No. 26-1301

In the United States Court of Appeals for the Seventh Circuit

ELI LILLY AND COMPANY,

Plaintiff-Appellant,

v.

ROBERT F. KENNEDY JR., ET AL.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of Indiana
No. 24-cv-1503 (Hon. Tanya Walton Pratt)

SUPPLEMENTAL BRIEF OF APPELLANT

Allon Kedem
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave., N.W.
Washington, DC 20001
(202) 942-5000
allon.kedem@arnoldporter.com

Counsel for Eli Lilly and Company

October 8, 2026

TABLE OF CONTENTS

TABLE OF CONTENTS i
TABLE OF AUTHORITIES ii
INTRODUCTION 1
ARGUMENT 2
I. Supreme Court Precedent Permits a Private Party to Appeal a Remand Order 2
II. Circuit Precedent Permits a Private Party to Appeal a Remand That Grants the Party Only Partial Relief 7
III. Other Circuits Follow a Similar Rule 8
IV. This Court Has Jurisdiction 10
V. FDA's Remand Decision Further Confirms This Court's Jurisdiction 13
CONCLUSION 15
CERTIFICATE OF COMPLIANCE 16
CERTIFICATE OF FILING AND SERVICE 17

TABLE OF AUTHORITIES

Page(s)

Cases

Am. Wild Horse Pres. Campaign v. Jewell,
847 F.3d 1174 (10th Cir. 2016) 9

Chatrie v. United States,
146 S. Ct. 2193 (2026) 13

City of Council Bluffs v. DOI,
11 F.4th 852 (8th Cir. 2021) 9

Clark v. Martinez,
543 U.S. 371 (2005) 4

Cohen v. Beneficial Indus. Loan Corp.,
337 U.S. 541 (1949) 6

Edgewater Found. v. Thompson,
350 F.3d 694 (7th Cir. 2003) 5, 7, 8, 11, 14

Edgewater Found. v. Thompson,
No. 00-cv-6600, 2003 WL 260336 (N.D. Ill. Feb. 5, 2003) 7

FDA v. Wages & White Lion Invs., L.L.C.,
604 U.S. 542 (2025) 5

Forney v. Apfel,
524 U.S. 266 (1998) 1, 3, 4, 5, 6, 7, 11, 12, 13

Koyo Seiko Co. v. United States,
95 F.3d 1094 (Fed. Cir. 1996) 8

Limnia, Inc. v. United States Dep't of Energy,
857 F.3d 379 (D.C. Cir. 2017) 8, 9, 10, 12

Littlefield v. Mashpee Wampanoag Indian Tribe,
951 F.3d 30 (1st Cir. 2020) 8

In re Long-Distance Tel. Serv. Fed. Excise Tax Refund Litig.,
751 F.3d 629 (D.C. Cir. 2014) 9, 12

MCI Telecomms. Corp. v. BellSouth Telecomms. Inc.,
298 F.3d 1269 (11th Cir. 2002) 9

Mitchell v. Forsyth,
472 U.S. 511 (1985) 6

NAACP v. U.S. Sugar Corp.,
84 F.3d 1432 (D.C. Cir. 1996) 9

Navin v. Park Ridge Sch. Dist. 64,
49 F. App'x 69 (7th Cir. 2002) 5

Nixon v. Fitzgerald,
457 U.S. 731 (1982) 6

Occidental Petroleum Corp. v. SEC,
873 F.2d 325 (D.C. Cir. 1989) 9

Perlman v. Swiss Bank Corp. Comprehensive Disability Prot. Plan,
195 F.3d 975 (7th Cir. 1999) 5, 7, 11, 14

Rush Univ. Med. Ctr. v. Leavitt,
535 F.3d 735 (7th Cir. 2008) 5, 8, 10

Sierra Forest Legacy v. Sherman,
646 F.3d 1161 (9th Cir. 2011) 8, 11

Silver v. Smith,
70 F. App'x 17 (2d Cir. 2003) 8

Sullivan v. Finkelstein,
496 U.S. 617 (1990) 1, 3, 5, 11

United Steelworkers of Am. Loc. 1913 v. Union R.R. Co.,
648 F.2d 905 (3d Cir. 1981) 8

