No. 18-817

In the Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC., AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LTD., N/K/A HIKMA PHARMACEUTICALS INTERNATIONAL LTD., PETITIONERS

v.

VANDA PHARMACEUTICALS INC., RESPONDENT

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

SUPPLEMENTAL BRIEF FOR PETITIONERS

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The Rule 29.6 Statement included in the petition for a writ of certiorari, as updated by the brief in opposition for respondents, remains accurate.

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INTRODUCTION

As the government's brief dramatically illustrates, there is a raging debate over the scope and wisdom of this Court's unanimous decision just seven years ago in *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012). That decision set forth a general approach to determining the patentability of methods that consist merely of natural laws and recommendations to doctors about dosage levels of previously existing drugs. An ambiguous dictum in *Mayo* suggested that "a typical patent on * * * a new way of using an existing drug" might present a different case. Br. 13 (quoting 566 U.S. at 87). The Court in *Mayo* observed that the steps in such a patent might be "less conventional" than the dosage recommendations at issue there. 566 U.S. at 87.

As the government explains, the majority below read that dictum in a manner that conflicts with the decision's overall "logic," which "arguably implies the opposite." Br. 8. Although *Mayo*'s holding suggests that Vanda's "concrete treatment step" is "conventional activity because it is not independently new" (Br. 13, 14), the majority below exploited *Mayo*'s dictum to effectively nullify the *Mayo* framework in cases involving method-of-treatment patents.

As the government further explains, the resulting "uncertainty" has "considerable practical consequences for various types of medical innovations," "tens of thousands" of method-of-treatment claims, and the PTO's "ability to provide direction." Br. 15, 9, 16. The government thus agrees that the decision below "implicates important and recurring questions" that "warrant[] review in an appropriate case." Br. 8.

There are three basic ways for the Court to resolve the alleged tension between *Mayo*'s holding and its dictum. First, it could reaffirm *Mayo*'s holding and make clear that it means what it says, notwithstanding the dictum. Second, it could repudiate *Mayo*, as the government prefers. This would also entail repudiating *Bilski* v. *Kappos*, 561 U.S. 593 (2010), which the government regards as the original sin in this area of law. Third, it could embrace the split-the-baby approach. This would entail confining *Mayo* to its facts and defining method-of-treatment patents as categorically patentable without regard to *Mayo*'s second step—an odd approach in that, as the government then noted, *Mayo* itself involved a "method of treating a patient." U.S. *Mayo* Br. I (No. 10-1150).

The Court has before it two relevant petitions: this one, and one in *Athena Diagnostics, Inc.* v. *Mayo Collaborative Services., LLC* (No. 19–430). This case involves a method-of-treatment patent; *Athena* involves a method-of-diagnosis patent. The first approach—reaffirming *Mayo* and *Bilski*—would entail reversing in this case and affirming in *Athena*. The second approach—repudiating *Mayo* and *Bilski*—would entail affirming in this case and reversing in *Athena*. The third approach—categorically distinguishing between method-of-diagnosis and method-of-treatment claims—would entail affirming in both.

The government says *Athena* is a better "vehicle." Br. 8, 21. But that claim is predicated entirely on the government's questionable view of the merits—namely, that *Mayo* should be repudiated. Br. 8. On that view, the government suggests that a decision here would not make a "practical difference." Br. 8, 9. But all that the government means by this is that, under its view of the law, the decision below would be

affirmed—as if there were some rule that this Court should only grant certiorari to reverse. On the same reasoning, if this Court reaffirms *Mayo*, there will be no "practical difference" in *Athena*.

It thus turns out that the Solicitor General's "vehicle" objection is not a "vehicle" objection at all; it is entirely merits-based, and it is untenable. It is the majority decision below, not *Athena*, that breaks from this Court's precedents. Indeed, the government all but admits that Hikma would prevail if "*Mayo*'s approach" were applied as this Court applied it in *Mayo*. Br. 12–14.

