United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 24-5180 **September Term, 2024**

FILED ON: MAY 22, 2025

AGENDIA INC.,

APPELLANT

v.

ROBERT F. KENNEDY, JR., SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 1:22-cv-03242)

Before: WALKER, PAN, and GARCIA, *Circuit Judges*.

J U D G M E N T

This appeal was considered on the record from the United States District Court for the District of Columbia and on the briefs and oral argument of the parties. The court has afforded the issues full consideration and has determined that they do not warrant a published opinion. *See* D.C. Cir. R. 36(d). For the reasons stated below, it is:

ORDERED and **ADJUDGED** that the order of the district court entered on July 26, 2024, denying Agendia's motion for summary judgment and granting the Secretary's motion for summary judgment, be **AFFIRMED**.

* * *

Agendia is a clinical laboratory that provides diagnostic tests for breast cancer patients. Medicare pays for diagnostic tests if they are deemed "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). A Medicare administrative contractor issued a "local coverage determination" (LCD) that denied Medicare coverage for Agendia's tests, and the Secretary of Health and Human Services gave "substantial deference" to the LCD when affirming the coverage denials. Agendia appealed a tranche of coverage denials in the Ninth Circuit, arguing that Medicare's reliance on private administrative contractors and their

LCDs is unlawful. The Ninth Circuit rejected those claims. Now, Agendia appeals several more tranches of coverage denials, again challenging the legality of the LCD framework, as well as arguing that certain coverage decisions were not supported by substantial evidence. The district court concluded that Agendia's present challenges to the LCD framework are barred by issue and claim preclusion, in light of Agendia's prior suit in the Ninth Circuit, and it upheld the agency's coverage decisions as supported by substantial evidence. We affirm.

I.

A.

Medicare is a federal health insurance program that covers certain healthcare services for people sixty-five or older, as well as for younger people with qualifying disabilities. 42 U.S.C. § 1395c. A service is covered if it is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *Id.* § 1395y(a)(1)(A). To administer the Medicare program, the Secretary of Health and Human Services contracts with private entities, called Medicare administrative contractors (MACs). *Id.* § 1395kk-1(a)(1). A medical provider that furnishes a service to a Medicare beneficiary can submit claims for reimbursement to a MAC, which makes the initial determination as to whether the service is "reasonable and necessary" and therefore covered. A MAC's initial decision may be guided by a "local coverage determination" (LCD), which states the contractor's own policy as to whether a specific service is covered. *Id.* § 1395ff(f)(2)(B). At all times relevant to this appeal, LCDs were not subject to any notice-and-comment procedure. Unlike Medicare beneficiaries, medical providers do not have standing to facially challenge LCDs and thus may only challenge LCDs as applied to individual coverage decisions. *Id.* § 1395ff(f)(5).

If a MAC denies a reimbursement claim, the medical provider can appeal through a four-level administrative appeal process, which involves: (1) redetermination by the MAC; (2) review by a different "qualified independent contractor" (QIC); (3) a hearing before an administrative law judge (ALJ); and (4) review by the Medicare Appeals Council (Council). 42 U.S.C. § 1395ff; 42 C.F.R. § 405.904(a)(2). A MAC's LCDs are not binding at subsequent levels of the review process. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II). But QICs "shall consider" LCDs, *id.*, and applicable regulations further require QICs, ALJs, and the Council to give "substantial deference" to applicable LCDs or else "explain the reasons why the policy was not followed." 42 C.F.R. § 405.968(b)(2)–(3); *id.* § 405.1062(a)–(b). Even if no party appeals an ALJ's decision, non-party contractors "may refer a case to the Council for it to consider," and "[t]he Council may decide on its own motion to review a decision or dismissal issued by an ALJ." *Id.* § 405.1110(a). The Council's decision — or the ALJ's, if the Council does not act within 90 days of a request for review — is final agency action subject to judicial review. 42 U.S.C. § 1395ff(b)(1)(A); *id.* § 1395ff(d)(3)(B).

B.

Agendia has developed several molecular diagnostic tests that are used by doctors to treat breast cancer patients. The tests identify and analyze genetic material, which provide patient-specific information that can be "relevant to the patient's prognosis and the physician's assessment of treatment options." J.A. 130. Agendia sought Medicare coverage for two of its tests, BluePrint and TargetPrint, by submitting hundreds of reimbursement claims to certain MACs between 2012 and 2015. But the MACs operated under LCDs which declared that the MACs "will consider all" molecular diagnostic tests "not a covered service" unless and until a "technical assessment" determines otherwise. J.A. 14; J.A. 29–30. The MACs developed their own "molecular diagnostic services program" (MolDX) to perform the technical assessments, deploying "unbiased subject matter experts" to review published data regarding a test's "clinical utility" and other criteria. J.A. 18, 21. In August 2012, a MolDX assessment of BluePrint determined that the MACs will "deny BluePrint services" because "there is insufficient evidence to support reasonable and necessary criteria for Medicare reimbursement." J.A. 26. No technical assessment was performed for TargetPrint. Accordingly, the MACs denied Agendia's reimbursement claims for both tests.

