No. 18-____

In the Supreme Court of the United States

OCTOBER TERM, 2018

WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED,
HIKMA PHARMACEUTICALS USA, INC., PETITIONERS

v.

VANDA PHARMACEUTICALS, INC., RESPONDENT

APPLICATION FOR AN EXTENSION OF TIME TO FILE
A PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

UNOPPOSED APPLICATION OF PETITIONERS TO THE HONORABLE JOHN G. ROBERTS, JR. AS CIRCUIT JUSTICE FOR 45-DAY EXTENSION OF TIME TO FILE PETITION FOR WRIT OF CERTIORARI

To the Honorable John G. Roberts, Jr., Chief Justice of the United States and Circuit Justice for the United States Court of Appeals for the Federal Circuit:

Pursuant to 28 U.S.C. §§ 1257(a), 2101(c), and Supreme Court Rules 13.5 and 22, petitioners West-Ward Pharmaceuticals International Limited and Hikma Pharmaceuticals USA, Inc. respectfully request a 45-day extension of time, to and including December 27, 2018, within which to file a petition for a writ of certiorari in this case. In support thereof, petitioners state as follows:

CORPORATE DISCLOSURE STATEMENT

1. Petitioners Hikma Pharmaceuticals USA, Inc. and West-Ward Pharmaceuticals International Limited are wholly-owned subsidiaries of Hikma Phar-

maceuticals PLC, which is a publicly held corporation traded on the London Stock Exchange under the symbol HIK.L. No other publicly held corporation owns 10% or more of the stock in Hikma Pharmaceuticals USA, Inc. or West-Ward Pharmaceuticals International Limited.

JUDGMENT FOR WHICH REVIEW IS SOUGHT

2. The judgment for which review is sought is the decision of the Federal Circuit in *Vanda Pharmaceuticals, Inc., et al.* v. *West-Ward Pharmaceuticals International Limited, et al.* (Nos. 2016-2707, 2016-2708) (Exhibit A). That decision was issued on April 13, 2018, and petitioner's timely rehearing application was denied on August 14, 2018 (Exhibit B).

JURISDICTION

3. This Court will have jurisdiction over the petition in this case pursuant to 28 U.S.C. §§ 1254(1) and 2101(c). Under Rule 13.1 of the Rules of this Court, the petition for certiorari is currently due on or before November 12, 2018. As provided in Rule 13.5, this application is being filed more than 10 days before that date.

BACKGROUND

4. This patent infringement case arises under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 1984 Stat. 1538 (codified in scattered sections of 21 & 35 U.S.C.), commonly known as the Hatch-Waxman Act. Hikma seeks to market a generic version of iloperidone, a schizophrenia drug that Vanda markets under the brand name Fanapt®. Vanda's patent claims a method consisting essentially of the following steps: (i) determining wheth-

er the patient has a certain characteristic; (ii) administering a larger or smaller dosage depending on whether the patient has the characteristic in question.

5. Petitioners seek review of a divided Federal Circuit decision upholding that patent against a challenge that it claims ineligible subject matter under 35 U.S.C. § 101. This Court has repeatedly held that "laws of nature" are not patentable. *Alice Corp. Pty. Ltd.* v. *CLS Bank Int'l, Inc.*, 134 S. Ct. 2347, 2354 (2014); *Ass'n for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013); *Mayo Collaborative Servs*. v. *Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *Parker* v. *Flook*, 437 U.S. 584, 589 (1978).

6. In a decision with broad implications for the pharmaceutical industry and method-of-treatment patents, the Federal Circuit held that, although the patents' claims "recognized" the natural law at issue, they were not "directed to" a natural law, and thus were valid. Exhibit A at 30, 28.

7. As Judge Prost argued in dissent, that decision squarely conflicts with this Court's precedents and creates the potential for clever drafting to create a major loophole in the foregoing decisions, as patentees may circumvent § 101 by merely adding a simple treatment step that follows from the diagnosis. In *Mayo*, for example, the patent claimed a method of determining the level of certain metabolite in the body, wherein the level of metabolite indicated a need to increase or decrease the dosage of drug. *Mayo*, 566 U.S. at 74-75. Those claims "set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or

cause harm." *Id.* at 77. As Judge Prost recognized, "*Mayo* warned against 'drafting effort[s] designed to monopolize the law of nature itself.' The majority does not heed that warning." Exhibit A Dissent at 5 (quoting *Mayo*, 566 U.S. at 77).

8. The Federal Circuit's split decision has generated extensive commentary, and the decision will now be cited to create an unfounded exception to the teaching of *Mayo* and other decisions of this Court that a patent may not be obtained for the simple application of a natural law to medical diagnosis. Jennifer Lane Spaith & Angela L. Morrison, *Federal Circuit Finds Personalized Medicine Invention Subject Matter Eligible*, Dorsey & Whitney LLP (Apr. 17, 2018) <https://www.dorsey.com/newsresources/publications/client-alerts/2018/04/federal-circuit-finds-personalized-medicine> (acknowledging that "drafting efforts seemed to help Vanda Pharmaceuticals in the present case" and recognizing that "including an affirmative step of administering a drug, especially a step of administering one or more specific dosages of the drug, may help render claims patent eligible"); Stephanie Sivinski, *Vanda v. West-Ward: This Time, Dosage Adjustment Claims are Patent Eligible Subject Matter*, IPWatchdog (May 16, 2018) <https://www.ipwatchdog.com/2018/05/16/vanda-v-west-ward-dosage-adjustment-claims-patent-eligible/id=97117/> ("Generic drug manufacturers accused of infringement should fully appreciate the subjective nature of a § 101 defense when evaluating their litigation risk."). As one leading commentator put it, "the majority's approach appears to latch onto simple patent drafting tricks as the basis for distinguishing *Mayo*—an approach directly rejected by the Supreme Court in *Mayo*,"

and "the denial of en banc review" reflected "a high flaunting of Supreme Court precedent." Dennis Crouch, *Vanda on Rehearing: Will the Federal Circuit Defy SCOTUS?* Patently-O (Jun. 27, 2018) <https://patentlyo.com/patent/2018/06/rehearing-federal-circuit.html>. As the petition will explain, this Court should grant certiorari and reverse.

REASONS JUSTIFYING AN EXTENSION OF TIME

9. Respondents do not oppose the extension, for which there is good cause under Rule 13.5.

10. The undersigned counsel did not handle this case in the court below, and has only recently been retained to prepare the petition. Accordingly, additional time is required to become familiar with this case.

11. In addition, the undersigned counsel is or has been engaged in other prior commitments, including preparation for oral argument in *Cisco Systems, Inc.* v. *Leadfactors LLC* (Cal. Ct. App.) (argument scheduled for Nov. 13, 2018), a complex trade secrets dispute, preparation of two post-hearing arbitration briefs in *Rauner* v. *Kirkpatrick* (AAA No. Case 01-17-0004-4001), a complex commercial dispute, and preparation of the merits brief for respondents in this Court in *Helsinn Healthcare S.A.* v. *Teva Pharmaceuticals USA, Inc.* (No. 17-1229). These and other matters preclude counsel from preparing the petition for certiorari before the current deadline, giving priority to the preparation of the brief.

12. This extension is not requested for any purpose of delay.

CONCLUSION

For the foregoing reasons, petitioners West-Ward Pharmaceuticals International Limited and Hikma Pharmaceuticals USA, Inc. request a 45-day extension of time, to and including December 27, 2018, within which to file a petition for certiorari.

Respectfully submitted,

/s/Steffen N. Johnson

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OCTOBER 26, 2018