No. 21-3128

In The United States Court of Appeals for the Seventh Circuit

ELI LILLY AND COMPANY and LILLY USA, LLC,
Appellants,

v.

XAVIER BECERRA, DANIEL J. BARRY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIANA ESPINOSA, AND HEALTH RESOURCES AND SERVICES ADMINISTRATION
Appellees.

On Appeal from the United States District Court
for the Southern District of Indiana, Indianapolis Division
Case No. 1:21-cv-00081-SEB-MJD
Honorable Sarah Evans Barker

APPELLANTS' JURISDICTIONAL MEMORANDUM

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November 30, 2021

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Pursuant to this Court's November 16, 2021 order, *see* CA7.Dkt.3, Appellants Eli Lilly and Company and Lilly USA (together, "Lilly") submit this memorandum concerning this Court's appellate jurisdiction. Jurisdiction is proper, and Lilly's appeal should proceed, because the district court unambiguously intended to and did enter a partial final judgment that determines the rights and obligations of the parties in ways both favorable and adverse to Lilly; the claims that remain pending before the district court do not overlap with the claims resolved by the final judgment; and Lilly has standing to appeal the parts of the final judgment entered against it.

BACKGROUND

This case arises from three distinct unlawful agency actions relating to the federal 340B Drug Pricing Program ("340B Program"). *See generally* Veterans Health Care Act of 1992, Pub. L. No. 102-585, §602(a), 106 Stat. 4943, 4967 (codified as amended at 42 U.S.C. §256b) (establishing 340B Program). Under the 340B statute, drug manufacturers that participate in Medicare and Medicaid must offer their prescription drugs at steep discounts to certain non-profit "covered entities," which are defined by statute. 42 U.S.C. §256b(a)(1); *see also id.* §§256b(a)(4), (b)(1), 1396r-8(a)(1), (5). The statute is silent, however, about manufacturers' obligations with respect to so-called "contract pharmacies," *i.e.*, commercial pharmacies that contract with covered entities, obtain drugs at 340B-discounted prices, and resell them for a profit. R.144 ("Order") 41 ("The 340B

statute is silent as to contract pharmacy arrangements and drug manufacturers' delivery obligations." (emphasis omitted)).[1]

In its operative complaint in the district court, R.103, Lilly sought declaratory and other relief under the Administrative Procedure Act ("APA") and the Constitution concerning three separate agency actions touching the 340B Program: (1) a final rule establishing Administrative Dispute Resolution, or "ADR," procedures; (2) a so-called "Advisory Opinion" issued by the general counsel of the U.S. Department of Health and Human Services ("HHS" or "the Department") purporting to require manufacturers to deliver 340B-priced drugs to an unlimited number of contract pharmacies on demand; and (3) a May 17, 2021 enforcement letter determining, without analysis, that Lilly's distribution limitations vis-à-vis contract pharmacies violated the 340B statute, thus triggering adverse consequences.

As explained below, the district court's partial final judgment fully resolved the latter two challenges. Lilly prevailed with respect to the Advisory Opinion. However, with respect to the May 17 enforcement letter, the district court issued a split decision: vacating the letter on procedural grounds, but resolving in the

[1] *Accord AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27, 2021 WL 2458063, at *9 (D. Del. June 16, 2021) ("[T]he statute is simply silent on this point. The statute's total omission of contract pharmacies renders it ambiguous with respect to the central issue in this case."); *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1686, 2021 WL 5161783, at *6 (D.D.C. Nov. 5, 2021) ("The statute's silence on these questions suggests that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies." (internal quotation marks omitted)).

government's favor Lilly's broader challenge that the letter is contrary to law. Order 59-60 (declaring that "the statute, correctly construed, does not permit drug manufacturers, such as Lilly, to impose unilateral extra-statutory restrictions on its offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements," but that the enforcement letter "is arbitrary and capricious"); *see also* R.145 (entering final judgment on all of Lilly's enforcement letter claims). That is the subject of this appeal. A different federal judge has since examined the district court's reasoning on that legal question, rejected it, and granted two other drug manufacturers the relief Lilly seeks here. *See Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1686, 2021 WL 5161783, at *7 n.4 (D.D.C. Nov. 5, 2021) (Friedrich, J.) ("The Court does not find the reasoning of *Eli Lilly & Co. v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-81, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021), persuasive.… [T]his Court rejects HRSA's interpretation….").

