No. 23-788

In the
Supreme Court of the United States

HOPE MEDICAL ENTERPRISES, INC.
DBA Hope Pharmaceuticals,
Petitioner,

v.

FAGRON COMPOUNDING SERVICES, LLC; JCB LABORATORIES, LLC; ANAZAOHEALTH CORPORATION; COAST QUALIFY PHARMACY, LLC,
Respondents.

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

REPLY BRIEF FOR PETITIONER

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REPLY

The Ninth Circuit in *Nexus* and the decision below created an oxymoronic form of conflict preemption that requires no conflict between state and federal law. Hope sued Fagron under state unfair-competition statutes to enforce state statutes that prohibit the sale of drugs not approved by FDA. Fagron concedes that, under both state and federal law, its sodium thiosulfate drug needs but lacks FDA approval. It is thus undisputed that Fagron's drug violates state statutes that, as applied here, impose the *exact same* drug-approval requirement as the FDCA. Enforcing those parallel state requirements cannot conflict with federal law.

To get around that problem, Fagron contends that Hope's "ostensible" state-law claims are *really* private FDCA claims preempted by 21 U.S.C. § 337(a) because they are "predicated" on an FDCA violation. BIO 1. And that is indeed what the Ninth Circuit held. But that holding creates multiple circuit splits and conflicts with this Court's precedent. Pet.18-31. In defending the decision below, Fagron highlights how far the Ninth Circuit departed from other courts' approach to FDCA preemption.

As its final Hail Mary, Fagron claims for the first time that this case became moot when—more than a year before the Ninth Circuit issued its decision—FDA found no clinical need for compounders to make drugs from bulk sodium thiosulfate. BIO 21-22. But Fagron's mere assertion that it will cease its illegal conduct cannot create mootness, and the parties maintain a concrete interest in the district court's award of attorney fees to Hope. Fagron's last-ditch mootness

argument thus presents no obstacle to review. To the contrary, it underscores that this case is an ideal vehicle because FDA *agrees* that the FDCA equally prohibits Fagron's conduct—cleanly teeing up the Ninth Circuit's holding that § 337(a) preempts any state-law claim "predicated" on an FDCA violation, even *without* any conflict.

ARGUMENT

I. The decision below and *Nexus* create multiple conflicts on an important question.

In *Nexus* and the decision below, the Ninth Circuit held that § 337(a) preempts any "private cause of action under state law predicated on a violation of [the FDCA]." BIO 14-15; *see Nexus Pharms., Inc. v. Cent. Admixture Pharm. Servs., Inc.*, 48 F.4th 1040, 1046 (9th Cir. 2022). That holding creates multiple splits of authority on a deeply important question. Pet.18-31. Fagron's attempts to dispute that conclusion only confirm its truth.

1. It is first necessary to get a few things straight about Hope's claims. Hope sued Fagron to enforce *state drug-approval* requirements, not (as Fagron pretends) *compounding* requirements. And the district court found Fagron liable under state law for violating those state *drug-approval* requirements. App.38-46.

Hope sued under *state* unfair-competition statutes, not the FDCA. BIO 1. And Hope claimed Fagron violated those *state* unfair-competition statutes because its drug violated premarket approval requirements imposed by *state* drug-approval statutes. *Id.*; Supp.App.29-35. Fagron does not deny that its sodium thiosulfate drug is a "drug" under

those state laws, and it concedes its drug is unapproved. BIO 12. That establishes all the essential pieces of Hope's claims.

Where, then, does the FDCA come in? It comes in with *Fagron's* assertion that state drug-approval laws cannot be applied to drugs that comply with the FDCA's compounding provisions. Fagron contends it would conflict with the FDCA, which "authorizes drug compounding," if "showing that a particular drug product was unapproved were sufficient to establish a violation of state unfair-competition laws." BIO 12-13. That may or may not be right, but Hope removed that issue from the case by limiting its claims to situations where Fagron's drug violated both state *and* federal drug-approval requirements. Pet.17.

That is why Hope alleged and proved Fagron's (now undisputed) noncompliance with the FDCA's compounding requirements. Hope's theory is not, as Fagron asserts, "that Fagron violated state drug-approval laws … *because it violated the FDCA's compounding requirements*." BIO 10. Fagron violated state drug-approval laws *by selling an unapproved drug*. It was *Fagron*'s theory that compliance with federal compounding requirements trumps state drug-approval laws. By proving Fagron does *not* comply with the FDCA's compounding requirements, Hope made Fagron's theory irrelevant. As a result, it is undisputed that the state laws at issue, as applied here, prohibit the *exact same conduct* as federal law.

