Nos. 21-3128, 21-3405

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

ELI LILLY AND COMPANY and LILLY USA, LLC,

Plaintiffs-appellants–cross-appellees,

v.

XAVIER BECERRA, et al.,

Defendants-appellees–cross-appellants.

On Appeal from the United States District Court
for the Southern District of Indiana,
No. 21-81 (Barker, J.).

SUPPLEMENTAL BRIEF FOR THE FEDERAL DEFENDANTS

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Pursuant to the Court's order of November 1, 2022, this supplemental brief addresses the following issues:

1. Whether this Court has appellate jurisdiction given the district court's partial final judgment under Rule 54(b) of the Federal Rules of Civil Procedure.

2. Whether the enforcement letter is a final agency action.

3. Whether *Health & Hospital Corp. of Marion County v. Talevski*, No. 21-806 (U.S.), has bearing on this case.

ARGUMENT

I. Appellate Jurisdiction

This Court has appellate jurisdiction in light of the district court's entry of partial final judgment under Rule 54(b) of the Federal Rules of Civil Procedure. Rule 54(b) allows a district court to direct entry of final judgment as to one or more claims if the district court expressly determines that there is no just reason for delay. In reviewing a district court's Rule 54(b) certification, "[t]he court of appeals must, of course, scrutinize the district court's evaluation of such factors as the interrelationship of the claims so as to prevent piecemeal appeals in cases which should be reviewed only as single units." *Curtiss-Wright Corp. v. General Elec. Co.*, 446 U.S. 1, 10 (1980). "But once such juridical concerns have been met, the

discretionary judgment of the district court should be given substantial deference," and "[t]he reviewing court should disturb the trial court's assessment of the equities only if it can say that the judge's conclusion was clearly unreasonable." *Id.*; *see also General Ins. Co. of America v. Clark Mall Corp.*, 644 F.3d 375, 379-80 (7th Cir. 2011) (applying the principles set out in *Curtiss-Wright*).

A. The claims that remain in district court are not intertwined with the claims on appeal

The operative complaint challenged three agency actions: the enforcement letter; the advisory opinion; and the 2020 regulation that established an administrative process for resolving certain disputes between manufacturers and covered entities. *See* Second Amended Complaint, Dkt. No. 103, Counts I-IV (challenging the advisory opinion), Counts V-IX (challenging the 2020 regulation), Counts X-XIII (challenging the enforcement letter). The district court resolved the claims challenging the enforcement letter and the advisory opinion. *See* SA66 (partial final judgment vacating the enforcement letter and the advisory opinion); SA70-71 (amended partial final judgment specifying the grounds on which the

enforcement letter and advisory opinion were vacated and the grounds that were rejected by the district court).[1]

The district court did not resolve the claims challenging the 2020 regulation, *see* SA2 n.1, but those claims are not intertwined with the claims on appeal. The enforcement letter was not issued pursuant to the administrative dispute resolution process that the 2010 amendments directed the Secretary to establish by regulation. Instead, the enforcement letter was an exercise of the agency's longstanding authority to take enforcement action on its own initiative. As the Supreme Court explained in discussing the pre-2010 law, "[i]f a manufacturer overcharges a covered entity," the agency "may require the manufacturer to reimburse the covered entity" and "may also terminate the manufacturer's" Pharmaceutical Pricing Agreement, "which terminates as well the manufacturer's eligibility for Medicaid coverage of its drugs." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 115-116 (2011) (citing 42 U.S.C. § 1396r–8(b)(4)(B)(i), (v) (2006 ed.); and 42 U.S.C. § 1396r–8(a)(1), (5)). The 2010 amendments maintained that preexisting enforcement authority and also gave the

[1] "SA" refers to plaintiffs' required short appendix (Doc. 20). "A" refers to plaintiffs' appendix (Doc. 23). "Suppl. App'x" refers to defendants' supplemental appendix (Doc. 41).

agency additional authority to require refunds to covered entities and to impose civil monetary penalties. *See* 42 U.S.C. § 256b(d)(1)(B)(ii), (vi).

The administrative dispute resolution process is distinct and not at issue on appeal. The 2010 amendments directed the Secretary to establish, by regulation, an administrative process to resolve (1) claims by covered entities that they were overcharged by manufacturers and (2) claims by manufacturers, after the conduct of audits as authorized by 42 U.S.C. § 256b(a)(5)(C), that covered entities violated the statutory prohibitions on diversion or duplicate discounts. *See* 42 U.S.C. § 256b(d)(3). An implementing regulation was issued in 2020. *See* 85 Fed. Reg. 80632 (Dec. 14, 2020). Eli Lilly alleged that the 2020 regulation is invalid on the ground that (1) the rule designates officials to serve on the administrative dispute resolution panel whose appointment does not comport with the Appointments Clause (Count V); (2) the rule empowers such panels to issue judgments that are the province of federal courts under Article III (Count VI); (3) the rule exceeds the agency's statutory authority by assigning to such panels responsibilities that Congress did not authorize (Count VII); (4) the rule was issued without adhering to the notice-and-comment procedures required by the Administrative Procedure Act (Count VIII); and (5) the rule is arbitrary and capricious in various

respects, including the selection of allegedly biased officials to serve on the panels (Count IX).