Further, virtually every argument pressed by the government was rejected just seven years ago in *Mayo*—unanimously. The Court has since reaffirmed *Mayo*'s two-step framework—unanimously. *Alice Corp. Pty. Ltd.* v. *CLS Bank, Int'l*, 573 U.S. 208 (2014). The suggestion (Br. 8) that *Mayo*, *Bilski*, and *Alice* reconceptualized patent-eligibility law rests on a *highly* selective reading of precedent. And it is the majority ruling below that threatens to make patentability for method-of-treatment claims "depend simply on the draftsman's art," thus rendering this Court's "bright-line" "prohibition against patenting laws of nature" a "dead letter." *Mayo*, 566 U.S. at 72, 89.

For all these reasons, this case is the better vehicle. Alternatively, the Court should review both cases, which would enable it to consider both a method-of-treatment case (this one) and a method-of-diagnosis case (*Athena*) in resolving the alleged tension between *Mayo*'s holding and dictum. Unless the Court is certain that it unanimously erred in *Mayo* and *Alice*, however, it makes little sense to review only *Athena*. Certiorari should thus be granted.

ARGUMENT

1. According to the government, the majority below "marshaled very weighty evidence" that its ruling was faithful to *Mayo*. Br. 14–15. In support, however, the government quotes just one half-sentence from *Mayo*—its "language" distinguishing "'a typical patent on a new drug or a new way of using an existing drug.'" Br. 14 (citations omitted).

This language warrants due consideration. But it is dictum, and ambiguous dictum at that. The half-sentence does not explain what makes method-of-treatment claims "typical," and it does not suggest that method-of-treatment patents are exempt from case-specific analysis of whether they genuinely claim *new* or *conventional* uses of old drugs. In fact, the same paragraph elsewhere suggests that what might distinguish another patent are "less conventional" features than the dosage steps there (566 U.S. at 87) —a step-two analysis.

This case is almost identical to *Mayo*. Vanda's claims call for administering a prior art drug for a prior art purpose, and they cover any dosage "of 12 mg/day or less"—*i.e.*, *every* possible reduction from the prior art dosage of 12–24 mg/day. Pet. 11–12; cf. *Mayo*, 566 U.S. at 72, 78 (involving "processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high," where "doctors used [the] drugs to treat patients suffering from [those] disorders long before anyone asserted these claims"). This case thus provides an opportunity to clarify what *Mayo*'s dictum means—i.e., when methods of using existing drugs are "new"—and whether *Mayo* implicates method-of-treatment claims

that "apply a natural law using only routine and conventional steps." Pet. i.

Further, the government admits that *Mayo*'s "logic" and "reasoning" support the *dissent* below. Br. 8, 13–14; see also Br. 8, 14 (the opinions below track *Mayo*'s "internal inconsistency," "conflicting signals," and "conflicting strands"). For example, the government acknowledges that if, as in *Mayo*, "the metabolizing of a drug" is "an 'entirely natural process[]'" and "precise mathematical correlations" are "'laws of nature,'" "the same would arguably be true" here. Br. 12, 13. Further, the government states that while "Vanda's patent concludes with a concrete treatment step," "the Court's reasoning in *Mayo*" suggests that it might well "be discounted as routine, conventional activity." Br. 13–14.

Unlike "dicta," a decision's "rationale" is *binding*; "it is not only the result but also those portions of the opinion necessary to that result by which [the Court is] bound." *Seminole Tribe* v. *Florida*, 517 U.S. 44, 66–67 (1996). That makes the government's merits analysis quite untenable, except as a disguised call for overruling *Mayo*.

2. More broadly, the government contends that *Mayo* and *Bilski* "recast decades of precedent" and calls for a return to the good old days. Br. 17. This is a tendentious account of precedent.

Most remarkably, the government never mentions *Parker* v. *Flook*, 437 U.S. 584 (1978), which *Mayo* called "controlling." 566 U.S. at 80. As *Flook* held, "[t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance." 437 U.S. at 590. Be-

cause "[a] competent draftsman could attach some form of post-solution activity to almost any [natural phenomenon]," "the discovery of [a natural] phenomenon cannot support a patent unless there is some other inventive concept in its application." *Id*. at 590, 594; see *Mayo*, 566 U.S. at 81–82 (the *Flook* "steps" were "'well known,'" not "inventive"). Likewise, *Diamond* v. *Diehr*, 450 U.S. 175 (1981)—another decision that *Mayo* deemed "controlling"—taught that § 101 "'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity.'" 566 U.S. at 80, 73 (quoting *Bilski*, 561 U.S. at 610–611 ((quoting *Diehr*, 450 U.S. at 191–192)). Yet the government never mentions this portion of *Diehr*.

