No. 09-1159

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IN THE

Supreme Court of the United States

BOARD OF TRUSTEES OF THE
LELAND STANFORD JUNIOR UNIVERSITY,
Petitioner,

v.

ROCHE MOLECULAR SYSTEMS, INC., *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

SUPPLEMENTAL BRIEF FOR RESPONDENTS IN RESPONSE TO BRIEF OF THE UNITED STATES

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CORPORATE DISCLOSURE STATEMENT

The Rule 29.6 statement included in Respondents' brief in opposition remains accurate.

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Respondents respectfully submit this response to the government's brief filed at the Court's invitation ("Inv. Br.").

SUMMARY

1. The government offers a reformulated Question Presented untethered to the facts, which the government seeks to dismiss as "fortuit[ies]." Inv. Br. 15, 21. The actual facts cannot be brushed aside. Dr. Mark Holodniy was not a rogue inventor who secretly "defeated" Stanford's rights. Inv. Br. I. Ra-

ther, as the district court found, Holodniy went to Cetus at Stanford's direction, and Stanford had actual and imputed notice of his assignment. Pet. App. 16a-17a, 64a. The invention was conceived before Holodniy left Cetus. *Id.* 14a, 56a-58a. This chronology, as well as the agreements' terms, necessarily informed and limited the Federal Circuit's ruling, and the court made clear that the government's rights were not at issue. Pet. App. 20a n.1. There is no reason for this Court to review a limited decision on an unusual factual record in search of an issue that is not presented here and may never be presented at all. Indeed, the government cannot identify *even one* other case that the ruling below would affect.

2. The government's proposed resolution of the question it urges on the Court is both unsupported by the Bayh-Dole Act and misguided as a matter of policy. The statute does not allow a contractor to "obtain" title (Inv. Br. 17), nor does it create a "presumption" of contractor ownership (*id.* 16-17)—a notion the government derives not from the Act's text, but from a committee report that considered a materially different House bill. The Bayh-Dole Act governs funding agreements between the government and federally-funded research institutions; it does not confiscate intellectual property rights from non-funded entities whose private resources and expertise lead to the conception of inventions. The government's rule would chill collaboration between universities and private research firms; indeed, it would put privately-funded firms in a *worse* position than entities who take federal funds.

ARGUMENT

I. THE DECISION BELOW DOES NOT WARRANT REVIEW

The government replaces Stanford's Question Presented with yet another one the Federal Circuit did not decide. The government's reformulation—"Whether an inventor who is employed by a contractor that elects to retain rights in an invention ***may defeat*** the contractor's right to retain title under the Bayh-Dole Act" (Inv. Br. I (emphasis added))—ignores critical facts that circumscribe the effect of the decision below.

The government's assertion that "[t]he patented process was developed by researchers at [Stanford] using federal funds" (Inv. Br. 7) is wrong. The invention was conceived and the assay completed at Cetus *before* Stanford performed any work using federal funds. *Id.* 14a, 56a-58a. Stanford offered no alternative conception date. *Id.* 58a n.7.

Before any involvement of federal funding in the research, Stanford itself (through Thomas Merigan) directed Holodniy to "spend time at Cetus to develop a better assay." *Id.* 4a, 35a, 64a, 69a. Holodniy arrived at Cetus "with the specific intent" and "goal" of developing such an assay. *Id.* 56a, 64a. Holodniy executed the assignment "in the course of Stanford's business," and Stanford had actual and imputed notice of it. *Id.* 16a-17a, 64a. Accordingly, the invention was conceived and the assay completed while Holodniy "was assigned a lab bench in Cetus' Clinical Group, and had access to Cetus personnel, materials, and equipment." *Id.* 35a. Holodniy spent approximately nine months "receiving technical infor-

mation from Cetus scientists and proprietary physical materials from Cetus," all of which were the fruits of private investment, not Bayh-Dole funds. *Id.* 36a.[1]

This is not a case, as the government suggests, of an inventor's "wishes" overriding the Bayh-Dole Act. Inv. Br. 11. Instead, the inventor acted with notice to the contractor. Pet. App. 16a-17a, 64a. And the Federal Circuit clearly linked its ruling to the facts of this case, particularly the nature and timing of Holodniy's agreements. *E.g.*, *id.* 12a (discussing Stanford's use of a future assignment, rather than present assignment); *id.* 16a (Stanford had "at least" constructive notice of Holodniy's agreement with Cetus); *id.* 19a (relying on the fact that Holodniy's assignment to Cetus predated Stanford's election to retain title by six years); *id.* (finding no authority suggesting that Stanford could use the Act to void "any *prior*, otherwise valid assignments" (emphasis added)); *id.* 20a ("*prior* contractual assignments" (emphasis added)); *id.* 21a (similar).