Statutes

5 U.S.C. § 706(2) 4

18 U.S.C. § 3731 4

21 U.S.C. § 360bbb-2(b) 2, 12

21 U.S.C. § 360bbb-2(c) 2

28 U.S.C. § 1291 ..... 1, 2, 3, 4, 6, 7, 10, 11, 13

28 U.S.C. § 1292(a)(1) 5

Other Authorities

Lilly's Triple Agonist, Retatrutide, Delivered Substantial Weight Loss and A1C Reduction, Eli Lilly and Company (Sept. 29, 2026), https://investor.lilly.com/news-releases/news-release-details/lillys-triple-agonist-retatrutide-delivered-substantial-weight.....14

INTRODUCTION

The Supreme Court has held that the finality of a ruling under Section 1291 turns on the "class of orders" being appealed, not the party seeking appellate review. *Forney v. Apfel*, 524 U.S. 266, 270 (1998) (quoting *Sullivan v. Finkelstein*, 496 U.S. 617, 628 (1990)). Consistent with that precedent, this Court has repeatedly held that a district court decision remanding to an administrative agency is appealable by both parties so long as the decision is appealable by either of them. A judgment that terminates a civil action in a manner such that decided issues may not return to court is accordingly "final," within the meaning of Section 1291, both for agencies and for private litigants alike.

Those principles establish jurisdiction here. There is no question that FDA could have sought immediate review of the district court's decision remanding the analogous-products issue, placing the court's ruling within the "class of orders" deemed final under Section 1291. The ruling is thus similarly appealable by Lilly because, under *Forney*, *Finkelstein*, and this Court's precedent, the district court's judgment cannot be a "final decision" for the agency alone. The same result would follow in at least eight other circuits, including the D.C. Circuit.

Several additional considerations confirm that this Court has jurisdiction and make this case a particularly poor vehicle for reconsidering settled Seventh Circuit law. The questions presented on appeal are distinct from any issue remanded to FDA. As a result, there was never a risk that this Court would issue an opinion on those remanded issues. In any event, FDA has now issued a new decision on remand (after this Court held argument) rejecting Lilly's position that retatrutide is "analogous" to a protein. That decision confirms that this appeal is the only proceeding that can address the issues presented here.

In addition, Lilly's present appeal raises an argument that neither the district court's remand order nor FDA's subsequent decision encompasses: that a remand was improper under the statutory provision giving automatic effect to a sponsor's recommendation within "60 days" absent a valid decision by the agency. 21 U.S.C. § 360bbb-2(b), (c). As a result, even if Lilly obtains a future favorable decision from a district court on the "analogous" issue, that *still* would not grant Lilly its requested relief here based on the automatic take-effect provision; only an order from this Court would have such an effect. Lilly is not aware of any court of appeals that has declined jurisdiction over an appeal under comparable circumstances.

ARGUMENT

Section 1291 authorizes appeals of "all final decisions of the district courts." The district court's judgment in this case satisfies that standard under the precedent of the Supreme Court, this Court, and other circuits. FDA's recently issued remand decision on the "analogous" product issue—though issued months after the district court's judgment—further confirms that appellate jurisdiction is proper.

I. Supreme Court Precedent Permits a Private Party to Appeal a Remand Order

The Supreme Court has held that both the government and private litigants may appeal from adverse decisions awarding partial relief and remanding to an agency.

A. In *Finkelstein*, the Supreme Court held that an order invalidating agency standards for a disability-benefits determination, which also remanded a benefits claim for consideration under a new standard, was appealable by the government under Section 1291. Although the Court reserved the question "whether remands to administrative agencies are *always* immediately appealable," it allowed appeal of a district court decision holding

that the standard the agency had used to assess impairment contravened the Social Security Act. *Finkelstein*, 496 U.S. at 623-24 (emphasis added). Such a "remand order," the Court explained, "was unquestionably a 'judgment.'" *Id.* at 625.

The Court also determined that the remand order was "final." *Id.* As the Court explained, the order "terminated the civil action challenging the Secretary's final determination that respondent was not entitled to benefits, set aside that determination, and finally decided that the Secretary could not follow his own regulations in considering the disability issue." *Id.* The remand order thus fell within the "class of orders" that qualify as "final judgments" and are accordingly "appealable under § 1291." *Id.* at 628 (quotation marks omitted).