Lilly now appeals the district court's judgment, invoking this Court's *de novo* review to obtain that broader relief it sued for and was erroneously denied below.

A. Lilly's Challenge to the ADR Rule

Lilly's claims challenging the Department's ADR regulation (Counts V-IX) do not concern contract pharmacies, and they are not part of this appeal. Those claims seek relief against a rule establishing an Administrative Dispute Resolution ("ADR") process for the 340B Program, *see* 85 Fed. Reg. 80,632-01 (Dec. 14, 2020)

("ADR Rule"), which HHS published ten *years* after its congressionally mandated deadline, *see* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §7102(a), 124 Stat. 119, 826-27 (2010) (codified at 42 U.S.C. §256b(d)(3)) (requiring HHS to promulgate ADR regulations within 180 days of the ACA's passage). Lilly's complaint alleges that the ADR Rule violates Articles II and III of the Constitution, and was promulgated in violation of the APA. R.103 ¶¶223-75.

Because the (belated) promulgation of the ADR Rule was immediately followed by a number of ADR petitions filed against Lilly, Lilly filed a motion for preliminary injunction on its ADR claims (and only its ADR claims). R.18. The district court found that Lilly was likely to succeed on its claim "that Defendants violated notice-and-comment rulemaking requirements under the APA" in issuing the ADR Rule, and therefore granted Lilly's motion. R.81 at 23, 28-29. The court then entered a preliminary injunction limited to the ADR Rule. R.82 ("Defendants, … [and] all persons in active concert or participation with them, are hereby PRELIMINARILY ENJOINED until further order of this Court from implementing or enforcing against Plaintiffs the [ADR] Regulations published at 85 Fed. Reg. 80,632 and codified at 42 C.F.R. §§10.20–24."). Defendants did not appeal that preliminary injunction, and it remains in effect. *See* Order 2 n.1.[2]

[2] Defendants subsequently proposed a new version of the rule (without providing notice or allowing comment). That new proposal is currently before OMB, pending review. *See* RIN: 0906-AB28, https://bit.ly/3xHr1Ob (last visited Nov. 29, 2021).

The parties subsequently cross-moved for summary judgment on Lilly's challenges to the ADR Rule. The district court has not yet resolved those motions. As explained in Lilly's Jurisdictional Statement, *see* CA7.Dkt.5 at 3-4, and further below, Lilly's challenges to the ADR Rule are distinct from the claims on appeal.

B. Lilly's Challenge to the Advisory Opinion

On December 30, 2020, the Department's general counsel issued an "Advisory Opinion" requiring manufacturers to deliver 340B-priced drugs to an unlimited number of contract pharmacies. *See* HHS, *Advisory Opinion 20-06* (Dec. 30, 2020), https://bit.ly/357nqfk. Lilly's complaint alleged that the Advisory Opinion was final agency action, and that it was contrary to law and arbitrary and capricious in violation of the APA. R.103 ¶¶176-222.

The government then tried—unsuccessfully—to thwart a merits ruling on Lilly's challenges to the Advisory Opinion. On June 16, 2021, a different district court invalidated the Advisory Opinion as arbitrary and capricious. *AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27, 2021 WL 2458063 (D. Del. June 16, 2021) (Stark, C.J.). As Chief Judge Stark there explained, "the [Advisory] Opinion is based on the 'unjustified assumption' that Congress imposed th[e] interpretation" the Advisory Opinion advances "as a statutory requirement." *Id.* at *11. In response, the Department "withdrew" the Advisory Opinion and took the position that that meant no court could enter judgment on the merits of any challenges to it. Both

Chief Judge Stark and the court here rejected that gambit, and instead proceeded to address the challenges to the Advisory Opinion on the merits. Order 28-29.