In March 2021, the district court preliminarily enjoined the application of the 2020 regulation to Eli Lilly on the ground that the regulation was likely issued without complying with the notice-and-comment requirements of the Administrative Procedure Act. *See* Dkt. No. 81 at 17-23. The court did not address Eli Lilly's other challenges to the 2020 regulation. *See id*. at 23. The agency subsequently announced that it intends to issue a new proposed regulation to implement the administrative dispute resolution process. *See* Office of Management and Budget, Executive Office of the President, *340B Drug Pricing Program; Administrative Dispute Resolution* (Fall 2021), https://perma.cc/E2JL-U83B. The regulatory agenda indicates that the new regulation—which will replace the 2020 regulation—will correct deficiencies in the 2020 regulation and better align with the current state of the 340B program. *See id*.

Eli Lilly's challenges to the 2020 regulation do not bear on the issues presented on appeal. Although our appellate brief relied in part on the 2010 amendments to the 340B statute—including the provisions directing the agency to establish an administrative dispute resolution process—we cited those statutory provisions to support an argument about the correct

interpretation of the statute in light of its overall text and structure. That argument does not depend on the particulars of the 2020 regulation or the disposition of Eli Lilly's challenges to that regulation. Moreover, as noted above, Eli Lilly's challenges to the 2020 regulation may be overtaken by a new regulation.

B. The district court's assessment of the equities was within its discretion

The district court's determination that there was no just cause to delay these appeals was not "clearly unreasonable." *Curtiss-Wright*, 446 U.S. at 10. To the contrary, all affected parties have a strong interest in the prompt resolution of the central legal issue presented: whether a drug manufacturer can refuse to ship discounted drugs to the contract pharmacies on which a covered entity relies to dispense drugs to the covered entity's patients.

The district court ruled as a matter of law that "42 U.S.C. § 256b, correctly construed," does not allow drug manufacturers "to impose unilateral extra-statutory restrictions on their offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements." SA71. The court thus rejected the central argument that Eli Lilly advanced in defense of its policy. *See, e.g.*, Suppl. App'x 129 (Eli Lilly's categorical argument to the agency that "contract pharmacy transactions constitute

prohibited diversion"). The district court's legal ruling is subject to de novo review on appeal. Until that issue is conclusively resolved, Eli Lilly will continue to accrue potential liability for each overcharge that results from its policy, and covered entities will continue to suffer from the lost savings and revenues that are critical to their ability to serve their patients. *See, e.g.*, Suppl. App'x 12-107 (examples of informal complaints submitted by covered entities, itemizing overcharges for Eli Lilly drugs); Suppl. App'x 113-116 (declaration describing the impact of the Eli Lilly policy on a federally qualified health center that serves thousands of uninsured, low-income patients in Augusta, Georgia and surrounding areas); Suppl. App'x 117-121 (declaration describing the impact of the Eli Lilly policy on a federally qualified health center that serves 25,000 patients across a 10,000 square mile area in rural Michigan).

Under these circumstances, the district court acted within its discretion in entering partial final judgment under Rule 54(b).

C. The appeals were timely

Although the Court did not direct the parties to address the timeliness of the appeals, we address that issue for the sake of completeness.

The federal defendants filed a notice of appeal of the original partial final judgment on December 28, 2021, *see* Dkt. No. 151, which was within

the 60-day period allowed under Federal Rule of Appellate Procedure 4(a)(1)(B). Plaintiffs filed a notice of appeal of the original partial final judgment on November 10, 2021, *see* Dkt. No. 146, which was likewise timely.

After these appeals were noticed, this Court issued a limited remand for the district court to issue an amended partial final judgment "that fully and completely implements its decision, declaring specifically and separately the respective rights of the parties." Doc. 16 (Apr. 7, 2022). This Court's order indicated that once the district court amended its judgment "the original appeal will come into force" and "[a]n amended notice of appeal is unnecessary." *Id.* (citing Fed. R. App. P. 4(a)(2)). Accordingly, the parties did not file amended notices of appeal from the amended partial final judgment.

II. Final Agency Action

As a threshold matter, the Court need not and should not decide whether the enforcement action was a final agency action. The Administrative Procedure Act's requirement of final agency action is not jurisdictional. *See Dhakal v. Sessions*, 895 F.3d 532, 538 n.9 (7th Cir. 2018). Although the agency argued below that the *advisory opinion* was not a final agency action, *see* Dkt. No. 88 at 14-17, the agency made no such

argument with respect to the enforcement letter, *see* Dkt. No. 125 at 12-39. Instead, the agency explained below that the enforcement letter marked "the culmination of a separate process begun months before the [advisory opinion] was issued and based directly on the statute itself," "along with copious evidence gathered through [the agency's] investigative process." *Id*. at 12 (emphasis omitted). The agency thus waived any argument that the enforcement letter was not a final agency action, and the district court properly did not address that issue.