In *Forney*, the Supreme Court extended *Finkelstein* to allow appeals by *private* litigants from remand orders. As the Court explained, rather than creating an asymmetrical rule favoring the government, "*Finkelstein* focused upon a 'class of orders' that Congress had made 'appealable under § 1291.'" *Forney*, 524 U.S. at 270 (quoting *Finkelstein*, 496 U.S. at 628). And, crucially, "[n]othing in the language, either of the statute or the Court's opinion, suggests that such an order could be 'final' for purposes of appeal only when the Government seeks to appeal but not when the claimant seeks to do so." *Id.*

B. Although *Finkelstein* and *Forney* arose in the disability-benefits context, they confirm that remand orders are appealable and foreclose a party-based theory of finality under the same statutory provision (Section 1291) that confers jurisdiction here: "Section 1291 of Title 28 of the United States Code grants the 'courts of appeals … jurisdiction of appeals from all *final decisions* of the district courts.'" *Forney*, 524 U.S. at

269 (emphasis in original). That statutory language extends to a decision setting aside agency action on final judgment, the principal remedy for which the APA provides. *See* 5 U.S.C. § 706(2). Section 1291 makes an entire class of "decisions" appealable; it does not assign appellate rights to *some* parties but not *other* parties to the same decision. *See Forney*, 524 U.S. at 273 ("statutes governing appealability normally proceed by defining 'classes' of cases where appeals will (or will not) lie"). By contrast, where Congress has sought to confer appellate rights on the government alone (typically for otherwise nonfinal orders), it has done so expressly. *See, e.g.*, 18 U.S.C. § 3731.

The fact that Section 1291 applies based on the class of decisions being appealed, rather than differentiating in its application to particular parties, is unsurprising. The Supreme Court has consistently rejected "the dangerous principle that judges can give the same statutory text different meanings in different cases." *Clark v. Martinez*, 543 U.S. 371, 386 (2005). Indeed, the Court in *Forney* noted with approval the Ninth Circuit's recognition "that … [a] judgment, which end[s] [a] 'civil action,' must be 'final' in a formalistic sense … for all parties to it." 524 U.S. at 270 (quotation marks omitted). A contrary rule, the Supreme Court explained, "would deny a [private] claimant the right to seek reversal (instead of remand) through a cross-appeal in cases where the Government itself appeals a remand order, as the Government has every right to do." *Id.* at 271-72. Nor did the Court suggest that its ruling was tied to something unique about the disability-benefits context. To the contrary, in concluding that a party may ordinarily appeal a decision denying full relief, *Forney* pointed to cases outside the disability-benefits context. *See id.* at 272-73.

To the extent *Finkelstein* relied on the Social Security Act's text, its reasoning applies with equal force to litigants seeking appellate review under the Administrative Procedure Act. For instance, the Court observed that the Social Security Act authorizes a district court to enter judgment "with or without remanding" to the agency. *See Finkelstein*, 496 U.S. at 625 (emphasis omitted). The APA similarly confers such authority on district courts reviewing agency decisions. *See FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 589-91 (2025).

Accordingly, as explained below, this Court has held that the principles governing finality under *Finkelstein* and *Forney* "are equally applicable" to challenges outside the Social Security Act. *Rush Univ. Med. Ctr. v. Leavitt*, 535 F.3d 735, 738 (7th Cir. 2008) (citing *Edgewater Found. v. Thompson*, 350 F.3d 694 (7th Cir. 2003)); *see, e.g.*, *Perlman v. Swiss Bank Corp. Comprehensive Disability Prot. Plan*, 195 F.3d 975, 979 (7th Cir. 1999) (describing *Forney* and *Finkelstein* as stating the rule for "administrative-law" remands generally, and applying the rule to find jurisdiction over appeal by private litigant under ERISA); *Navin v. Park Ridge Sch. Dist. 64*, 49 F. App'x 69, 70 (7th Cir. 2002) (applying *Forney* and *Finkelstein* to find jurisdiction over appeal by private litigant in suit under IDEA).[1]

[1] This Court's order in *Navin* also illustrates that even if the decision below were nonfinal, Lilly could still appeal it as an order "refusing … [an] injunction[]." 28 U.S.C. § 1292(a)(1). As the Court observed there, "two grounds" supported this Court's jurisdiction over the private plaintiff's appeal from an administrative remand. *Navin*, 49 F. App'x at 70. First, the appeal involved "the sort of remand that, if made to a federal agency, would not prevent finality and immediate appeal." *Id.* (citing *Forney*, 524 U.S. 266, and *Finkelstein*, 496 U.S. 617). "Second, the relief [the plaintiff] [wa]s seeking (and did not obtain) appears to be injunctive in character, so that an appeal would lie even if the judgment were deemed interlocutory." *Id.* Both grounds support jurisdiction here as well.