C. Lilly's Challenge to the May 17, 2021 Enforcement Letter

The withdrawal of the Advisory Opinion did not signal a retreat from the position the government put forward. Even though multiple district courts were currently reviewing the legality of its interpretation, the government proceeded to take enforcement action against Lilly for violating the very statutory provision under review.[3] On May 17, 2021, the Acting Administrator of the Health Resources and Services Administration ("HRSA"), an HHS component agency, sent Lilly a letter purporting to "determine[]," without analysis, that Lilly's distribution policy relating to contract pharmacies violates Lilly's obligations under the 340B statute. R.103-17 at 1 ("May 17 Enforcement Letter" or "Letter"). The Letter is substantively identical to letters sent to every other manufacturer that had adopted *any* limitations on the distribution of 340B-priced drugs to contract pharmacies.

As Lilly's complaint explains, that determination is contrary to law under the 340B statute and the Constitution, and is arbitrary and capricious in violation of the APA. R.103 ¶¶276-310. Under Lilly's policy, Lilly not only (1) offers all of its

[3] That is consistent with the government's position throughout the case. *See, e.g.*, 5/27/21 Hr'g Tr. at 44:24–45:2 (advising the district court that even "if [it] were to issue" "the declarations that Lilly has asked [for]" with respect to the Advisory Opinion, that "would in no way stop HRSA's enforcement"); *id.* at 51:6-22 (similar).

covered drugs to all covered entities at or below the 340B price, as the 340B statute requires, but also (2) delivers 340B-priced drugs to (a) each covered entity that buys them, (b) all contract pharmacies that share a corporate parent with a covered entity, and (c) one contract pharmacy per covered entity if the covered entity lacks an in-house dispensing pharmacy.[4] *Id.* ¶¶80-82. The May 17 Enforcement Letter, however, announced HRSA's "determin[ation]" that Lilly had violated its statutory obligations, ordered Lilly immediately to "credit or refund all covered entities for overcharges that have resulted from Lilly's policy," and threatened Lilly with civil monetary penalties ("CMPs") of more than $5,000 per instance of alleged overcharging—which could total in the billions of dollars—if Lilly did not entirely abandon all contract-pharmacy-distribution limitations. R.103-17 at 1-2; *see* 42 U.S.C. §256b(d)(1)(B)(vi) (CMPs may be imposed only for "knowing[]" and "intentional[]" overcharges); 82 Fed. Reg. 1,210, 1,227-28 (Jan, 5, 2017) (same). HRSA made this "determin[ation]" and issued these threats even though the district court (and other federal courts around the country) were still considering the very legal interpretation HRSA was purporting to enforce.

Lilly's complaint asserted four claims challenging the May 17 Enforcement

[4] Reflecting its commitment to ensuring that insulin products are affordable to people who need them, Lilly has also made an exception to this policy for insulin patients. Lilly will deliver insulin to multiple contract pharmacies so long as the patients receive the full 340B discount.

Letter. Lilly's principal allegation, in Count X, is that the agency's determination was contrary to law because the 340B statute is silent concerning contract pharmacy arrangements, and the agency has supplied no persuasive legal analysis showing that Congress actually required manufacturers not only to *offer* 340B-priced drugs to *covered entities* (which is what the statute says, and Lilly does), but also to *deliver* 340B-priced drugs to an unlimited number of *contract pharmacies* (which Lilly does not). R.103 ¶¶276-82. A different district court has recently invalidated two substantially identical enforcement letters that were sent on the same day (May 17, 2021) to two other manufacturers in the 340B Program, for precisely this reason. *See Novartis*, 2021 WL 5161783, at *6-9. Lilly also alleged that the May 17 Enforcement Letter constitutes an unconstitutional Taking (Count XI), is arbitrary and capricious (Count XII), and was unlawfully promulgated in the absence of a notice-and-comment rulemaking (Count XIII). The parties cross-moved for summary judgment on all four of these claims.