Fagron, therefore, must argue that state laws imposing the same requirements as the FDCA somehow *conflict with* the FDCA. Fagron, like the Ninth Circuit, rests that argument on § 337(a),

arguing that it preempts any "private lawsuit predicated on alleged FDCA violations, even if ostensibly based on state law." BIO 1. But the Ninth Circuit is the only appellate court to have adopted that extreme interpretation of § 337(a). Under the decisions of other federal circuits and the California Supreme Court, this Court's precedent, and the United States' view of FDCA preemption, state-law claims "predicated on alleged FDCA violations" are *not* federal claims preempted by § 337(a). *Id.* They are parallel state-law claims that do not conflict with the FDCA. Pet.18-31.

2. The Ninth Circuit itself recognized in *Nexus*, 48 F.4th at 1049-50, that its approach to FDCA preemption conflicts with the Federal Circuit's decision in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (2013).

Fagron's claim that *Nexus* and *Athena* are consistent (BIO 16) would come as a surprise to the Ninth Circuit. The *Athena* plaintiff, like Hope, claimed the defendant violated California's drug-approval law (the Sherman Law) by selling an unapproved drug. 738 F.3d at 1353. Deciding whether the defendant violated the Sherman Law required the court to decide "whether the federal regulations incorporated therein [were] violated." *Id.* at 1354 (cleaned up). The defendant thus argued that § 337(a) preempts state drug-approval statutes "that simply incorporate[] FDCA provisions." *Id.* at 1355. The Federal Circuit rejected that argument. *Id.* But *Nexus* came to the opposite conclusion, holding that "the FDCA's prohibition of private enforcement" preempts the

Sherman Law *because* it "incorporate[s] FDCA requirements." 48 F.4th at 1048-49.[1]

It is pure sophistry for Fagron to argue that "Hope's claims are predicated on alleged violations of the FDCA" while the claim in *Athena* was not. BIO 15-16. Hope, like the *Athena* plaintiff, claims Fagron violated state drug-approval laws, including the Sherman Law, by selling an unapproved drug. Supp.App.29-30. And, just as Fagron argues about Hope's claims, the claim in *Athena* required a court to decide whether "federal regulations" were "violated." 738 F.3d at 1354 (cleaned up).[2] If § 337(a) bars courts from deciding whether "there has been a violation of the FDCA" when resolving a state-law claim (BIO 3)—if such an embedded FDCA issue renders a state-law claim an improper FDCA claim—then *Athena* was wrongly decided. And that, after all, is what *Nexus* held—creating a clear circuit split.

The *Nexus* rule likewise conflicts with the Solicitor General's invitation briefs in *Athena* and

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[1] Fagron correctly consigns to a footnote its argument that *Nexus* and *Athena* do not technically conflict because *Athena* was interpreting Ninth Circuit precedent. BIO 16 n.*. The Federal Circuit held § 337(a) does not preempt the same provision of the same state statute that *Nexus* held § 337(a) preempts, and *Nexus* expressly rejected its holding and rationale.

[2] Fagron says state drug-approval statutes do not "'borrow' or 'parallel' the FDCA's compounding requirements" (BIO 11), but if that's right, it underscores that the FDCA entered this case through Fagron's defense that state drug-approval statutes cannot apply to compounded drugs that comply with the FDCA. Even Fagron's quote from the district court's decision shows the court's conclusion that Fagron had not "established any valid defenses." BIO 7-8; App.31.

Farm Raised Salmon Cases, 175 P.3d 1170, 1181 (Cal. 2008). Pet.20-21. In *Farm Raised Salmon* in particular, the Solicitor General rejected the Ninth Circuit's and Fagron's theory that § 337(a) preempts state-law claims "predicated" on FDCA violations: "[E]ven when state-law claims are *predicated on violations of the FDCA*, they remain state-law claims." U.S. Amicus Curiae Br. 13, *Albertson's, Inc. v. Kanter*, 555 U.S. 1097 (2009) (No. 07-1327) (emphasis added).

The Fifth Circuit has held the same. While the Ninth Circuit held "that States cannot create a private cause of action under state law predicated on a violation of [the FDCA]" (BIO 14-15), the Fifth Circuit has held that § 337(a) does "not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Spano ex rel. C.S. v. Whole Foods, Inc.*, 65 F.4th 260, 264 (2023) (cleaned up) (citing *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 775 (5th Cir. 2011)). Even when a state-law claim is "predicated on violations of FDA regulations," the Fifth Circuit treats it as a state-law claim. *Bass v. Stryker Corp.*, 669 F.3d 501, 514 (5th Cir. 2012).

