No. 24A-___

In the Supreme Court of the United States

VANDA PHARMACEUTICALS INC.,

Applicant,

v.

FOOD AND DRUG ADMINISTRATION, ET AL.

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 DISTRICT OF COLUMBIA CIRCUIT

TO THE HONORABLE JOHN G. ROBERTS, JR., CHIEF JUSTICE AND CIRCUIT JUSTICE FOR THE D.C. 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 60-day extension of time, to and including May 16, 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 D.C. Circuit in this case.

The D.C. Circuit entered judgment on December 17, 2024. Unless extended, the time to file a petition for a writ of certiorari will expire on March 17, 2025. 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 FDA's "Fast Track" program, which Congress enacted to accelerate the development and approval of certain novel therapies. The program requires FDA to provide benefits, including additional meetings and accelerated review of the new drug application (NDA) for any drug "intended * * * for the treatment of a serious or life-threatening disease or condition" if "it demonstrates the potential to address unmet medical needs for such a disease or condition." 21 U.S.C. § 356(b)(1). The Fast Track provision exists to ensure "prompt arrival of safe and effective new drugs" which is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease." 21 U.S.C. § 379g note.

Congress doubled down on the importance of expedited drug review programs in 2012 when it enacted the Food and Drug Administration Safety and Innovation Act (FDASIA). Pub. L. No. 112-144, 126 Stat. 993. It explained that "[p]atients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases." *Id.* § 901(a)(1)(D). Congress thus declared that "FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions." *Id.* § 901(a)(1)(C). It identified the Fast Track program as a primary mechanism to achieve that goal. *See id.* § 901(a)(2).

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 has invested millions of dollars over more than a decade to develop its drug, tradipitant, for the

treatment of symptoms in gastroparesis patients. Gastroparesis is a rare but serious digestive disorder in which patients cannot empty food from their stomachs into their small intestines normally. The result is a constant onslaught of gastrointestinal symptoms, including nausea, vomiting, bloating, and abdominal pain. Gastroparesis symptoms are often so severe that they interfere with patients' employment, social lives, and ability to maintain normal eating patterns. The condition tends to be progressive, with symptoms worsening over time as damage to the gastrointestinal system accretes.

Despite the suffering gastroparesis causes for hundreds of thousands of Americans, treatment options are exceedingly limited. FDA approved one drug, Reglan (metoclopramide) for the treatment of one *kind* of gastroparesis more than 40 years ago. But Reglan is associated with serious adverse reactions preventing long-term use. FDA's most serious category of warning advising patients of the risk of developing tardive dyskinesia, an untreatable and often irreversible movement disorder. FDA recommends avoiding treatment with Reglan for longer than 12 weeks. Because of the paucity of treatment options for gastroparesis, FDA has long recognized the need for novel therapies to aid suffering patients.

In 2021, when Vanda submitted its request for Fast Track designation for tradipitant, Vanda had collected substantial evidence resulting from a well-controlled, four-week investigational study. In the study, participants receiving tradipitant experienced clinically meaningful improvements in nausea and other gastroparesis symptoms compared to subjects receiving a placebo. In addition to study participants, several patients have taken tradipitant for extended periods of time—some beyond a year—under the Expanded Access program, which allows patients to access

unapproved drugs when no other therapies are available and the benefits of treatment outweigh the risks. 21 U.S.C. § 360bbb. Available data uniformly suggested that tradipitant was safe and well-tolerated in human patients. None of the nearly 1,000 patients who had taken tradipitant reported any significant adverse effect; the most common side effects, which were observed in less than 10% of the population, were fatigue and sleepiness.

FDA acknowledged that gastroparesis was a serious medical condition with an unmet medical need, but denied Vanda's Fast Track application. During the development of tradipitant, FDA imposed a partial clinical hold to prevent Vanda from studying the drug in human trials longer than 12 weeks until it conducted an additional, long-term study in dogs. Ex. A at 6; *see* 21 U.S.C. § 355(i)(3). Vanda has declined to conduct the studies FDA has demanded, which Vanda maintains are scientifically inappropriate and will lead to the needless destruction of hundreds of animals. Because the program was under partial clinical hold, FDA automatically concluded that tradipitant lacks the "potential" to treat the unmet medical needs of gastroparesis patients.