D. The District Court's Judgment

Recognizing the urgency of the two sets of contract pharmacy claims (concerning the Advisory Opinion and the May 17 Enforcement Letter, respectively) and the questions of the parties' rights and obligations under 42 U.S.C. §256b(a)(1), the district court committed to "resolve the[] immediate issues … on an expedited basis." R.139 at 68:8-18. The district court did so, issuing an order on October 29,

2021, determining the parties' respective rights and obligations under §256b(a)(1), the APA, and the Constitution. Specifically, the district court:

(1) denied the government's motion to dismiss, *see* Order 30-33;

(2) granted summary judgment for Lilly on its claim that the Advisory Opinion is arbitrary and capricious and vacated the Advisory Opinion, but did not remand because the agency has withdrawn it (which is why the court denied Lilly's remaining challenges to it without prejudice), *see id.* at 34 (agreeing with Chief Judge Stark "that the Advisory Opinion is 'legally flawed' in its "'unjustified assumption" that Congress imposed [HHS'] interpretation as a statutory requirement'");

(3) granted summary judgment for Lilly on its claim that the May 17 Enforcement Letter is arbitrary and capricious, and thus vacated and remanded the Letter on that basis alone, *see id.* at 52-58; but

(4) granted summary judgment for the government on Lilly's claims that the May 17 Enforcement Letter is contrary to law or in excess of statutory authority, violates the Takings Clause, and needed to go through notice and comment, *see id.* at 36-52.

See also id. at 60-61. The court also emphasized that, under Rule 54(b), there was "no just reason for delay; thus, partial final judgment shall issue … to allow the parties to decide whether to seek expedited appellate review." *Id.* at 62.

The district court issued a separate "partial final judgment" the same day. R.145. The court reiterated its finding that, under Rule 54(b), there was "no just reason for delay." *Id.* The court thus entered final judgment "in favor of Defendants [the government] and against Plaintiffs [Lilly] on Counts X, XI, and XIII," the counts alleging that the May 17 Enforcement Letter exceeds statutory authority, violates the Takings Clause, and was unlawfully issued without notice and comment.

Id. And the court granted partial summary judgment "in favor of Plaintiffs [Lilly] and against Defendants [the government] on Counts III and XII," the counts alleging that the Advisory Opinion and May 17 Enforcement Letter, respectively, are arbitrary and capricious. The district court then "SET ASIDE and VACATED" the Advisory Opinion and May 17 Enforcement Letter, and "REMANDED" the May 17 Enforcement Letter. *Id.* The court did not remand the Advisory Opinion, as "the agency ha[d] already withdrawn [it]." Order 61.

Lilly appeals only the district court's Rule 54(b) final judgment decreeing that the May 17 Enforcement Letter does not exceed the agency's statutory authority (Count X), does not violate the Takings Clause (Count XI), and is exempt from the APA's notice-and-comment requirements (Count XIII).

ARGUMENT

I. The District Court Determined The Parties' Rights And Obligations With Respect To The Claims On Which Final Judgment Was Entered.

A. Because "judgment[s] must provide the relief to which a prevailing party is entitled," *Phila. Indem. Ins. Co. v. Chicago Tr. Co.*, 930 F.3d 910, 912 (7th Cir. 2019), "[w]hen a district court grants declaratory relief, the court 'must declare specifically and separately the respective rights of the parties.'" *Sterling Nat'l Bank v. Block*, 984 F.3d 1210, 1216 (7th Cir. 2021) (quoting *Calumet River Fleeting, Inc. v. Int'l Union of Operating Eng'rs, Local 150, AFL-CIO*, 824 F.3d 645, 651 (7th Cir. 2016)). The district court did so here vis-à-vis Lilly and the government's

respective rights and obligations under 42 U.S.C. §256b(a)(1).

After (correctly) concluding that "[t]he 340B statute [*i.e.*, 42 U.S.C. §256b] is silent as to contract pharmacy arrangements and drug manufacturers' delivery obligations," Order 41 (emphasis omitted), the district court (mistakenly) proceeded to find, notwithstanding this statutory silence, that a manufacturer's failure to deliver 340B-priced drugs to a contract pharmacy "directly conflicts with the statutory requirement otherwise," *id.* at 46. Based on that interpretation, the district court concluded: "Construing the 340B statute not to permit drug manufacturers to impose extra-statutory conditions on covered entities' access to discounted medications is … the construction that best aligns with congressional intent." *Id.* at 49. That unambiguous determination of Lilly's rights and obligations—*i.e.*, the conclusion that Lilly cannot "impose extra-statutory conditions on covered entities' access to discounted medications," because it "directly conflicts with the statutory requirement otherwise" (*id.* at 46, 49)—is the subject of Lilly's appeal to this Court.