Agendia appealed those denials, bundling their hundreds of claims into six tranches. In each of the six appeals, the MAC and the QIC denied Agendia's claims for coverage. The first ALJ to review a tranche of claims reversed the coverage denial and was subsequently reversed by the Council. Agendia sought judicial review of the Council's decision in the Ninth Circuit, arguing that the administrative process unconstitutionally delegates regulatory power to private entities; that LCDs should be subject to notice-and-comment rulemaking; and that the Council's decision was not supported by substantial evidence. The Ninth Circuit rejected Agendia's claims. *See Agendia, Inc. v. Becerra (Agendia I)*, 4 F.4th 896, 898 n.2, 901–03 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 898 (2022).

After *Agendia I*, the ALJs reviewing the remaining five tranches issued their decisions. Four decisions denied coverage, and those decisions became final agency action when the Council did not review them within the statutory time frame. 42 U.S.C. § 1395ff(d)(3)(B). The ALJ who considered the last tranche granted Agendia's request for coverage, concluding that Agendia's tests were "medically reasonable and necessary." J.A. 229. After a non-party referred the favorable ALJ decision to the Council, the Council overturned the ALJ on its own motion. The Council concluded that the ALJ failed to "giv[e] substantial deference to the applicable LCDs, or explain[] his reasons for not doing so," and it further found "no reason to not give substantial deference to the LCD or to question the MolDX program's findings." J.A. 235.

Agendia sought judicial review of all five decisions in the D.C. district court, arguing that: (1) Medicare's reliance on private contractors creates a private nondelegation problem; (2) the regulation requiring substantial deference to LCDs is contrary to the Medicare statute; (3) LCDs should be subject to notice-and-comment rulemaking; and (4) the agency's coverage decisions were not supported by substantial evidence. The district court concluded that Agendia's first three claims — its constitutional and statutory claims — were precluded by *Agendia I*. The district court

then concluded that each of the agency's decisions denying coverage was procedurally correct and supported by substantial evidence.

Agendia timely appealed. We have jurisdiction under 28 U.S.C. § 1291.

II.

On appeal, Agendia seeks to revive its claim that the regulation requiring substantial deference to LCDs is contrary to the Medicare statute, arguing that claim preclusion is inapplicable because that argument was not raised in the prior appeal before the Ninth Circuit. Agendia further argues that two of the agency's coverage decisions were not supported by substantial evidence.[1] We are not persuaded.

A.

We review the district court's application of claim preclusion *de novo*. *See Havens v. Mabus*, 759 F.3d 91, 97 (D.C. Cir. 2014). "A subsequent lawsuit is barred by claim preclusion if there has been prior litigation (1) involving the same claims or cause of action, (2) between the same parties or their privies, and (3) there has been a final, valid judgment on the merits, (4) by a court of competent jurisdiction." *NRDC v. EPA*, 513 F.3d 257, 260 (D.C. Cir. 2008) (cleaned up). The only element in dispute here is the first: whether the litigation in *Agendia I* and this suit involve "the same claims or cause of action." *Id.* "Whether two cases implicate the same cause of action turns on whether they share the same nucleus of facts." *Apotex, Inc. v. FDA*, 393 F.3d 210, 217 (D.C. Cir. 2004) (cleaned up). "Said another way, the test is whether the latter case involves issues that were or could have been raised in the earlier case." *Ashbourne v. Hansberry*, 894 F.3d 298, 302 (D.C. Cir. 2018) (cleaned up).

Although Agendia did not raise the specific legal argument at issue here in *Agendia I*, its claim is just another facial challenge and does not depend on the facts of this particular case. Agendia may not now "offer different legal theories to support the same claim" that was previously litigated. *NRDC*, 513 F.3d at 261. Agendia itself admits, *see* Oral Arg. 8:18–9:55, that its new theory "could have been raised in the earlier case." *Ashbourne*, 894 F.3d at 302 (cleaned up). Moreover, it makes no difference that Agendia here challenges a different tranche of Medicare reimbursement claims than those challenged in *Agendia I* because Agendia's "claim in fact remains the same" — that the overarching statutory and regulatory scheme is unlawful. *NRDC*, 513 F.3d at 260–61; *accord Irish Lesbian & Gay Org. v. Giuliani*, 143 F.3d 638, 643–44, 646 (2d Cir. 1998) (looking past the agency action under review to determine whether the petitioner

[1] Agendia does not challenge the district court's conclusion that two of the legal theories it offers in this case are identical to those raised in *Agendia I* and are thus barred by both issue and claim preclusion. Nor does Agendia challenge the remaining three agency decisions for lack of substantial evidence.

challenged the same regulatory scheme as an earlier action); *United States v. 5 Unlabeled Boxes*, 572 F.3d 169, 174 (3d Cir. 2009) (same).