C. At oral argument, a question arose regarding Supreme Court cases authorizing appeal of collateral orders before final judgment. As the panel noted, a decision denying a claim of immunity is treated as final under Section 1291, and thus immediately appealable, even if the suit remains ongoing in the district court. *See, e.g.*, *Mitchell v. Forsyth*, 472 U.S. 511, 525 (1985); *Nixon v. Fitzgerald*, 457 U.S. 731, 742 (1982). That is because, under the collateral-order doctrine, the category of final decisions appealable under Section 1291 includes rulings "which finally determine claims of right separable from, and collateral to, rights asserted in the action, too important to be denied review and too independent of the cause itself to require that appellate consideration be deferred until the whole case is adjudicated." *Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541, 546-47 (1949).

The appealability of immunity orders reinforces, rather than undermines, the basis for this Court's jurisdiction here, because the appealability of such an order rarely turns on which party prevailed in the district court. Where a party claims immunity from suit, the district court's decision on that issue will generally be appealable *regardless* of the result. If the court determines that immunity bars the suit, then the decision will be appealable by the plaintiff as a final judgment because it ends the case. If the court denies immunity, the sovereign or official would be entitled to appeal that collateral order, which finally determines "its possessor's entitlement not to have to answer for his conduct in a civil damages action." *Mitchell*, 472 U.S. at 525.

To be sure, a *plaintiff* would lack standing to appeal a decision denying immunity to the defendant, because "a party normally may not appeal a decision in its favor." *Forney*,

524 U.S. at 271 (cleaned up). But that limitation flows from the prevailing-party rule, not from principles of finality. By contrast, where—as here—a district court issues an order "granting in part and denying in part the remedy requested," the party requesting relief "is 'aggrieved' and ordinarily can appeal [the] decision." *Id.* (citation omitted).

II. Circuit Precedent Permits a Private Party to Appeal a Remand That Grants the Party Only Partial Relief

While earlier decisions of this Court imposed party-specific limits on appeals from agency remands, "that premise was undermined by [the Supreme Court's decision in] *Finkelstein*, and *Forney* has completed the process of making administrative remands generally appealable." *Perlman*, 195 F.3d at 979.

In *Perlman*, this Court relied upon *Forney* to conclude that a remand order was appealable by a private litigant (an ERISA beneficiary) so long as the order was appealable by the administrator. The Court reasoned that "an appeal under § 1291 does not depend" on which party seeks review. *Id.* So long as the district court "finds that [an agency] decision was erroneous and enters a judgment wrapping up the litigation, that decision is appealable even if extra-judicial proceedings lie ahead." *Id.* And if the decision is appealable by the agency, then it is appealable by the other party as well—provided that the other party received less than full relief. *Id.*

The Court followed the same rule four years later in *Edgewater*, where it rejected a private litigant's appeal where the district court had entered only a limited remand to the agency to resolve discrete *factual* questions, thus merely "postpon[ing] adjudication until after additional evidence has been analyzed." *Edgewater*, 350 F.3d at 697; *see Edgewater Found. v. Thompson*, No. 00-cv-6600, 2003 WL 260336, at *3 (N.D. Ill. Feb. 5, 2003). Given

the limited nature of the remand, "the suit ha[d] *not* been 'terminated' in the district court; it [wa]s apparent that the judge expect[ed] to resume the proceedings after receiving the agency's findings … [by] an appropriate motion in the *existing* civil action." *Edgewater*, 350 F.3d at 698 (second emphasis added).

Most recently, the Court in *Rush* explained that Supreme Court precedent dictates "that any decision final from the agency's perspective also is final from the private litigant's." 535 F.3d at 738. A decision remanding to the agency is thus appealable by either party even if the decision is "'final' only because the agency may be unable to obtain review after its own action on remand." *Id.* The Court accordingly permitted a hospital to appeal a decision holding that the Department of Health and Human Services must allow the hospital to submit further documentation and remanding to the agency. *Id.* at 737-38.

