No. 23A-___

In the Supreme Court of the United States

VANDA PHARMACEUTICALS INC.,

Applicant,

v.

TEVA PHARMACEUTICALS USA, INC.; APOTEX INC.; APOTEX CORP.,

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 FEDERAL CIRCUIT

TO THE HONORABLE JOHN G. ROBERTS, JR., CHIEF JUSTICE AND CIRCUIT JUSTICE FOR THE FEDERAL 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 January 12, 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 Federal Circuit in this case.

The Federal Circuit denied a timely request for rehearing on August 16, 2023. Unless extended, the time to file a petition for a writ of certiorari will expire on November 14, 2023. 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 denying rehearing are attached as Exhibits A and B, respectively.

1. This case concerns the standard governing the "obviousness" inquiry under the Patent Act. Pursuant to 35 U.S.C. § 103, "[a] patent for a claimed invention may

not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains."

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 acquired a molecule—tasimelteon—that another pharmaceutical innovator had abandoned. Through painstaking, significant, and costly clinical testing, Vanda developed the drug into a useful therapeutic. Tasimelteon is now Hetlioz®—the first drug that the Food and Drug Administration (FDA) approved to treat two different orphan conditions: Non-24-Hour Sleep-Wake Disorder (Non-24), a debilitating circadian-rhythm disorder that disproportionately afflicts individuals who are totally blind, and sleep disturbances in individuals with Smith-Magenis Syndrome, a rare genetic neurodevelopment disorder.

The patents at issue reflect the fruits of Vanda's extensive clinical work and ingenuity, which led to the successful FDA approval of Hetlioz® as the first therapy to treat Non-24. The patents at issue cover:

- tasimelteon's unexpected efficacy in entraining a Non-24 patient's circadian rhythm when administering a certain dose on a specific schedule (C.A. App. 77-118),
- tasimelteon's previously unknown interaction with a certain class of drugs (C.A. App. 119-159, C.A. App. 160-194); and

- tasimelteon's unpredicted need to be administered without food (C.A. App. 195-198).

The district court found the asserted claims addressing each of these innovations obvious. The Federal Circuit affirmed.

The petition for certiorari will demonstrate that, in affirming, the Federal Circuit applied a flawed standard in assessing obviousness. The petition will show that the Federal Circuit's approach to obviousness has deviated materially from *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 416 (2007), which trains the obviousness inquiry on whether prior art combinations "do more than yield a predictable result." In failing to apply the appropriate standard, the petition will demonstrate that the Federal Circuit deeply erred—and further that this error embedded in Federal Circuit jurisprudence warrants this Court's review.

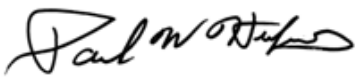
2. Good cause exists for an extension of time to prepare a petition for a writ of certiorari in this case. Undersigned counsel has, and has had, several other matters with proximate due dates, including a reply brief in an intervenor's brief in *Shell* v. *FERC*, No. 22-1116 (D.C. Cir.), filed September 12, 2023; a motion to dismiss in *Johnson* v. *Yuga Labs*, No. 2:22-cv-08909 (C.D. Cal.), filed September 12, 2023; an opposition brief to a motion to dismiss in *Vanda Pharmaceuticals Inc.* v. *United States*, No. 23-629C (Fed. Ct. Cl.), filed September 28, 2023; an opening/response brief in *Benton* v. *Telecom Network Specialists*, Nos. B318867 and B321869 (Cal. Ct. App.), filed October 6, 2023; oral argument in *Elec. Power Supply Assn.* v. *FERC*, No. 22-3176 (6th Cir.), on October 19, 2023; an opening brief in *Astellas Pharma, Inc.* v. *Sandoz*, No. 23-1878 (Fed. Cir.), due October 27, 2023; a reply brief in *Vanda Pharmaceuticals Inc.* v. *Ctrs. for Medicare and Medicaid Servs.*, No. 23-1457 (4th Cir.), due October 30,

2023; a petition for a writ of certiorari in *Martinez* v. *Jenneiahn*, No. 22-1219 (10th Cir.), due November 5, 2023; a conditional cross petition in *Dutra* v. *Jackson*, No. 23A61 (U.S.), due November 6, 2023; a brief in opposition in *Dutra* v. *Jackson*, No. 23A61 (U.S.), due November 6, 2023; and an intervenor brief in *N.Y. State Pub. Serv. Comm'n* v. *FERC*, No. 23-1192 (D.C. Cir.), due December 8, 2023.

For the foregoing reasons, the application for a 59-day extension of time, to and including January 12, 2024, within which to file a petition for a writ of certiorari in this case should be granted.

October 13, 2023

Respectfully submitted.



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