This case is thus nothing like cases in which this Court has held that it lacks jurisdiction due to a Rule 58 deficiency. In fact, those cases actually confirm that jurisdiction exists here. In those cases, "it was unclear whether the court believed the case was over[] … or what relief the court granted." *Alpine State Bank v. Ohio Cas. Ins. Co.*, 941 F.2d 554, 559 (7th Cir. 1991). For instance, in *Philadelphia Indemnity Insurance*, the judgment purported to "dismiss[]" the case, contradicting

the district court's opinion and "awarding the prevailing party a loss"; failed to mention one defendant; failed to address any counterclaims; and was improperly entered by a clerk, not the court. 930 F.3d at 912. This case is completely different. The order and judgment here not only make clear which party prevailed on what specific issues (and why), but explain, rightly or wrongly, what that means for the parties' rights and obligations under the APA, the 340B statute, and the Constitution.

B. The district court's actions also "evince[] an unambiguous intent to render a final judgment" on the claims on appeal. *Alpine*, 941 F.2d at 559. The court declared its intent to "resolve" Lilly's challenges to the May 17 Enforcement Letter "on an expedited basis," R.139 at 68:8-18, then did so in a comprehensive, 62-page order, declaring that the May 17 Enforcement Letter "is not contrary to law or in excess of the agency's statutory authority nor is it unconstitutional or issued in violation of the APA's notice and comment procedures," Order 59. And in case there was any doubt that the district court "intended to dispose" of all claims related to the Letter, *see Sterling*, 984 F.3d at 1216-17, the court explicitly stated that it was issuing a "partial final judgment … *to allow the parties to decide whether to seek expedited appellate review of these issues*," Order 62 (emphasis added).

That is more than enough. To be sure, Rule 58 requires district courts to "declare specifically and separately the respective rights of the parties, not simply state in a memorandum opinion, minute order, or a form prescribed for judgment in

a civil case that a motion has been granted or denied." *Sterling*, 984 F.3d at 1216. But while "[c]ompliance with Rule 58 makes appellate jurisdiction simpler for the parties and the courts," this Court "may still have jurisdiction if [it] 'know[s] from other sources' that there has been a final judgment." *Calumet*, 824 F.3d at 650. That assessment requires this Court to elevate substance over form and exercise jurisdiction when—as here—"the practicalities weigh heavily toward a common sense conclusion that the district court intended to enter a final judgment." *Sterling*, 984 F.3d at 1217; *see also First Nat'l Bank of Chicago v. Comptroller of Currency of U.S.*, 956 F.2d 1360, 1363 (7th Cir. 1992) (collecting cases).

There can be no doubt that the district court here both intended to and in fact did resolve the parties' disputes over the May 17 Enforcement Letter. The court went out of its way to underscore that it was issuing a "partial final judgment" pursuant to Rule 54(b) specifically "*to allow the parties to decide whether to seek expedited appellate review of these issues*." Order 62 (emphasis added). "Accordingly," the district court "entered" "partial final judgment … in favor of Defendants and against Plaintiffs on Counts X, XI, and XIII"—which challenged the May 17 Enforcement Letter as exceeding the agency's statutory authority (X), constituting a Taking (XI), and violating the APA's notice-and-comment requirements (XIII)—"and in favor of Plaintiffs and against Defendants on Counts III and XII"—which challenged the Advisory Opinion (III) and May 17

Enforcement Letter (XII) as arbitrary and capricious. R.145. Counts X, XI, XII, and XIII are the only claims challenging the Letter, *see* R.103 ¶¶276-310, and the district court entered final judgment *as to each and every one of them*, *see* R.145.

The basis for this Court's jurisdiction is also particularly clear given that the judgment denied or granted the relevant claims *in full*. Just as in *Sterling*, 984 F.3d at 1216, then, this Court can be "confident that the district court intended to enter a final judgment here," because it (a) denied in full Lilly's claims seeking a declaration that the May 17 Enforcement Letter exceeds statutory authority, violates the Takings Clause, and was unlawfully issued without notice and comment, but (b) granted Lilly's claim seeking a declaration that the May 17 Enforcement Letter is arbitrary and capricious. What is more, and as further explained below, *see* Part III, *infra*, that (admittedly divided) ruling unquestionably aggrieves Lilly. The district court denied relief Lilly explicitly sought, remanding the Letter *so the agency may continue its enforcement efforts*, instead of properly rejecting those efforts because they exceed the agency's authority for the reasons Lilly argued. *See* Order 58-62.