Spano, *Bass*, and *Hughes* did not involve any "parallel provision of state law" independently imposing the same requirements as the FDCA. BIO 18. In *Spano* and *Bass*, for example, the plaintiffs claimed the defendants violated Texas's unfair-competition statute *by violating the FDCA*. *Spano*, 65 F.4th at 262; *Bass*, 669 F.3d at 514, 518. To succeed on those claims, the plaintiffs had to prove "violations of federal requirements." *Bass*, 669 F.3d at 517-18; *see Spano*, 65 F.4th at 265. Despite that, the Fifth Circuit held, in direct conflict with the Ninth Circuit, that

§ 337(a) did not preempt the plaintiffs' claims. *Spano*, 65 F.4th at 263-65; *Bass*, 669 F.3d at 513-14, 517-18. In the Fifth Circuit, therefore, § 337(a) would not preempt Hope's claims.

3. The Ninth Circuit's holding that a state-law claim predicated on FDCA violations is a private FDCA claim preempted by § 337(a) further conflicts with this Court's decisions in *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986), and *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014). Pet.29-31.

Fagron ignores *Merrell Dow*, which demonstrates that a state-law claim does not become an FDCA claim merely because "a claimed violation of the [FDCA] [i]s an element of [the] state cause of action." 478 U.S. at 814. If a state-law claim premised on FDCA violations were, for that reason, an FDCA claim, it would "arise under" the FDCA. *Id.* at 808. But *Merrell Dow* held that such a claim does *not* arise under federal law. *Id.* at 817.

POM Wonderful is equally clear. It reversed the Ninth Circuit's holding that § 337(a) precludes Lanham Act claims premised on FDCA violations, holding that a suit "to enforce the Lanham Act" is not a suit to enforce "the FDCA or its regulations" even if it requires litigating FDCA issues. 573 U.S. at 117. Yet *Nexus* relied on a pre-*POM Wonderful* decision holding that § 337(a) *does* "forbid[]" Lanham Act claims that "would require litigation of the alleged underlying FDCA violation." 48 F.4th at 1049 (quoting *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010)).

That is also why the *Nexus* rule conflicts with the First Circuit's decision in *Azurity Pharmaceuticals, Inc. v. Edge Pharma, LLC*, 45 F.4th 479, 495 (2022), where a Lanham Act claim required proving noncompliance with the FDCA's compounding requirements. The First Circuit held that § 337(a) did not preclude the claim because it sought "to enforce the Lanham Act, not the FDCA or its regulations." *Id.* at 500 (cleaned up).

Fagron argues Lanham Act preclusion cases are irrelevant to preemption (BIO 18), but *POM Wonderful* rebuts that notion. Even though "preemption precedent does not govern preclusion," this Court still held that preemption "principles are instructive." 573 U.S. at 111-12. It then repeatedly cited *Wyeth v. Levine*, 555 U.S. 555 (2009), an FDCA preemption decision, to support its conclusion. 573 U.S. at 113-18.

Fagron's argument also makes no sense on its own terms. If § 337(a) bars courts from deciding whether "there has been a violation of the FDCA" (BIO 3) in private lawsuits, that would be true regardless of whether such a suit is brought under state or federal law. *Merrell Dow*, 478 U.S. at 812 ("[I]t would flout congressional intent to provide a private federal remedy for the violation of the [FDCA]."). That is no doubt why *Nexus* relied on the overruled *PhotoMedex* Lanham Act decision. But since *POM Wonderful* holds that a Lanham Act claim predicated on FDCA violations does not thereby become a private FDCA claim barred by § 337(a), neither does a state-law claim predicated on FDCA violations. Hope's claims really *are* state-law claims—not "ostensible" state-law

claims—just as the claim in *POM Wonderful* really *was* a Lanham Act claim.[3]

4. The Ninth Circuit and Fagron's reliance on FDA's enforcement discretion also conflicts with this Court's and other circuits' decisions. Fagron argues judges and juries may not "determine that there has been a violation of the FDCA before the FDA itself has made such a determination." BIO 3. But "the possibility that federal enforcement priorities might be upset" by state law "is not enough" for preemption. *Kansas v. Garcia*, 589 U.S. 191, 212 (2020). The FDCA in particular does *not* make "FDA oversight … exclusive." *Wyeth*, 555 U.S. at 575.

Fagron never cites *Wyeth*. Nor does it engage with *POM Wonderful*, which *reversed* the Ninth Circuit's holding that litigating FDCA issues through Lanham Act claims "risk[s] undercutting the FDA's expert judgments and authority." 573 U.S. at 111 (cleaned up). Because FDA lacks "expertise in assessing market dynamics that day-to-day competitors possess" and "does not necessarily pursue enforcement measures" against all lawbreakers, *id.* at 115-16, "state law offers an additional, and important, layer of consumer protection," *Wyeth*, 555 U.S. at 579.

