No. 18-817

In the Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC., ET AL.,
PETITIONERS

v.

VANDA PHARMACEUTICALS INC.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SUPPLEMENTAL BRIEF FOR THE RESPONDENT

KANNON K. SHANMUGAM
MASHA G. HANSFORD
WILLIAM T. MARKS
PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP
2001 K Street, N.W.
Washington, DC 20006

NICHOLAS GROOMBRIDGE
Counsel of Record
ERIC ALAN STONE
KIRA ALEXIS DAVIS
JOSEPHINE YOUNG
DANIEL J. KLEIN
PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
ngroombridge@paulweiss.com
(212) 373-3000

In the Supreme Court of the United States

No. 18-817

HIKMA PHARMACEUTICALS USA INC., ET AL.,
PETITIONERS

v.

VANDA PHARMACEUTICALS INC.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SUPPLEMENTAL BRIEF FOR THE RESPONDENT

The government agrees with respondent that certiorari should be denied in this case and that the court of appeals "arrived at the correct result" in holding that the particular method-of-treatment claims at issue here were patent-eligible. Br. 8. In particular, the government ultimately agrees with respondent (and disagrees with petitioner) that the decision below is consistent with this Court's existing Section 101 jurisprudence, including *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012). See Br. 14-15. While the government observes that review would be warranted in an appropriate case to clarify that jurisprudence and avoid an excessively cramped view of patent eligibility, the government correctly notes that this is "not an optimal vehicle" in which to provide that clarification. Br. 21.

The government suggests that review may be warranted in *Athena Diagnostics, Inc.* v. *Mayo Collaborative Services, LLC*, 927 F.3d 1333, petition for cert. pending, No. 19-430 (filed Oct. 1, 2019), where the Federal Circuit held that diagnostic-method claims were not patent-eligible, or in "another such case." Br. 22-23. While the government suggests as a fallback that the Court could hold the petition in this case if it grants review in *Athena*, see Br. 23, the government agrees the result here would not be affected by the outcome in that case, see Br. 9-10. Indeed, while Federal Circuit judges disagreed in *Athena* about the patent eligibility of *diagnostic*-method claims (at issue in both *Athena* and *Mayo*), not one of them suggested that method-of-*treatment* claims such as the ones at issue here were ineligible for patenting. There is no realistic possibility that holding the petition in this case would lead to a different outcome. Regardless of whether the Court grants the petition in *Athena*, therefore, the petition in this case should be denied.

1. As the government recognizes, "[t]he court of appeals correctly held that the relevant claims of Vanda's patent constitute patent-eligible subject matter under 35 U.S.C. 101." Br. 8. The patent at issue here claims a method of treating a medical condition (schizophrenia) using a manmade drug (iloperidone) at dosages specific to individual patient populations. As the government notes, "[h]istorically, it was well understood that such methods were patent-eligible." Br. 9. The text of the Patent Act, the consistent practice at the Patent and Trademark Office, and more recent congressional action all support the conclusion that such methods of treatment constitute patent-eligible subject matter. See Br. 9-10. And while petitioner contends that the decision below established a categorical rule of patent eligibility for *all* method-of-

treatment claims, subsequent events disprove that contention. See *INO Therapeutics LLC* v. *Praxair Distribution Inc.*, 782 Fed. Appx. 1001, 1012 (Fed. Cir. 2019) (holding particular method-of-treatment claims ineligible under Section 101).