Simply put, nothing about Lilly's challenges to the Letter remains pending in district court. Indeed, neither the district court nor the parties have taken any further action below on the claims in this appeal. Nor could they; the decision leaves no room for further activity in district court relating to the dispute over the Letter. "[T]he district court's memorandum and the absence of any other claims or later

actions by the court make sufficiently plain both what the court declared and that the district court was finished with the case." *Calumet*, 824 F.3d at 651.

II. The Claims That Remain Pending Before The District Court Do Not Overlap With The Claims Resolved In The Rule 54(b) Judgment.

As the district court recognized, the only claims that now remain pending below are Lilly's "APA claims challenging the ADR Rule."[5] Order 62. Those claims (Counts V-IX) not only arise from a different agency action than the one at issue in the claims on appeal, but also arise from a different set of facts and involve different legal issues. *See Peerless Network, Inc. v. MCI Commc'ns Servs., Inc.*, 917 F.3d 538, 543 (7th Cir. 2019). As noted above, Lilly's ADR claims arise from HHS' issuance of regulations contemplated by 42 U.S.C. §256b(d)(3). The claims on appeal, by contrast, arise from HRSA's "determin[ation]" that Lilly's contract pharmacy policy violates §256b(a)(1). Whether Lilly prevails on some, all, or none of its challenges to the ADR Rule will have no impact on the resolution of any of its claims on appeal. Thus, the district court properly exercised its discretion in entering final judgment pursuant to Rule 54(b) on the claims now on appeal.

[5] As noted above, although the district court "denied" the parties' cross-motions for summary judgment with regard to Counts I, II, and IV "without prejudice," those claims do not remain pending below and are not live. "[T]he agency ha[d] already withdrawn the Advisory Opinion," which is why the district court vacated the Advisory Opinion without remanding it. Order 60-61; *see id*. at 34-35. Regardless, these claims do not overlap with the claims certified for appeal under Rule 54(b): Counts I, II, and IV relate to a different agency action (the Advisory Opinion) than the one at issue in Lilly's appeal (the May 17 Enforcement Letter).

III. Lilly Has Appellate Standing.

The fact that the district court vacated the May 17 Enforcement Letter as arbitrary and capricious, for reasons having nothing to do with the district court's declarations of Lilly's statutory obligations that Lilly now appeals, does not deprive Lilly of standing to appeal the district court's denial of the more fulsome relief it sued for; nor does it divest this Court of appellate jurisdiction.

The Supreme Court has long held that a prevailing party may appeal "so long as that party retains a stake in the appeal satisfying the requirements of Art. III." *Deposit Guaranty Nat'l Bank v. Roper*, 445 U.S. 326, 334 (1980); *see, e.g.*, *Elec. Fittings Corp. v. Thomas & Betts Co.*, 307 U.S. 241, 241-42 (1939) (defendant, alleged infringer, found not liable but allowed to appeal to challenge finding that plaintiff's mark was valid); *see also Transamerica Ins. Co. v. South*, 125 F.3d 392, 396 (7th Cir. 1997) ("[S]tanding to appeal is recognized if the appellant can show[] an adverse effect of the judgment." (quoting 15A Wright & Miller, *Fed. Prac. & Proc.* §3902 (2d ed.))). And the easiest way to establish that a prevailing party has a continuing stake sufficient for appellate standing is to show that the party did not receive everything it asked for—and the clearest indication of that is when the appealed-from "decision grant[s] in part and den[ies] in part the remedy requested." *Amazon, Inc. v. Dirt Camp, Inc.*, 273 F.3d 1271, 1275 (10th Cir. 2001).

These longstanding principles confirm Lilly's standing to appeal. The

judgment below could not be clearer: "partial final judgment is entered in favor of Defendants *and against Plaintiffs* on Counts X, XI, and XIII." R.145 (emphasis added). The judgment entered "against Plaintiffs on Counts X, XI, and XIII" is the judgment from which Lilly appeals here. The court denied Lilly the full scope of the declaratory relief that it sought, *i.e.*, a declaration that Defendants lack authority to require it to provide 340B discounts on sales made through contract pharmacies or to deliver 340B-priced drugs to contract pharmacies. Order 49-50.