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[3] More broadly, what does Fagron mean by its "ostensible" slur? The state drug-approval and unfair-competition statutes it violated are real. Not even Fagron claims the FDCA is, like ERISA, a "complete preemption" statute that transforms any state-law claim into a federal claim. *Aetna Health Inc. v. Davila*, 542 U.S. 200, 207-09 (2004). *Merrell Dow* forecloses any such notion.

Other circuits and the United States agree. As the government has explained, "[n]o conflict with a supposed FDA position … can be inferred from the absence of FDA enforcement." U.S. Amicus Curiae Br. 10, *Athena Cosmetics, Inc. v. Allergan, Inc.*, 576 U.S. 1054 (2015) (No. 13-1379). The Fifth Circuit, accordingly, has held that "a formal finding of a violation by the FDA [is] not required to plead a parallel action." *Bass*, 669 F.3d at 509. And the First Circuit, as Fagron concedes, held that deciding "whether a particular drug substance appears on" FDA's 503B bulks list does not "conflict" with "FDA policy discretion." BIO 19 (quoting *Azurity*, 45 F.4th at 501-02). *Nexus* and the decision below conflict with those decisions.

II. This case is an ideal vehicle.

While arguing that Hope's claims somehow conflict with FDA's authority, Fagron asks this Court to deny certiorari because FDA *agrees* with Hope that Fagron cannot lawfully compound its drug. BIO 21-22. But Fagron's mootness argument, which it never raised below, poses no obstacle to review.

1. Fagron's bare assertion that it will not make its drug due to FDA's decision that there is no clinical need for use of bulk sodium thiosulfate in compounding (BIO 21) cannot satisfy its "formidable" burden to prove it will not "resume its challenged conduct." *FBI v. Fikre*, 144 S. Ct. 771, 778 (2024) (emphasis omitted). Sodium thiosulfate has *never* appeared on the bulks list, App.25, but that didn't stop

Fagron before, App.37.[4] Fagron even told the Ninth Circuit its drug was "exempt from pre-market approval" *after* FDA's decision. C.A.Dkt.29 at 30; C.A.Dkt.75 at 6-7. Fagron's history of violating the requirement it now claims it will follow prevents it from proving it will not "return to [its] old ways." *Friends of Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 189-90 (2000) (cleaned up).

Fagron also ignores the other provisions of the district court's injunction. Even if sodium thiosulfate is added to the bulks list or Hope's drug appears on the shortage list, Fagron *still* cannot sell its drug without the sort of "clinical difference" statements it never obtained. Supp.App.77-81; Pet.16. Fagron does not claim it will voluntarily comply with that aspect of the injunction. Hope's interest in maintaining the district court's *full* injunction precludes any finding of mootness.

2. Fagron is also incorrect that this "case is limited to declaratory and injunctive relief." BIO 20-21. The district court entered an enforceable judgment awarding Hope mandatory attorney fees under South Carolina law. C.A.ER-46-47. The Ninth Circuit reversed that award, App.3, and this Court's reversal of the Ninth Circuit would reinstate it.

Nothing Fagron says could moot that "controversy over attorney's fees already incurred." *Anderson v. HHS*, 3 F.3d 1383, 1385 (10th Cir. 1993) (cleaned up). Even if Fagron never again sells its drug, "both parties

[4] FDA did not "remove[]" sodium thiosulfate from the bulks list. BIO 8, 21. FDA decided not to *add* it to the list. 87 Fed. Reg. 4240, 4249-50 (Jan. 27, 2022).

retain an interest in recovering or retaining the fees" the district court awarded. *Goldin v. Bartholow*, 166 F.3d 710, 721 n.13 (5th Cir. 1999); *see Chafin v. Chafin*, 568 U.S. 165, 176-77 (2013) (no mootness when appellant challenged fee award).[5]

These concrete "real-world consequences" (BIO 22) no doubt explain why Fagron did not suggest to the Ninth Circuit that this case was moot. FDA issued its decision almost a year before Fagron filed its opening brief below. If that mooted the case, the Ninth Circuit lacked jurisdiction to decide Fagron's appeal—and Hope's judgment would stand. But Fagron never told the Ninth Circuit FDA's decision made its appeal "pointless." *Id.* Fagron's aggressive litigation below casts significant doubt on the sincerity of its new assertion that it has no interest in this case.

3. Fagron identifies no other vehicle problems with the case, which cleanly presents an important legal issue on an undisputed factual record. Indeed, Fagron's failed attempt to turn FDA's decision into a vehicle problem highlights that FDA's agreement that Fagron cannot lawfully sell its drug makes this case an ideal candidate for certiorari. Pet.34-35.

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[5] Fagron, for its part, has sought "prevailing party" fees from the Ninth Circuit under Florida law. C.A.Dkt.76.

CONCLUSION

The Court should grant Hope's petition.

Respectfully submitted,

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