III. Other Circuits Follow a Similar Rule

Consistent with *Forney*, the overwhelming weight of circuit authority permits a private litigant to appeal an administrative remand order that grants the litigant something less than the full relief it requested. At least eight courts of appeals, including the D.C. Circuit, have so held. *See, e.g.*, *Limnia, Inc. v. United States Dep't of Energy*, 857 F.3d 379, 385-86 (D.C. Cir. 2017) (Kavanaugh, J.) (appeal by regulated battery manufacturer); *Koyo Seiko Co. v. United States*, 95 F.3d 1094, 1097 (Fed. Cir. 1996) (appeal by importer); *Littlefield v. Mashpee Wampanoag Indian Tribe*, 951 F.3d 30, 36 (1st Cir. 2020) (appeal by intervenor tribe); *Silver v. Smith*, 70 F. App'x 17, 19 (2d Cir. 2003) (appeal by taxpayer as to issue not subject to remand); *United Steelworkers of Am. Loc. 1913 v. Union R.R. Co.*, 648 F.2d 905, 909 (3d Cir. 1981) (appeal by railroad company); *Sierra Forest Legacy v.*

Sherman, 646 F.3d 1161, 1176 (9th Cir. 2011) (appeal by nonprofits and state); *Am. Wild Horse Pres. Campaign v. Jewell*, 847 F.3d 1174, 1184-85 (10th Cir. 2016) (appeal by nonprofits); *MCI Telecomms. Corp. v. BellSouth Telecomms. Inc.*, 298 F.3d 1269, 1271 (11th Cir. 2002) (appeal by telecom). Only one court of appeals has held, as a categorical matter, that only an agency may appeal a remand order that would otherwise escape appellate review. *See City of Council Bluffs v. DOI*, 11 F.4th 852, 856 (8th Cir. 2021).

Of note, the D.C. Circuit has allowed private litigants to appeal administrative remand orders in circumstances closely analogous to those at issue here. *See, e.g.*, *Limnia*, 857 F.3d at 386 (allowing private litigant to appeal where remand effectively denied full relief).[2] Most significantly, in *Limnia*, the D.C. Circuit permitted a battery manufacturer to appeal an order remanding to an agency in a suit challenging the denial of a loan application. *Id.* at 382, 385-86. The manufacturer argued that remand would be inappropriate unless the district court's judgment involved a further form of relief: an order directing the agency to honor a previous application-fee waiver. *Id.* at 384-85. But the district court "sided with the Department" and remanded *without* imposing any such condition. *Id.* at 384.

[2] Some prior D.C. Circuit decisions, relying on a line of cases predating *Forney*, have suggested that only agencies may appeal a remand order. *See NAACP v. U.S. Sugar Corp.*, 84 F.3d 1432, 1436 (D.C. Cir. 1996) (citing *Occidental Petroleum Corp. v. SEC*, 873 F.2d 325, 329 (D.C. Cir. 1989)). These cases do not even acknowledge *Finkelstein* and *Forney*, much less attempt to reconcile their analysis with those binding Supreme Court precedents. Regardless, even in this now-superseded line of cases, the D.C. Circuit acknowledged that "the rule is not absolute" and instead permits a private party to appeal a remand order immediately if the party "may wind up with no opportunity to appeal later." *In re Long-Distance Tel. Serv. Fed. Excise Tax Refund Litig.*, 751 F.3d 629, 633 (D.C. Cir. 2014) (allowing private litigant to appeal where agency "ha[d] not taken any reviewable action in the two years since the district court's remand order") (citation omitted).

The D.C. Circuit held that the private litigant could appeal in those circumstances. "Rulings 'that terminate an action' fall within the 'core' of Section 1291's requirement of finality." *Id.* at 385. Under that standard, the D.C. Circuit explained, it had jurisdiction to review whether "the District Court abused its discretion by remanding the case to the [agency]," because the district court's decision to issue a remand order that "accepted the Department's conditions on the proposed remand proceedings" (*i.e.*, by remanding *without* requiring the agency to honor the fee waiver) "effectively terminated" the manufacturer's claim. *Id.* at 384-86. And without immediate appellate review, "there would be no avenue—administrative or judicial"—by which the manufacturer could obtain relief on that issue. *Id.* at 386. *Limnia* thus underscores the D.C. Circuit's view that disputes about "conditions on the remand," which a remand order places (or fails to place) on further agency proceedings, are appropriately subject to immediate appellate review even in cases where the appellant is a private litigant. *Id.* at 384.

IV. This Court Has Jurisdiction

Under the Supreme Court's decisions in *Finkelstein* and *Forney*—and under longstanding circuit precedent construing those decisions—this Court has jurisdiction over the present appeal.

