**No. 24A-___**

# In the Supreme Court of the United States

VANDA PHARMACEUTICALS INC.,

*Applicant*,

v.

CENTERS FOR MEDICARE & MEDICAID SERVICES; CHIQUITA BROOKS-LASURE, ADMINISTRATOR FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES,

*Respondents*.

## APPLICATION FOR AN EXTENSION OF TIME WITHIN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

TO THE HONORABLE JOHN G. ROBERTS, JR., CHIEF JUSTICE AND CIRCUIT JUSTICE FOR THE FOURTH CIRCUIT:

Pursuant to 28 U.S.C. § 2101(c) and Rule 13.5 of the Rules of this Court, applicant Vanda Pharmaceuticals Inc. respectfully requests a 59-day extension of time, to and including September 6, 2024, within which to file a petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fourth Circuit in this case.

The Fourth Circuit entered judgment on April 10, 2024. Unless extended, the time to file a petition for a writ of certiorari will expire on July 9, 2024. The jurisdiction of this Court will be invoked under 28 U.S.C. § 1254(1). Copies of the lower court's opinion and its order entering judgment are attached as Exhibits A and B, respectively.

1. This case concerns the scope of "line extension" drugs for purposes of the Medicaid Drug Rebate Program, which Congress enacted to control the cost to Medicaid of rising drug prices. The program requires a drug manufacturer to pay an "additional rebate" on Medicaid sales when the price of its drug increases above the rate of inflation. 42 U.S.C. § 1396r-8(c)(2). Under the rebate program as initially designed, the additional rebate for a drug is the amount by which the drug's current average price exceeds its price when first marketed, adjusted for inflation. *Id.* § 1396r-8(c)(2)(A)-(B).

But because a separate rebate attaches to each dosage form and strength of a drug, drugmakers could circumvent their additional rebate obligations by marketing new dosage forms and strengths of an existing drug. Even if the new dosage form or strength only slightly modified the original drug without producing clinical benefits, the new formulation would reset the drug's base date for purposes of the additional rebate calculation.

To close this loophole, Congress amended the Medicaid statute to establish a special additional rebate calculation for certain "line extension" drugs. The "line extension" additional rebate is the higher of two amounts. The first amount is the normal additional rebate calculation for the line extension drug: the amount by which the current average price of the line extension drug exceeds its inflation-adjusted price when first marketed. The second amount reflects how much the original drug has increased over inflation, and is obtained by multiplying the highest additional rebate for any strength of the original drug, expressed as a percentage, by the price of the line extension drug. *Id.* § 1396r-8(c)(2)(C). The "line extension" additional rebate calculation thus negates any advantage that a drug manufacturer might gain

from the gamesmanship of releasing its existing products in slightly altered new formulations.

The Medicaid statute carefully delineates when the special calculation applies: only "[i]n the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form." *Id.* § 1396r-8(c)(2)(C)(i). The statute defines the term "line extension" to mean, "with respect to a drug, a new formulation of the drug, such as an extended release formulation." *Id.* § 1396r-8(c)(2)(C)(iii). The statute also defines the terms "single source drug" and "innovator multiple source drug" to refer only to drugs approved by the Food and Drug Administration (FDA) "under a new drug application." *Id.* § 1396r-8(k)(7)(A)(ii), (iv). In other words, the "line extension" additional rebate calculation applies only when a drug in an oral solid dosage form is marketed in a new formulation that is also in an oral solid dosage form and that has changed so little from the original formulation that no New Drug Application is required for FDA approval, only a Supplemental New Drug Application.

Despite Congress's restriction of the "line extension" additional rebate calculation to carefully delimited circumstances, and departing from its own prior, longstanding interpretation, the Centers for Medicare and Medicaid Services (CMS) promulgated a final Rule in 2020 vastly expanding the line extension provision's scope. *See Medicaid Program; Revising Medicaid Drug Rebate Requirements*, 85 Fed. Reg. 87,000 (Dec. 31, 2020). First, the Rule adopts a sweeping definition of a "new formulation" of a drug, extending to any "change to the drug," including any "change in release mechanism" and any "change in dosage form, strength, route of admin-

istration, or ingredients." *Id*. at 87,101-87,102 (codified at 42 C.F.R. § 447.502). Second, in the preamble to the Rule, CMS "finaliz[ed]" an interpretation of the line extension provision that only the "initial brand name listed drug must be an oral solid dosage form." 85 Fed. Reg. at 87,034. This interpretation greatly inflated the universe of potential line extension drugs.