The government also implies that the patent in *Funk Brothers Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127 (1948), claimed only a natural phenomenon: "the tendency of particular bacteria to inhibit other bacterial species' growth." Br. 11. The claim there, however, required "aggregation of select strains of the several species into one product"—*i.e.*, "an application of that newly-discovered natural principle." 333 U.S. at 131. The claim was invalidated because this "simple step" lacked creativity, and an application must not only be "new and useful," but "also satisfy the requirements of invention or discovery." *Id*. at 132, 131.

Flook, *Funk Brothers*, *Diehr*, and "[o]ther cases" confirm that *Mayo* did not create its two-step framework out of whole cloth. *Mayo*, 566 U.S. at 82. And *Mayo* itself rejected "the Government['s] argu[ment] that virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application," noting that it "would make the 'law of nature' exception

to § 101 patentability a dead letter." *Id.* at 89. Thus, Vanda's claims are not patent-eligible simply because they "'claim[] an application of [a natural] relationship'" by requiring "administration of a specific dosage." Br. 7 (quoting Pet. App. 32a).

3. Indeed, nearly every argument in the government's brief was made and rejected in *Mayo*.

First, the government complains that *Mayo*'s second step "causes the Section 101 inquiry to overlap" with "the novelty and nonobviousness requirements of Sections 102 and 103." Br. 18, 19. Likewise, in *Mayo* the government argued that "the barrier to patentability is imposed not by Section 101 but by 35 U.S.C. § 102 and § 103." U.S. *Mayo* Br. 11. Recognizing that these inquiries "might sometimes overlap," however, the Court explained that "shift[ing] the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do." 566 U.S. at 90. The Court thus "decline[d] the Government's invitation to substitute §§ 102, 103, and 112 inquiries for the better established inquiry under § 101," reaffirming that § 101 poses a threshold bar on conventional claims. *Id.* at 91.

Nor is that approach "atextual." Br. 8. Rather, 35 U.S.C. § 101 requires an "invention" or "discovery" that is "new and useful." Despite decades of opportunity, Congress—which made major revisions to the Patent Act in 1952 and 2011—has not disturbed the Court's settled framework for analyzing patent eligibility. See *Helsinn Healthcare S.A.* v. *Teva Pharm. USA, Inc.*, 139 S. Ct. 628, 634 (2019) ("In adopting the language used in [an] earlier act, Congress 'must

be considered to have adopted also the construction given by this Court to such language[.]'" (citation omitted); Antonin Scalia & Bryan A. Garner, *Reading Law* 331 (2012) ("Legislative revision of law clearly established by judicial opinion ought to be by express language or unavoidably implied contradiction. We know of no case to the contrary.").

Second, the government stresses that iloperidone is "human-made," and that "the relevant distinction under Section 101" is "between products of nature" and "human-made inventions." Br. 11 (internal quotations omitted). Similarly, in *Mayo* it argued that thiopurine drugs are "products of human ingenuity," and that "[t]he reaction of the human body to thiopurine drugs is not an unaltered 'law of nature.'" U.S. *Mayo* Br. 9, 20. But the Court, aware that thiopurine was "human-made," held that the claimed "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" were "laws of nature." 566 U.S. at 77.

Third, the government criticizes treating "highly specific relationships" like dosing regimens as "laws of nature." Br. 12. So too in *Mayo*. U.S. *Mayo* Br. 23 ("'laws of nature'" should not "be defined at that level of particularity"). The Court, however, refused to rule on the basis that "the particular laws of nature that its patent claims embody are narrow and specific," explaining: "[O]ur cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow." *Mayo*, 566 U.S. at 88-89 (collecting cases).

In sum, the Court's analysis in *Mayo* was no oversight. The Court carefully considered the very points

pressed again here, unanimously rejecting them based on precedent going back decades and in some cases more than 150 years. The government's admission that *Mayo*'s "logic" and "reasoning" support the dissent below (Br. 8, 15) is thus a powerful reason to *grant* review. Rule 10(c) (review is warranted where a federal court of appeals "has decided an important federal question in a way that conflicts with relevant decisions of this Court").