"[T]he Supreme Court has held that a remand to an agency is final when the proceedings may end without further litigation." *Rush*, 535 F.3d at 738. There is no question that the district court's remand here was "the sort of remand … that might well conclude without a return to court, so the decision is appealable" both by the government and by Lilly. *Id.* If FDA had designated retatrutide as a biological product on remand, no further

litigation would have occurred—or would even have been possible. Lilly would not have been able to challenge the district court's decision on the protein-definition issue; nor would the agency have had any further opportunity to challenge the district court's decision on the analogous-products issue. The district court's decision accordingly falls within the "'class of orders' that Congress ha[s] made 'appealable under § 1291.'" *Forney*, 524 U.S. at 270 (quoting *Finkelstein*, 496 U.S. at 628); *see id.* at 273 (courts lack "the power to redefine, or to subdivide, those classes, according to whether or not they believe, in a particular case, further agency proceedings might obviate the need for an immediate appeal"). And since the district court's decision falls within this "class of orders," it is appealable either by the agency or by Lilly under *Forney*, *Finkelstein*, and *Rush*.

This case also presents special circumstances that differentiate it from a run-of-the-mill remand case, making the existence of appellate jurisdiction especially clear. For one thing, the district court's order resolved "legal issues distinct from those to be addressed in the agency remand." *Sierra Forest Legacy*, 646 F.3d at 1176; *see Edgewater*, 350 F.3d at 697 (distinguishing a remand that merely "postpone[d] adjudication until after additional evidence ha[d] been analyzed" from one that resolves the legal merits of a party's claim) (quoting *Perlman*, 195 F.3d at 979). As noted above, the only issues that Lilly has raised on appeal—the protein-definition claim and the propriety of the district court's remand order under the automatic take-effect provision—were not part of the district court's remand order and cannot be redressed by further agency or district-court proceedings.

This case is also distinctive in another important respect: Lilly challenges the district court's remand order *itself*, making this case just like *Limnia*. There, the D.C. Circuit held

that a private litigant could immediately appeal a remand order where the remand *itself* effectively denied the private litigant a measure of its requested relief. *See Limnia*, 857 F.3d at 386; *see also In re Long-Distance Tel. Serv. Fed. Excise Tax Refund Litig.*, 751 F.3d at 633 (permitting private litigant to appeal where agency's delay in "tak[ing] any reviewable action" following remand order would have "effectively preclude[d]" review) (citation omitted). So too here. In the district court below, after the court determined that FDA had acted arbitrarily and capriciously in rejecting Lilly's "analogous" argument, the court asked the parties to state their position on the relief that the court's final judgment should contain. D. Ct. Dkt. 49. Citing the statutory automatic take-effect provision, Lilly argued that "the agency was required to resolve [Lilly's request for designation] within '60 days,'" and further asked the court, at minimum, to "order FDA to act expeditiously following remand." A.291-92 (quoting 21 U.S.C. § 360bbb-2(b)). The government, by contrast, opposed Lilly's request. A.293. The district court then issued an order and final judgment remanding *without* any further limitation, ShA.18-19, thereby "siding with the [agency]," *Limnia*, 857 F.3d at 386.

In so ruling, the district court ordered a remand that *itself* "denies [Lilly] the relief [it] has sought." *Forney*, 524 U.S. at 271. "Without appellate review by this Court, there would be no avenue—administrative or judicial—by which [Lilly] could obtain" the relief Lilly requested under the automatic take-effect provision: immediate designation of retatrutide as a biological product. *Limnia*, 857 F.3d at 386. Indeed, requiring Lilly to file a new civil suit to challenge FDA's remand decision would result in "further delay" and

inefficiency (possibly including additional remands on the "analogous" issue). *Forney*, 524 U.S. at 271. Only a decision by this Court can vindicate Lilly's request for relief.

V. FDA's Remand Decision Further Confirms This Court's Jurisdiction

On October 2, 2026—following months of delay and shortly after this Court's supplemental briefing order—the agency issued a decision on remand rejecting Lilly's argument that retatrutide is "analogous" to a protein.[3] That remand decision cannot retroactively affect whether the district court's judgment constituted a "final decision" under Section 1291. But insofar as the agency's remand decision has any bearing here, it further confirms that this Court has appellate jurisdiction.