The Federal Circuit did not decree a broad rule governing all federal funding cases, and it did not address the alternative fact patterns that the government imagines. Inv. Br. 17 (hypothesizing situation in which "the terms or even existence of [an assignment are] unknown to the contractor"). Indeed, the court left open the possibility that Stanford or

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[1] Holodniy's salary was paid by a National Research Service Award. Decl. of Thomas C. Merigan ¶13 (Dkt. 112, Nov. 15, 2006). Such awards are not subject to the Bayh-Dole Act. *See* 35 U.S.C. 212.

the government might have "some other legal recourse to recover Holodniy's rights" in this very case. Pet. App. 20a n.1.

Accordingly, as Respondents explained (Opp. 11-17), certiorari is inadvisable for at least four reasons: (1) the question Stanford presented for review is far broader than the question actually decided; (2) the government's rights are the same regardless of the outcome of this petition; (3) a reversal in this case may well ultimately have no effect on the outcome, due to the judgment that the patents are invalid; and (4) the peculiar facts that implicated the Bayh-Dole Act are not known to have arisen in any other case.

The government does not meaningfully contest these facts. First, the government acknowledges that the question in Stanford's petition—whether Stanford's rights could be "terminated unilaterally by an individual inventor" (Pet. i)—is not presented. Inv. Br. 21 (Stanford "has not been deprived of all rights in the inventions because it obtained valid assignments from Holodniy's co-inventors"). Second, the government admits that its own rights—an irrevocable paid-up license—are exactly the same under the Federal Circuit's judgment as they would be were this Court to reverse. *Id.* Third, the government acknowledges that, because the district court held the patents invalid as obvious, a reversal by this Court may have no effect on the outcome. *Id.*

The government attempts to dismiss these serious vehicle problems as a "fortuity" (Inv. Br. 15, 21), even though *every* vehicle problem is in some sense a "fortuity" that happens to arise in one case but might not in another. *E.g.*, *Kenyeres* v. *Ashcroft*,

538 U.S. 1301, 1305-06 (2003) (Kennedy, J., in chambers) (certiorari was not "appropriate" given the particular facts of the case, even though the issue was "significant" and produced an "acknowledged disagreement among the lower courts"). Here, the "ameliorating circumstances" (Inv. Br. 21) limit any harm to Stanford and eliminate any harm to the government, thereby further disfavoring review.

Regarding the fourth reason for denying review—the apparently unprecedented factual scenario—the government says only that federal funding under the Bayh-Dole Act is widespread. Inv. Br. 1, 16. But the *statute's* general importance says nothing about the specific importance of the *Question Presented.* The government, Stanford, and Stanford's amici have not identified a single other case that would even arguably be affected by the Federal Circuit's ruling.[2]

For the decision below to apply as "binding precedent" (Inv. Br. 21), the following factual predicates would have to exist:

> 1. a university requires a researcher to execute an "agreement to assign" intellectual property, not a present assignment (Pet. App. 13a);

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[2] Unlike the petitioner in *Fidelity Federal Bank & Trust* v. *Kehoe*, 547 U.S. 1051 (2006), neither Stanford nor the government faces any liability here, much less "$40 billion." *Id.* (Scalia, J., concurring in denial of certiorari).

2. the university sends the researcher to collaborate with a private entity that receives no federal funds (*see supra* pp. 3-4);

3. the researcher signs a *present* assignment of intellectual property to the private entity as a condition of access to that entity's expertise and materials (Pet. App. 35a-36a);

4. the university has notice of the researcher's assignment under state law (*id.* 17a, 64a);

5. the researcher conceives of an invention while working at the private entity without using federal funds (*id.* 35a-36a; *supra* pp. 3-4);

6. the researcher returns to the university, which then uses the already-conceived invention in further work done subject to federal funding (Pet. App. 5a, 39a);[3]

7. the university obtains a patent covering the invention that was previously conceived at and assigned to the private entity (*id.* 3a-4a, 41a);

8. the private entity practices the invention (*id.* 5a); and

9. the university chooses to sue the private entity for infringement rather than cooperate

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[3] Stanford has never disclosed the terms of the federal grant that supposedly funded Stanford's work after Holodniy returned from Cetus. Opp. 6.

to commercialize the invention for the public good.