4. Citing the Hatch-Waxman Act (Br. 9–10), the government also argues that Congress contemplated "patents that 'claim[] a use for [a] drug.'" 21 U.S.C. § 355(b)(2)(A) and (j)(2)(A)(vii). Nothing in Hatch-Waxman, however, purports to alter substantive patentability requirements, much less make method-of-treatment claims *categorically* patent-eligible. Cf. *Bilski*, 561 U.S. at 608 ("while [35 U.S.C.] § 273 appears to leave open the possibility of some business method patents, it does not suggest broad patentability of such claimed inventions"). Rather, the statute contemplates that defendants will raise validity defenses in both their "Paragraph IV" certifications and court. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Whether an eligibility defense carries the day will thus turn on the specific facts of the individual case. Where a method-of-treatment patent either is not "directed to" natural laws (*Mayo*'s first step) or adds an "inventive concept" (*Mayo*'s second step), it will satisfy § 101. Patentees might satisfy § 101, for example, where they claim new methods of combining drugs to treat diseases not previously treated by the drugs. Cf. *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 409 (2012) (involving a patent that "claims a 'method for treating [diabetes by] administering * * * repaglinide in combination with metfor-

min'" (alterations in original)). As with other types of patents, however, whether method-of-treatment patents satisfy § 101 turns on case-by-case application of *Mayo*'s two-step framework.

5. The government identifies no actual "vehicle" problem barring review. Br. 8. It references the prevailing "uncertainty" and "confusion" in this area of the law no fewer than five times. Br. 8, 15, 16, 21, 22. Four more times, it notes that the proper § 101 analysis is "unclear." Br. 9, 10, 13, 14. And it candidly explains that the split between the majority and dissent below both is attributable to *Mayo*'s "conflicting signals" and "implicates important and recurring questions" that "warrant[] review in an appropriate case." Br. 8.

The government offers just one reason why this is not that case—its view that the "majority reached the correct result." Br. 21. As shown above, however, the Court would much more likely reverse. The government's admission that *Mayo*'s unanimous "logic" and "reasoning"—the binding stuff—support the dissent below (Br. 8, 13–14) provides ample reason to doubt its assessment of the merits. Not surprisingly, the petitioners in *Athena* (like the government here) advance mainly arguments unanimously rejected in *Mayo*. *E.g.*, Reply Br. for Petitioners 2 (No. 19–430) (stressing "the role of novel man-made molecules in method claims" and contending that the Federal Circuit used the wrong "level of abstraction"). And even if the Court affirmed in this case, the decision would end the uncertainty affecting "various types of medical innovations" and "tens of thousands" of method-of-treatment patents (Br. 15, 9)—patents the Federal Circuit continues to uphold at *Mayo*'s first step. *E.g.*, *Natural Alternatives Int'l, Inc.* v. *Creative Com-*

pounds, LLC, 918 F.3d 1338, 1344, 1345 (Fed. Cir. 2019) ("[t]hese are treatment claims and as such they are patent eligible" (citing the decision below)).

Denying certiorari here, moreover, would open the door to "drafting effort[s] designed to monopolize the law[s] of nature." *Mayo*, 566 U.S. at 77. Virtually any "diagnosis" claim can now avoid § 101 scrutiny by including "an instruction to doctors to apply the applicable laws when treating their patients." *Id*. at 79. The claim in *Mayo*, for example, could have survived under the majority opinion below if, rather than reciting that a certain metabolite level "indicates a need to" adjust the dosage "subsequently administered" to the patient, it had *expressly required* administering a different dose. As the dissent below recognized, however, "requiring a dosage instead of indicating a dosage" adds only "a conventional application of th[e] natural law." App. 49a–50a. And allowing clever draftsmanship to secure patent-eligibility would render the "bright-line" "prohibition against patenting laws of nature" a "dead letter." *Mayo*, 566 U.S. at 89.

The Court should therefore take this case—not *Athena*, which faithfully applies this Court's precedent. Alternatively, the Court should review both cases. But review should not be denied here because, on account of the government's policy preferences and continued opposition to *Mayo*, it views the prospect of reversal here as sub-"optimal." Br. 8.

CONCLUSION

For the foregoing reasons, and those stated in the petition and reply, certiorari should be granted.

Respectfully submitted.

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