Lilly's continued interest is further underscored by the fact that Defendants have taken the position, in multiple federal-court filings, that the district court's order in this case permits them to enforce *their view* of Lilly's obligations under 42 U.S.C. §256b(a)(1), unless and until the order is overturned. *See* Gov't's Notice of Suppl. Authority 4, *Novo Nordisk Inc. v. HHS*, No. 21-cv-634 (D.N.J. Nov. 2, 2021), R.69 ("[B]ecause Lilly's policy has been deemed unlawful, continued imposition of … restrictions … will continue to subject Lilly to liability under the statute, including the potential imposition of civil monetary penalties … (and a corresponding expulsion from Medicaid and Medicare Part B coverage) should Lilly persist in its unlawful behavior—even in the absence of the May 17 letter or a similar violation letter."); Gov't's Notice of Suppl. Authority 4, *United Therapeutics Corp. v. Espinosa*, No. 21-cv-1686 (D.D.C. Nov. 2, 2021), R.29 (same); Gov't's Notice of Suppl. Authority 4, *AstraZeneca Pharm. LP v. Becerra*, No. 21-cv-27 (D. Del. Nov.

2, 2021), R.106 (same).

So absent an appellate decision overruling the decision below, Lilly faces ongoing proceedings seeking to impose CMPs (or even revoke Lilly's Pharmaceutical Pricing Agreement), as well as other liability, if it does not capitulate to the government's position. That more than suffices to establish standing for Lilly to appeal and ask this Court to reverse the district court's adverse holdings on the Letter. *See, e.g.*, *Camreta v. Greene*, 563 U.S. 692, 702-03 (2011) (prevailing party had standing to appeal where lower court decision meant that he must "either change the way" he acted or risk adverse action); *City of Redding v. FERC*, 693 F.3d 828, 835 (9th Cir. 2012) (prevailing parties had standing to appeal because decision below announced a new rule "that could support a contract action against [them]").[6]

If, however, this Court were to disagree and conclude that Article III does not permit adjudication of Lilly's challenge to the May 17 Enforcement Letter because that letter has been vacated on separate, procedural grounds by the district court, the

[6] Indeed, all Lilly is asking for is for this Court, on *de novo* review, to grant the relief it was denied by the district court here and instead reach the result that a federal judge in D.C. recently reached in separate litigation challenging similar May 17 enforcement letters sent to different manufacturers. *See Novartis*, 2021 WL 5161783, at *9 ("The plain language, purpose, and structure of the statute do not prohibit the manufacturers from imposing *any* conditions on their offers of 340B-priced drugs to covered entities."). The judge in *Novartis* noted that she "does not find the reasoning" of the district court here "persuasive," and "reject[ed]" the "interpretation" the court here followed. *Id.* at n.4. There is appellate jurisdiction for this Court to say which interpretation is correct and, thus, which side is right.

correct result would not be dismissal of Lilly's appeal. Instead, that conclusion would mean that *the district court*, once it vacated the letter, should not have addressed Lilly's substantive challenges to the letter, either. If this Court so concludes, the proper remedy would be to vacate the district court's judgment with respect to Counts X, XI, and XIII, and the accompanying portions of its opinion.

CONCLUSION

This Court should hold that it has jurisdiction over Lilly's appeal, and set a new schedule for briefing on the merits.

Dated: November 30, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2)(A) because, according to the "word count" function of Microsoft Word 2016, it contains 4,733 words, excluding the parts of the brief exempted from the word count by Federal Rule of Appellate Procedure 32(f).

2. This brief, which has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman font, complies with the typeface and typestyle requirements of Federal Rules of Appellate Procedure 27(d)(1)(E), 32(a)(5), and 32(a)(6).

November 30, 2021

/s/ John C. O'Quinn
John C. O'Quinn

CERTIFICATE OF SERVICE

I hereby certify that on November 30, 2021, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

/s/ John C. O'Quinn
John C. O'Quinn