If anything in this case is a "fortuity," it is this chain of highly unusual and improbable facts. The government offers no reason to conclude that they have ever recurred or ever will. Universities can avoid the first factual predicate above by using present assignments, as many already do. Opp. 15. The government ventures that a "massive number of past and present agreements" exist between universities and researchers (Inv. Br. 20), but it does not suggest that many employ future assignment clauses or that *any* have produced events similar to those in this case.[4]

Unable to present this case as anything other than atypical, the government seeks to portray the Federal Circuit's decision as "not dependent on the particular facts of this case." Inv. Br. 19. But even if the government were right about the breadth of the court's ruling—and it is not—the government still identifies no case, past or present, where the Federal Circuit's ruling (even as misconstrued by the government) would affect the outcome. If the government is right, there will be other opportunities for this Court to address its reformulated question on an

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[4] Notably, state-law remedies for rescinding an assignment might be available if a "rogue inventor" were ever to execute a secret assignment without his employer's knowledge (*see* Inv. Br. 17). *E.g.*, *Larson* v. *Correct Craft, Inc.*, 569 F.3d 1319, 1326-27 (Fed. Cir. 2009) (remanding claims for rescission of patent assignments); *Heidelberg Harris, Inc.* v. *Loebach*, 145 F.3d 1454, 1457 (Fed. Cir. 1998) (patent assignment rescinded).

appropriate record. As the government admits, questions regarding the interplay of the Bayh-Dole Act and contract law may arise "in any type of property dispute" and, in fact, have arisen in circuits other than the Federal Circuit. Inv. Br. 20; *see* Opp. 14 (citing cases). The Federal Circuit's denial of rehearing en banc in *this* case does not suggest that "further percolation" is unlikely. Inv. Br. 20. The more plausible conclusion is that the en banc court, like the panel (Pet. App. 20a n.1), correctly viewed the panel's ruling as limited to its facts and unlikely to govern many (or perhaps any) future cases.

The Court should reject the government's contention that the Federal Circuit misunderstood the scope of its own decision. The panel did not purport to decide a "pure question of law" divorced from the peculiar record in this case. Inv. Br. 19. The government's concern about how the Federal Circuit *might* decide future cases on different facts is not a reason for this Court to review an issue that apparently has not arisen before and may never arise again; the government's issue "can await a day when the issue is posed less abstractly." *The Monrosa* v. *Carbon Black Export, Inc.*, 359 U.S. 180, 184 (1959) (dismissing writ); *see also Caldwell* v. *Quarterman*, 549 U.S. 970 (2006) (statement of Stevens, J.) (denial of certiorari is appropriate where the court of appeals' "narrow holding is unlikely to produce injustice"); *Conway* v. *California Adult Auth.*, 396 U.S. 107, 110 (1969) (declining to adjudicate "the purely artificial and hypothetical issue tendered by the petition for certiorari").

II. THE GOVERNMENT'S POSITION HAS NO SUPPORT IN THE STATUTE OR LEGISLATIVE HISTORY AND WOULD CHILL INNOVATIVE COLLABORATION

The government's position rests on two fundamental errors. First, the government misstates the statute, contending that it allows a federal contractor to "*obtain*" title, a word the Act does not use. Inv. Br. 17 (emphasis added). The Act provides only that a contractor may elect to "retain" title (35 U.S.C. 202(a)), a word that presumes that the contractor already has title to the invention, whether the contractor is an individual inventor who received title automatically or an organization that received a valid assignment from the inventor under 35 U.S.C. 261.

The government's second error is its belief that the Bayh-Dole Act created a "presumption" that a federal contractor automatically receives title to an invention developed using federal funds—a proposition the government bases not on the Act, but on a single sentence in a report of the House Committee on the Judiciary. H.R. Rep. No. 1307, 96th Cong., 2d Sess. Pt. 1 at 5 (1980) (House Report) (quoted at Inv. Br. 12, 16-17). But that report considered not the Act's final text, but an earlier version providing that a contractor "*will acquire title* to its contract invention" if certain prerequisites were met. *Id.* at 43 (quoting H.R. 6933, 96th Cong., 2d Sess. §383(a)) (emphasis added).

