Athena's state-level violation has been redressed by a state-level injunction.

Athena's attempt to rewrite *Buckman* to extend to all cases where a party "failed to file with the FDA" would, if accepted, transform *Buckman* preemption into *field* preemption, a result directly at odds with both *Buckman* and *Wyeth*. *Buckman*, 531 U.S. at 353 (holding that "certain state-law causes of actions that parallel federal safety requirements" are not preempted); *Wyeth*, 555 U.S. at 565 n.3 (recognizing that *Buckman* "involved state-law fraud-on-the-agency claims, and the Court distinguished state regulation of health and safety as matters to which the presumption does apply").

The government has advised the Court, in no uncertain terms, that "unlike the fraud-on-the-FDA claim in *Buckman*, [Allergan's] claim of unfair competition poses no 'obstacle to the accomplishment and execution' of federal objectives under the FDCA." U.S. Br. 11. That should be the end of the *Buckman* inquiry.

3. Athena predicts that a slew of hypothetical and inapposite lawsuits will "engulf the cosmetics industry," "clog[] the courts," and create a "crazy-quilt" of conflicting judgments. Pet. Supp. Br. 10–13.

Unlike the "toothpaste" and "Cheerios" hypothetical examples in Athena's brief, *all* externally applied products intended to grow hair—including Latisse and RevitaLash—are considered "new drugs" requiring premarket approval, because

they are *by definition* not generally recognized as safe and effective. This is true under *both* federal and California law. Cal. Health & Safety Code § 110110; 21 C.F.R. § 310.527; *United States v. Kasz Enters., Inc.*, 855 F. Supp. 524, 541–42 (D.R.I. 1994) (describing regulatory history leading to blanket rule regarding hair growth drugs). Thus, after reviewing the mountain of evidence demonstrating that RevitaLash was intended to be used for eyelash growth, the district court and the court of appeals correctly concluded that there can be "no dispute that Athena objectively intends that [RevitaLash] be used as [a] drug[]." Pet. App. 14a. As the government recognized, these decisions pose no threat to the uniformity of the FDCA regime. U.S. Br. 11.

Implied preemption ultimately and necessarily turns on conflicts between state and federal law. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995). But there is no conflict here between the state and federal prohibitions, or their application in the context of the drug at issue here. Athena has never identified an actual conflict between the judgment in this case and any aspect of federal law, and the Solicitor General—speaking for FDA—confirms that there is none. Given that Athena does not identify an actual conflict and the federal agency at issue has no concern with how the parallel state law has been applied, there is no reason for further review.

II. There Is No Conflict Of Authority On The Question Presented Here

Athena makes much of the fact that this is the first case of its kind in the history of the FDCA—normally the last thing one would expect to hear

from a party petitioning for certiorari. Pet. Supp. Br. 2. It is thus unsurprising that the lower court decisions cited by Athena as conflicting do not in fact conflict. *See* Br. in Opp. 13–15; U.S. Br. 17–20.

Athena cites in its supplemental brief one additional case to support the unremarkable point that FDCA preemption is not straightforward in all instances. In *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335 (10th Cir. 2015), the court held that the plaintiff's state-law claims were preempted by the medical device amendments (MDA) to the FDCA because those state-law claims imposed "substantially" more requirements on the device manufacturer than "any federal regulation." *Id.* at 1341 (noting that as to several claims, the plaintiff "has not attempted … to identify a single parallel federal statute or regulation"). The court analyzed what it viewed as "a number of opinions that embody 'divergent views' about the proper role of the MDA's preemption provision" (*id.* at 1337), a provision not at issue in this case.

Caplinger did not even cite the decision below, let alone disagree with it. Although *Caplinger* expressed the need for further guidance from this Court on a *different* implied preemption issue arising under the FDCA, that plea has no bearing here, where there is no circuit split on whether cases like this one conflict with federal law and the government—which would be expected to sound the alarm if the proper operation of FDA's regulatory program were imperiled—has instead reassured the Court that certiorari is not warranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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