First, FDA's remand decision did not address the protein definition or the propriety of the district court's remand order under the automatic take-effect provision. As to those issues—the only ones on appeal now—the district court's judgment remains the final word. No further proceedings on those issues are ongoing or contemplated before the agency or district court. Indeed, it is hard to see how further consideration of those issues by FDA or the district court would even be possible. There is accordingly no risk that this Court's decision on those issues would be advisory. *See Chatrie v. United States*, 146 S. Ct. 2193, 2204 n.4 (2026) (opinion is not "advisory" merely because there is some possibility that the court below could reach the same result on other grounds).

[3] While beyond the scope of this appeal, FDA's new decision did nothing to remedy the district court's conclusion that "FDA's 'bright line' approach flouts the statutory text." ShA.15. To the contrary, on remand the agency announced a nearly identical bright-line rule under which a product can be analogous to a protein only if it *both* is greater than 40 alpha amino acids in size *and* has a specific defined sequence.

Second, FDA's remand decision confirms that the district court's order was "final" in the sense that matters: The court found "that [FDA's] decision was erroneous and enter[ed] a judgment wrapping up the litigation." *Edgewater*, 350 F.3d at 697 (alteration omitted) (quoting *Perlman*, 195 F.3d at 979); *see* ShA.15-19 (finding FDA's decision on products "analogous to a protein was not in accordance with the law," vacating the decision, and entering final judgment). This case accordingly bears no resemblance to *Edgewater*, the lone case in which this Court has found jurisdiction unavailable to a private litigant under *Forney*. There, the district court merely "postponed adjudication until after additional evidence ha[d] been analyzed," making clear that the court "expect[ed] to resume the proceedings after receiving the agency's findings … [by] an appropriate motion in the existing civil action." *Edgewater*, 350 F.3d at 698 (citation omitted). Here, by contrast, there is no "existing civil action" anymore. The district court's final judgment terminated the civil litigation altogether, rendering it "appealable even if extra-judicial proceedings l[ay] ahead." *Id.* at 697. If Lilly decides to challenge the remand decision on the "analogous" issue, it will have to initiate a *new* suit in order to do so. And in that new suit, Lilly would not be able to re-raise the arguments on appeal now—concerning the "protein" definition and automatic take-effect provision—because the district court has already rejected them.

Finally, the untimely nature of FDA's remand decision confirms that only this Court can grant Lilly the relief it seeks. Lilly plans to file its application for retatrutide's approval no later than the first quarter of 2027. As it has consistently told FDA and the courts, Lilly needs to know which application pathway (biological product or drug) to pursue when filing. *See* Dkt. 33; A.291-92; *Lilly's Triple Agonist, Retatrutide, Delivered Substantial Weight*

Loss and A1C Reduction, Eli Lilly and Company (Sept. 29, 2026), available at https://investor.lilly.com/news-releases/news-release-details/lillys-triple-agonist-retatrutide-delivered-substantial-weight. For that reason, Lilly urged the district court, if it ordered a remand, to require FDA to act expeditiously—a request that FDA opposed, the district court denied, and the agency ignored by waiting nearly *ten months* to issue a decision (notwithstanding the statutory 60-day deadline for designation decisions).

If this Court sends the case back to the district court or requires Lilly to file a new civil action, it could force Lilly to choose between having retatrutide submitted when it is ready for patients and having it classified correctly. Yet the need for a classification decision that is *both* correct *and* timely—under the automatic take-effect provision—is the essence of Lilly's argument on appeal; it is also the very relief that the district court's judgment denied to Lilly. The jurisdictional precedents of the Supreme Court and this Court are designed to avoid forcing litigants like Lilly into such a Hobson's choice.

CONCLUSION

The Court has jurisdiction.

Dated: October 8, 2026

Respectfully submitted,

s/ Allon Kedem

Allon Kedem
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave., N.W.
Washington, DC 20001
(202) 942-5000
allon.kedem@arnoldporter.com

CERTIFICATE OF COMPLIANCE

This brief complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) and Circuit Rule 32(b) because this brief has been prepared in a proportionately spaced typeface using Microsoft Word 365 in Century Expanded BT 12-point font.

s/ Allon Kedem
Allon Kedem

CERTIFICATE OF FILING AND SERVICE

Pursuant to Federal Rule of Appellate Procedure 25, I hereby certify that on October 8, 2026, I electronically filed the foregoing Supplemental Brief of Appellant via ECF, and service was accomplished on counsel of record by that means.

s/ *Allon Kedem*
Allon Kedem