The Supreme Court's intervening decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), does not alter the consequences of claim preclusion. There is no general exception to claim preclusion for "dramatic shift[s] in the law." *Hardison v. Alexander*, 655 F.2d 1281, 1288 (D.C. Cir. 1981). Although we have contemplated in dicta that claim preclusion might yield in cases involving "paramount questions of constitutional law or exclusive jurisdiction," *id.* at 1288–89, we have never applied that exception, and, in any event, it is not satisfied here.

B.

We next review the district court's affirmance of specific agency decisions *de novo*, "as if the agency's decision had been appealed to this court directly." *Jones v. Astrue*, 647 F.3d 350, 355 (D.C. Cir. 2011) (cleaned up). Accordingly, we will not disturb the ALJ or the Council's refusals to disregard the applicable LCDs so long as those decisions were supported by substantial evidence. *See* 42 U.S.C. § 405(g) (providing that the Secretary's "findings . . . as to any fact, if supported by substantial evidence, shall be conclusive").[2] "Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Saunders v. Kijakazi*, 6 F.4th 1, 4 (D.C. Cir. 2021) (cleaned up). Agendia challenges only two agency decisions on appeal: ALJ Conway's decision denying coverage, and the Council's reversal of ALJ Amendola's favorable coverage decision. We reject each challenge in turn.

First, Agendia forfeited its argument that ALJ Conway failed to consider Agendia's studies by not raising that argument in the district court. *See Adams v. Rice*, 531 F.3d 936, 945 (D.C. Cir. 2008) (noting that arguments not made to the district court are forfeited on appeal). Before the district court, Agendia argued only that the studies were "included in full in each of the other administrative records" and that the ALJ "should have requested copies if they were not in the record supplied to him by the QIC in this case." ECF 20-1, at 32 n.17. On appeal, Agendia argues for the first time that the studies *were* in the record before the QIC, but Agendia "had no obligation to point out the location of the articles in the administrative record" because "ALJs are required to consider de novo the entire administrative record." Agendia Br. 43–44; Agendia Reply Br. 12–13. Because Agendia failed to preserve the argument it now advances, we decline to consider it.

Second, Agendia failed to raise any meaningful challenge to the Council's decision reversing ALJ Amendola. To begin, Agendia forfeited any challenge to the Council's conclusion

[2] Agendia's preferred framing of the standard of review — "whether there was substantial evidence in each administrative record to support a finding of the lack of medical necessity and reasonableness for the testing," Agendia Br. 41 — is erroneous. We are reviewing the ALJ's and the Council's application of a regulation that required them to give "substantial deference" to a pertinent LCD or else "explain the reasons why the policy was not followed." 42 C.F.R. § 405.1062(a)–(b).

"that the ALJ erred as a matter of law by not giving substantial deference to the applicable LCD . . . or explaining his reasons for not doing so," J.A. 235, by not raising such a claim in its opening brief. *See Hood River Distillers, Inc. v. NLRB*, 130 F.4th 204, 217 (D.C. Cir. 2025) ("Arguments raised for the first time in a reply brief are forfeited." (cleaned up)). Agendia also failed to develop a challenge to the Council's conclusion that there was "no reason to not give substantial deference to the LCD" where "the appellant has identified no facts particular to this case for departing from the LCD." J.A. 235–36. Although Agendia asserts that the Council "is incorrect" and cites a letter from a doctor and certain medical literature and references, Agendia Br. 48–49, Agendia does not explain how those documents provide the necessary "facts particular to this case for departing from the LCD," J.A. 236. Agendia also failed to develop its argument that the district court impermissibly upheld the Council's decision "on grounds not relied on by the Council." Agendia Br. 47–48. *See Gov't of Manitoba v. Bernhardt*, 923 F.3d 173, 179 (D.C. Cir. 2019) ("A party forfeits an argument by mentioning it only in the most skeletal way[.]" (cleaned up)). Finally, Agendia forfeited its argument that the Council impermissibly ruled on the sufficiency of the evidence by failing to raise that argument in its opening brief. *Compare* Agendia Reply Br. 5, 8–9, *with* Agendia Br. 47 (arguing instead that "the Council was required to conduct a de novo review of the record"); *Hood River Distillers, Inc.*, 130 F.4th at 217.[3]

For the foregoing reasons, we affirm the judgment of the district court.

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Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The Clerk is directed to withhold issuance of the mandate until seven days after resolution of any timely petition for rehearing or rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. R. 41(a)(1).

Per Curiam

FOR THE COURT:
Clifton B. Cislak, Clerk

BY: /s/
Daniel J. Reidy
Deputy Clerk

[3] Agendia's opening-brief argument that the Council *did not* consider certain documents does not preserve the argument first raised in its reply that the Council *could not* consider the sufficiency of the evidence at all. *Contra* Agendia Ltr., Doc. 2111186 (Apr. 15, 2025) (citing Agendia Br. 49 n.24). And the Secretary did not invite Agendia's late-raised argument simply by summarizing the Council's decision in the fact section of its brief. *Contra id.* (citing Sec'y Br. 14–15).