United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 21-5299 **September Term, 2022**

1:21-cv-01479-DLF
1:21-cv-01686-DLF

Filed On: October 27, 2022

Novartis Pharmaceuticals Corporation,

Appellee

v.

Carole Johnson, in her official capacity as Administrator, Health Resources and Service Administration and Xavier Becerra, in his official capacity as Secretary, United States Department of Health and Human Services,

Appellants

Consolidated with 21-5304

BEFORE: Katsas, Rao, and Childs, Circuit Judges.

O R D E R

Upon consideration of the record from the United States District Court for the District of Columbia, and of the briefs and oral argument of the parties, it is

ORDERED that the record be remanded for the district court to confirm that it has disassociated itself from the case.

This appeal arises from cross motions for summary judgment, granting in part and denying in part relief sought by the parties. The underlying complaints involve requests for declaratory and injunctive relief concerning the interpretation of certain aspects of the 340B Drug Pricing Program of the Public Health Service Act, 42 U.S.C. § 256b, which governs discounted purchases of covered outpatient drugs by covered entities.

On May 17, 2021, the Health Resources and Services Administration (HRSA) issued

Violation Letters to Novartis Pharmaceutical Corporation (Novartis) and United Therapeutics Corporations (UT). These Violation Letters notified Novartis and UT that their policies "plac[ing] restrictions on 340B pricing to covered entities that dispense medication through pharmacies . . . have resulted in overcharges and are in direct violation of the 340B statute." J.A. 35–36, 552–53. The Violation Letters directed, among other things, that the manufacturers "[i]mmediately begin offering [their] covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether [covered entities] purchase through an in-house pharmacy." *Id.* The Violation Letters also alerted the manufacturers that failing to do so may result in civil monetary penalties.

Both manufacturers brought suit against HRSA and others (collectively, HRSA) to challenge the threatened enforcement actions by HRSA. Novartis requested: (1) a declaration that HRSA's position regarding contract pharmacies is unlawful; (2) an order vacating and setting aside its letter on the grounds that it is unlawful, arbitrary, and capricious; and (3) temporary, preliminary, and permanent injunctive relief barring HRSA and any entities acting in concert with it from initiating or pursuing any enforcement actions against Novartis in connection with its 340B contract pharmacy policy. Novartis did not seek a declaration that its specific policy is permissible under 340B. For its part, UT requested a declaration that: (1) the 340B statute does not require pharmaceutical manufacturers to provide 340B discounted drugs to contract pharmacies; (2) UT's contract pharmacy policies are fully compliant with the 340B statute; (3) UT's contract pharmacy policies do not subject UT to civil monetary penalties under the 340B statute; and (4) HRSA's violation determination is arbitrary and capricious, an abuse of discretion, and not in accordance with the law. UT also requested injunctive relief and an order vacating and setting aside its HRSA letter as unlawful.

The issue before the district court was whether the Violation Letters were unlawful because HRSA concluded that the manufacturers violated the 340B statute. The district court ruled on the manufacturers' and HRSA's respective motions for summary judgment, granting in part and denying in part the manufacturers' motions and denying HRSA's motions entirely. The dispositions were as follows:

Manufacturers' Motions for Summary Judgment

1. Declaring that the manufacturers' policies do not violate Section 340B under the positions advanced in the Violation Letters and developed in this litigation. However, the district court did not declare that the manufacturers' policies were permissible under Section 340B.
2. Declining to issue injunctive relief because it was not warranted "at this time."
3. Expressing no view as to whether any other legal theory rules out the manufacturers' specific conditions.
4. Vacating HRSA's Violation Letters.
5. Denying the manufacturers' requests for other relief.

HRSA's Motion for Summary Judgment

1. Denying the motion as to all requests.

This appeal followed.

In considering this appeal, the panel must assure itself of its jurisdiction. The district court's order appeared to grant partial summary judgment to the manufacturers. Specifically, the district court declined to issue injunctive relief "at this time" and did not determine whether the manufacturers' specific policies contravene the 340B statute. Yet, the district court directed the clerk of court to close the case. The district court explained that it would not address "whether Section 340B permits or prohibits any of the specific conditions at issue," because: (1) the parties had not "adequately argued their respective positions on Section 340B's structure," and (2) those questions "likely turn, for example, on the mechanics of how audits work and the degree to which the manufacturer conditions at issue here undermine the operation of the 304B program." J.A. 408. Thus, the language in the order could be read to suggest that the district court intended to hold certain matters open for future development of the facts.

The district court's direction to the clerk of court to close the case is not by itself sufficient to convert the district court's order to a final judgment when unresolved and open issues remain. *See Murray v. Gilmore*, 406 F.3d 708, 712–13 (D.C. Cir. 2005) (determining that there was no final dismissal over a claim which the district court had left "unresolved" and open to "continued viability"); *see also Wilcox v. Georgetown Univ.*, 987 F.3d 143, 148 (D.C. Cir. 2021) (discussing our Court's "contextual approach" to determining whether a case was finally dismissed). Therefore, the panel hereby remands the record to the district court for the limited purpose of explaining whether it contemplates any further proceedings on the claim for injunctive relief or whether the district court's decision is final such that "it ends the litigation on the merits and leaves nothing for the court to do but execute the judgment." *Blue v. D.C. Pub. Sch.*, 764 F.3d 11, 15 (D.C. Cir. 2014) (quoting *Van Cauwenberghe v. Biard*, 486 U.S. 517, 521–22 (1988)).

It is **FURTHER ORDERED** that the case be held in abeyance pending further order of this Court. The Clerk is directed to transmit a copy of this order to the district court. Given the urgency of this appeal, the district court is requested to respond at its earliest convenience and within fifteen (15) days. Until then, this panel will retain jurisdiction over this appeal. *See West Virginia Ass'n of Cmty. Ctrs., Inc. v. Heckler*, 734 F.2d 1570, 1580 (D.C. Cir. 1984). The district court is requested to notify this court promptly upon its determination of the question on remand.

So ordered.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Daniel J. Reidy
Deputy Clerk