Vanda challenged FDA's denial under the Administrative Procedure Act (APA), arguing that FDA's interpretation and application of the FDCA's Fast Track provisions was contrary to law and arbitrary and capricious. Principally, Vanda argued that the statute requires that a *drug* have the "potential" to treat an unmet medical need, not that the drug is likely to be imminently approved or that the drug's *development program* have the potential to result in imminent approval. The district court rejected FDA's arguments that the challenge was moot, but also denied Vanda's claims. The D.C. Circuit affirmed.

3. The petition for certiorari will demonstrate that the D.C. Circuit misapplied the traditional tools of statutory interpretation to erroneously conclude that FDA's single-minded focus on tradipitant's development program is reconcilable with the plain language of the FDCA. Numerous patients have taken tradipitant and publicly described the drug's substantial effects. A drug that *actually* addresses these patients' medical needs undoubtably has the *potential* to do so. The lower court's contrary opinions and holdings are inconsistent with this Court's recent opinion in *Loper Bright Enters.* v. *Raimondo*, 144 S. Ct. 2244, 2266, 2273 (2024), as they held only that FDA's approach was "reasonable" and "consistent with" the statute, rather than that it was *right*. This error, which threatens to silently revive the *Chevron* deference this Court held to be anathema to courts' role as interpreters of the law, also results in the delay and potential abandonment of necessary treatments for countless patients, in direct contravention of Congress's statutory aims. The petition will present the Court with a uniquely attractive vehicle to address this frequently recurring but infrequently litigated issue.

4. 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: a hearing in *Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.* and *Vanda Pharmaceuticals Inc. v. Apotex Corp.*, Nos. 23-cv-152 and 23-cv-153 (D. Del.), on March 6, 2025; a reply brief in support of writ of mandate in *Mitchell v. Superior Court*, No. B344068 (Ct. App. Cal. 2d Dist.), due March 13, 2025; a brief on remedies in *Vanda Pharmaceuticals Inc. v. Food & Drug Administration*, No. 24-cv-351 (D.D.C.), due March 13, 2025; a reply brief in *Institutional Shareholder Services, Inc. v. SEC*, No. 24-5105 (D.C. Cir.), due March

13, 2025; an oral argument in *World Shipping Council v. Federal Maritime Commission*, No. 24-1088 (D.C. Cir.), on March 13, 2025; Oral argument in *Sam's West, Inc. v. County of Cook*, No. 1-24-229 (App. Ct. Ill. 1st Dist.), on March 31, 2025; a response brief in *Ellis v. Yasenchack*, No. 24-3892 (6th Cir.), due April 2, 2025; a brief in opposition to certiorari in *Moylan v. Guerrero*, No. 24-701 (U.S.), due April 2, 2025; an opening brief in *Taiho Pharmaceutical Co., Ltd. v. MSN Laboratories Private Ltd.*, No. 25-1407 (Fed. Cir.), due April 4, 2024; a brief in opposition to certiorari in *Chambers-Smith v. Ayres*, No. 24-584 (U.S.), due April 7, 2025; a petition for a writ of certiorari in *New England Carpenters Guaranteed Annuity & Pension Funds v. Newmark*, No. 20-1643 (2d Cir.), due April 7; oral argument in *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc.*, No. 23-2357 (Fed. Cir.), on April 11, 2025; an opening brief in *Vanda Pharmaceuticals v. United States*, No. 24-1434 (Fed. Cir.), due April 16, 2025; a reply brief in in *Vanda Pharmaceuticals Inc. v. Food & Drug Administration*, No. 24-cv-351 (D.D.C.), due April 17, 2025; a response brief in *Vann v. City of Rochester*, No. 24-3186 (2d Cir.), due April 17, 2025; and an opening brief in *Cox v. City of Rochester*, No. 25-254 (2d Cir.), due May 15, 2025.

For the foregoing reasons, the application for a 60-day extension of time, to and including May 16, 2026, within which to file a petition for a writ of certiorari in this case should be granted.

March 7, 2025

Respectfully submitted.

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