By contrast, a Senate report commenting on the language that was eventually enacted confirmed that a contractor's election permitted it to keep the rights *it otherwise possessed*: contractors "are to have the

right to elect to retain worldwide ownership *of their inventions*." S. Rep. No. 96-480, 96th Cong., 1st Sess. 31 (1979) (Senate Report) (emphasis added)); *see also id.* at 32 (failure to comply with reporting requirements could result in a contractor losing "*its rights* to an invention" (emphasis added)). Section 202(a), as enacted, simply does not govern a situation like this one, where a contractor does not possess all rights to an invention, but rather *shares* them with a private firm like Cetus that made major contributions to and enabled the invention without the benefit of receiving federal funds.[5]

Nothing in the legislative history the government cites suggests that Congress intended to supplant ordinary assignments that are valid under applicable law. *See Fenn* v. *Yale Univ.*, 393 F. Supp. 2d 133, 141-42 (D. Conn. 2004) (the Act regulates "relationships of small business and nonprofit grantees with the Government, not between grantees and the inventors who work for them"). Rather, Congress was concerned with allocating rights between contractors and *the government*. *See* House Report at 2 (bill evolved from "recommendations on government pa-

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[5] Section 202(d) gives agencies "the authority to leave rights with individual inventors in cases when contractors do not elect rights." Senate Report at 33. It has no application in situations where the contractor elects to retain the rights it otherwise obtained—here, Stanford's rights through assignments by Drs. Merigan and Katzenstein—but has not obtained, and therefore cannot "retain," the rights of a private entity whose contributions to the invention were not federally funded.

tent policy"). The Federal Circuit's ruling did not disturb that allocation.[6]

The government's reliance on 35 U.S.C. 210(a) is also misdirected. Inv. Br. 16. Section 210(a) provides that the Bayh-Dole Act "take[s] precedence" over other laws that would dispose of rights "in a manner that is inconsistent with this chapter" and then specifically lists 21 laws identifying agency patent policies. The canons of *ejusdem generis* and *expressio unius est exclusio alterius*, as well as the legislative history, confirm the limited effect of Section 210(a): to "take precedence over a number of statutory provisions that currently control to varying degrees *the patent policies of some agencies*." Senate Report at 35 (emphasis added). Section 210(a) never mentions the Patent Act's section governing assignments (35 U.S.C. 261)—a telling omission, given that the Bayh-Dole Act amended the Patent Act.

Finally, the policies underlying the Bayh-Dole Act are served by the status quo in this case, not by the government's position. Respondents commercialize HIV test kits built in Branchburg, New Jersey and distributed from Indianapolis, thereby creating American jobs and furthering American public health. 35 U.S.C. 200, 204. Stanford "retain[s]" full title from the co-inventors and rights to commercial-

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[6] *Platzer* v. *Sloan-Kettering Inst.*, 787 F. Supp. 360 (S.D.N.Y. 1992) (cited at Inv. Br. 13) ruled only that the Bayh-Dole Act did not imply a private right of action for inventors. *See id.* at 364-65. That conclusion supports the Federal Circuit's ruling that the Act does not regulate Holodniy's assignment.

ize the inventions. *Id.* 202(a). And the government retains its "march-in" rights to compel licensing as appropriate. *Id.* 203.

The Bayh-Dole Act envisions forfeiture of intellectual property only in rare situations where a contractor that has taken federal funds later *breaches* its obligations. 35 U.S.C. 202(c)(1)-(2); *Campbell Plastics Eng'g & Mfg., Inc.* v. *Brownlee*, 389 F.3d 1243, 1249 (Fed. Cir. 2004) (upholding forfeiture where contractor breached its contract by failing to disclose the invention). Nothing in the Act suggests that Congress meant to visit that punishment on an innocent company like Cetus that did not even assume obligations to the government, let alone breach them. The government's suggestion that Cetus has no right to use an invention conceived using Cetus's own resources puts Cetus in a worse place than it would have occupied had it actually *received* federal funds. The Act cannot be read to produce such an arbitrary result.

The government's contentions would chill the very "collaboration between commercial concerns and nonprofit organizations, including universities" that the Bayh-Dole Act sought to foster. 35 U.S.C. 200. The government does not suggest how, under its rule, a small firm like Cetus could protect its intellectual property while collaborating with a university. The government, like Stanford, appears to believe that discoveries conceived on the back of private investment may be snatched away retroactively if a university subsequently—and without notice to or consent from the private entity—decides to incorporate them into federally-funded projects. *See* Pet. 12. Such a rule would discourage scientific coopera-

tion with no countervailing public benefit, only a windfall for Stanford.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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