As the government further recognizes, this case is a poor vehicle in which to address any broader ferment about the Court's Section 101 precedents. Because "the court of appeals majority reached the correct result," a decision from this Court "would have little practical effect in this case." Br. 21. Indeed, to the extent the government seeks clarification of the Court's Section 101 precedents, this case would be unlikely to provide it. The Court already indicated in *Mayo* that Section 101 encompasses claims directed to "a new way of using an existing drug," 566 U.S. at 87, and the Federal Circuit has repeatedly reaffirmed since *Mayo* (in this case and others) that particular methods of treatment can be patent-eligible, see Pet. App. 30a-34a; *Endo Pharmaceuticals Inc.* v. *Teva Pharmaceuticals USA, Inc.*, 919 F.3d 1347, 1353 (2019); *Natural Alternatives International, Inc.* v. *Creative Compounds, LLC*, 918 F.3d 1338, 1345 (2019). In fact, there is no discernible disagreement at the Federal Circuit regarding that issue. The dissent below did not suggest that method-of-treatment claims are categorically ineligible under Section 101, but instead simply disagreed about the application of *Mayo* to the claims in this case. See Pet. App. 47a-49a. The Federal Circuit denied rehearing en banc without recorded dissent (even from the panel dissenter). See *id.* at 93a-94a.

Subsequent en banc activity in the Federal Circuit has only reinforced the point. In response to the court's decision to deny rehearing en banc in *Athena*, eight judges wrote separately to address the confusion surrounding Section 101—but none of the judges, even the dissenting

ones, went so far as to suggest that method-of-*treatment* claims such as the ones at issue here were ineligible. See *Athena*, 927 F.3d at 1334-1373. In fact, two of those opinions cited the decision in this case without indicating any disagreement with the result. See *id.* at 1336 (Lourie, J., concurring); *id.* at 1368 (Newman, J., dissenting); see also *id.* at 1351 n.5 (Chen, J., concurring) (agreeing with Judge Lourie's analysis regarding methods of treatment).

2. The government suggests as a fallback (Br. 23) that, if the Court grants review in *Athena*, it may wish to hold the petition here pending a decision on the merits in that case. Notably, petitioner does not ask for a hold in its supplemental brief, and there is no good reason for a hold here. Because the court of apppeals (correctly) held that the claims at issue here are patent-eligible under *Mayo*, see Pet. App. 30a-34a, a decision in *Athena* reaffirming the *Mayo* framework would presumably result in an eventual denial of certiorari. But the same would be true if the Court adopted any of the alternative interpretations of Section 101 proposed in *Athena*.

The claims at issue here would unquestionably be patent-eligible under the government's more expansive approach. See Br. 8. So too under the petitioner's approach in *Athena*, which focuses on the use of "man-made molecules" and the "recitation of specific chemical steps to achieve a new and useful result"—easily capturing the claims at issue here, which cover a specific method of treating a disease with a manmade molecule. Pet. at 29, 31, *Athena*, *supra*; see *id.* at i. And so too under the various interpretations of Section 101 offered by Federal Circuit judges at the rehearing stage in *Athena*, none of whom suggested that method-of-treatment claims such as the ones at issue here were ineligible. See 927 F.3d at 1335 (Lourie, J., concurring); *id.* at 1337 (Hughes, J., concurring); *id.* at 1340-1343 (Dyk, J., concurring); *id.* at 1351

n.5 (Chen, J., concurring); *id.* at 1359-1361 (Moore, J., dissenting); *id.* at 1365-1366 (Newman, J., dissenting); *id.* at 1370-1371 (Stoll, J., dissenting); *id.* at 1371-1373 (O'Malley, J., dissenting).

All told, there is no serious possibility that a decision on the merits in *Athena* would ultimately lead to a different result here. And the government stops short of definitively asserting that *Athena* is the optimal vehicle in which to obtain the clarification concerning Section 101 that it seeks, raising the possibility that the Court may want to call for views of the Solicitor General. See Br. 22-23 (suggesting only that the Court should grant review "in *Athena* or in another such case"). The Court should deny the petition in this case without imposing needless and potentially substantial further delay in what is already a five-year-long litigation.

* * * * *

The petition for a writ of certiorari should be denied.

Respectfully submitted.

KANNON K. SHANMUGAM
MASHA G. HANSFORD
WILLIAM T. MARKS
PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP
2001 K Street, N.W.
Washington, DC 20006

NICHOLAS GROOMBRIDGE
ERIC ALAN STONE
KIRA ALEXIS DAVIS
JOSEPHINE YOUNG
DANIEL J. KLEIN
PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
ngroombridge@paulweiss.com
(212) 373-3000

DECEMBER 2019