2. Vanda Pharmaceuticals Inc. (Vanda) is a pharmaceutical company focused on the development and commercialization of innovative therapies to address high-priority unmet medical needs and to improve the lives of patients. Vanda relied on CMS's longstanding interpretation of the line extension provision—that it does not apply to innovative new drugs that provide meaningful new clinical benefits, and that it applies only when both the original and the line extension drug are in an oral solid dosage form—to invest millions in transforming two of its approved drugs, Hetlioz and Fanapt, for new clinical applications in liquid and injectable formulations. Even though these new products—Hetlioz LQ and Fanapt LAI—treat different conditions and require standalone New Drug Applications for FDA approval, under the Rule they are mere line extensions that are subject to the special "line extension" additional rebate obligation.

Vanda brought claims under the Administrative Procedure Act (APA) challenging the Rule's unlawful expansion of the "line extension" provision's scope. Vanda alleged that the Rule's definition of "new formulation"—and, by extension, of "line extension"—and the interpretation of the oral-solid-dosage-form requirement to apply only to the original drug, were contrary to the Medicaid statute. Vanda also argued that the Rule should be set aside as arbitrary and capricious because CMS failed to support it by reasoned decision-making. The district court rejected Vanda's claims,

concluding that the Rule is neither in conflict with the Medicaid statute nor arbitrary and capricious. The Fourth Circuit affirmed.

The petition for certiorari will demonstrate that the Fourth Circuit misapplied the traditional tools of statutory interpretation to erroneously conclude that the Rule is reconcilable with the plain language of the Medicaid statute. The petition will also show that the Fourth Circuit applied an improperly deferential standard in conducting arbitrary and capricious review, effectively excusing CMS from its procedural obligation to take into account the serious reliance interests that Vanda and other pharmaceutical innovators have legitimately developed around the agency's longstanding interpretation of the line extension provision. These errors, which allow an unlawful and innovation-undermining Rule to remain in place, warrant this Court's review.

3. Good cause exists for an extension of time to prepare a petition for a writ of certiorari in this case. Undersigned counsel has, and has had, several other matters with proximate due dates, including: an opening brief in *Lopez Juarez v. Mayorkas*, 24-30188 (5th Cir.), due June 12, 2024; an opposition brief to a motion for judgment on the pleadings in *Vanda Pharmaceuticals Inc. v. United States*, 1:23-cv-00629 (Fed. Cl.), due June 20, 2024; an opening brief in *Singh v. Mayorkas*, No. 24-5260 (6th Cir.), due June 24, 2024; an opening brief in *Vanda Pharmaceuticals Inc. v. FDA*, No. 24-1049 (D.C. Cir.), due June 24, 2024; a combined reply and opposition brief in *Vanda Pharmaceuticals Inc. v. FDA*, No. 1:23-cv-280 (D.D.C.), due June 27, 2024; an amicus brief in *AstraZeneca Pharmaceuticals, LP v. Becerra*, No. 24-1819 (3d Cir.), due July 2, 2024; a petition for certiorari arising from *Miguel-Peña v. Garland*, No. 22-9580 (10th Cir.), due July 3, 2024; a brief in opposition to a petition for certiorari arising from *Baer v. Roberts*, No. 22-2340 (3d Cir.), due July 5, 2024; a reply brief in

*Guandique-De Romero v. Garland*, No. 24-1154 (4th Cir.), due July 9, 2024; an amicus brief in *Bristol Myers Squibb Co. v. Secretary, United States Department of Health & Human Services*, No. 24-1820 (3d Cir.), due July 19, 2024; a combined reply and opposition brief in *Vanda Pharmaceuticals Inc. v. FDA*, No. 1:24-cv-351 (D.D.C.), due July 29, 2024; and a reply brief in *Vanda Pharmaceuticals Inc. v. FDA*, No. 24-1049 (D.C. Cir.), due August 14, 2024.

For the foregoing reasons, the application for a 59-day extension of time, to and including September 6, 2024, within which to file a petition for a writ of certiorari in this case should be granted.

June 7, 2024

Respectfully submitted.

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