If this Court nonetheless reaches the issue, it should hold that the enforcement letter was a final agency action. First, the agency's determination that the Eli Lilly policy violated the 340B statute was definitive rather than "tentative or interlocutory." *U.S. Army Corps of Engineers v. Hawkes Co.*, 578 U.S. 590, 597 (2016) (quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997)). The enforcement letter stated that the agency had "completed its review" of the Eli Lilly policy, which "places restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy." A2. The enforcement letter definitively concluded: "After review of this policy and an analysis of the complaints [the agency] has received from covered entities," the agency "has determined that Lilly's

actions have resulted in overcharges and are in direct violation of the 340B statute." A2.

Second, the enforcement letter notified Eli Lilly that prompt compliance with the enforcement letter's directives to discontinue the policy and refund covered entities for past overcharges would avoid referral to the Office of Inspector General for an evaluation of possible civil monetary penalties—analogous to the "safe harbor" mechanism that the Supreme Court relied on in *Hawkes* in finding a final agency action. *Compare Hawkes*, 578 U.S. at 598 (explaining that a negative determination from the agency would have created a five year "safe harbor"), *with* A3 (enforcement letter's notification to Eli Lilly that "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies" may result in civil monetary penalties of up to $5,000 for each overcharge). The enforcement letter was thus final under "the 'pragmatic' approach" that the Supreme Court has "long taken to finality." *Hawkes*, 578 U.S. at 599 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)).

Moreover, the issues decided by the district court were "purely legal" and thus fit for review. *Abbott Labs.*, 387 U.S. at 149. The district court ruled as a matter of law that the enforcement letter did not exceed the

agency's statutory authority "because 42 U.S.C. § 256b, correctly construed," does not allow drug manufacturers "to impose unilateral extra-statutory restrictions on their offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements." SA71.[2] The court explicitly refrained from addressing fact-intensive issues, such as whether a particular covered entity's use of a "replenishment model" had led to diversion of 340B drugs to individuals who are not the covered entity's patients, which is prohibited by 42 U.S.C. § 256b(a)(5)(B). *See* SA47.

Finally, delaying adjudication of the legal issues presented would have caused hardship for both Eli Lilly and covered entities. Quantifying the overcharges that the Eli Lilly policy has caused and determining the full extent of its liability would be a protracted process. The regulations that govern civil monetary penalties allow a manufacturer to request a hearing before an administrative law judge, *see* 42 C.F.R. § 1003.1500, which includes discovery, witnesses, motions practice, and post-hearing briefing, *see id.* § 1005.2–1005.19. Eli Lilly presumably would raise fact-intensive

[2] The district court likewise ruled that Eli Lilly's constitutional and procedural challenges to the enforcement letter fail as a matter of law. *See* SA36-37; SA50-52. The district court vacated the enforcement letter on a purely legal ground: the court's (mistaken) belief that the enforcement letter was predicated on violations of nonbinding agency guidance rather than on violations of the statute itself and that the agency had taken inconsistent positions. *See* SA52-58.

objections to particular overcharge claims. And by Eli Lilly's own account, its policy implicates "tens of thousands of contract pharmacy locations across the country and more than 190,000 arrangements between contract pharmacies and covered entities." Dkt. No. 103, Second Amended Complaint ¶ 49.

III. ***Talevski***

The issues pending before the Supreme Court in *Health & Hospital Corp. of Marion County v. Talevski*, No. 21-806 (U.S.), do not bear on this case. The first question presented in *Talevski* involves the interpretation of 42 U.S.C. § 1983, which provides a private cause of action against state actors who violate "any rights, privileges, or immunities secured by the Constitution and [federal] laws." The petitioners in *Talevski* have urged the Supreme Court to overrule precedent and hold that laws enacted pursuant to Congress's Spending Clause power do not confer "rights" within the meaning of Section 1983. The second question presented in *Talevski* is whether the particular statutory provisions at issue in that case—which predominantly apply to privately owned nursing homes—are enforceable against municipally owned nursing homes under Section 1983.

This case is not a Section 1983 action against state officials. It is a suit under the Administrative Procedure Act that challenges the

enforcement action that the federal agency took against Eli Lilly. The Administrative Procedure Act provides an express cause of action to any party aggrieved by final agency action. *See* 5 U.S.C. §§ 702, 704. Thus, *Talevski* does not bear on the issues presented in this case.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this supplemental brief complies with the requirements of Fed. R. App. P. 32(a) (5) and (6) because it has been prepared in 14-point Georgia, a proportionally spaced font.

/s/ Alisa B. Klein
Alisa B. Klein