

No. 09-1159

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**

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Bayh-Dole Act permits a private university to void, unilaterally and retroactively, an inventor's otherwise valid contractual assignment of his rights in an invention, solely because that invention was developed in part with federal funds.

CORPORATE DISCLOSURE STATEMENT

Pursuant to the Court's Rule 29.6, Respondents state as follows:

1. Roche Molecular Systems, Inc., a Delaware corporation, is a wholly-owned subsidiary of Roche Holdings, Inc., a Delaware corporation, which is a subsidiary of Roche Finance Ltd, which is a subsidiary of Roche Holding Ltd. More than 10% of Roche Holding Ltd's voting shares are held by Novartis International Ltd (Switzerland) as direct holder, with its parent Novartis AG (Switzerland) as economic beneficiary.

2. Roche Diagnostics Corporation, an Indiana corporation, is a wholly-owned subsidiary of Roche Holdings, Inc.

3. Roche Diagnostics Operations, Inc., a Delaware corporation, is a wholly-owned subsidiary of Roche Diagnostics Corporation.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED.....	i
CORPORATE DISCLOSURE STATEMENT.....	ii
INTRODUCTION.....	1
STATEMENT	2
A. Cetus’s Groundbreaking Research.....	2
B. Stanford Sends Its Scientists To Learn From Cetus	3
C. The Inventive PCR Assay Is Conceived At Cetus	5
D. Stanford Continues The Research And Secretly Patents It.....	6
E. Stanford Sues Cetus’s Successor, Roche, To Prevent Commercialization Of The Invention.....	7
F. The District Court Decisions.....	7
G. The Court Of Appeals Decision.....	9
REASONS FOR DENYING THE PETITION	11
I. THE PETITION DOES NOT WAR- RANT THIS COURT’S ATTENTION	11
A. The Case Does Not Present The Is- sue On Which Stanford Seeks Review	11
B. This Case Presents No Issue Of Government Patent Rights	13
C. Stanford’s Objection Is Splitless, Fact-Bound, And Highly Unusual	14

TABLE OF CONTENTS—Continued

	Page
D. The Question Presented Will Not Be Outcome-Determinative.....	17
II. THE FEDERAL CIRCUIT'S DECISION IS CORRECT	18
A. The Bayh-Dole Act Does Not Alter A Co-Inventor's Right To Assign His Shared Interests In An Invention.....	18
B. Stanford's Additional Objections Do Not Merit Review	22
CONCLUSION	25

TABLE OF AUTHORITIES

CASES	Page
<i>Arachnid, Inc. v. Merit Indus., Inc.</i> , 939 F.2d 1574 (Fed. Cir. 1991).....	9, 16
<i>Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.</i> , 563 F. Supp. 2d 1016 (N.D. Cal. 2008).....	9, 12, 17
<i>Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.</i> , 482 F.3d 1347 (Fed. Cir. 2007).....	10, 19
<i>Crown Die & Tool Co. v. Nye Tool & Machine Works</i> , 261 U.S. 24 (1923)	18
<i>Curtis, Collins & Holbrook Co. v. United States</i> , 262 U.S. 215 (1923).....	23
<i>Fenn v. Yale Univ.</i> , 393 F. Supp. 2d 133 (D. Conn. 2004)	14, 19
<i>FilmTec Corp. v. Allied-Signal Inc.</i> , 939 F.2d 1568 (Fed. Cir. 1991).....	18
<i>Gayler v. Wilder</i> , 51 U.S. (10 How.) 477 (1850).....	18
<i>IpVenture, Inc. v. Prostar Computer, Inc.</i> , 503 F.3d 1324 (Fed. Cir. 2007).....	9
<i>In re Roche Molecular Sys., Inc.</i> , 516 F.3d 1003 (Fed. Cir. 2008)	8
<i>Santillan v. Roman Catholic Bishop of Fresno</i> , 163 Cal. App. 4th 4 (2008).....	23
<i>Talbot v. Quaker-State Oil Refining Co.</i> , 104 F.2d 967 (3d Cir. 1939)	13, 23
<i>Therien v. Trs. of Univ. of Pa.</i> , 2006 WL 83448 (E.D. Pa. Jan. 10, 2006)	19
<i>Univ. of Pittsburgh v. Townsend</i> , 2007 U.S. Dist. LEXIS 56860 (E.D. Tenn. Aug. 3, 2007), <i>aff'd</i> , 542 F.3d 513 (6th Cir. 2008).....	14, 21

TABLE OF AUTHORITIES—Continued

	Page
STATUTES	
Bayh-Dole Act, 35 U.S.C. §§ 200 <i>et seq.</i> <i>passim</i>	
35 U.S.C. § 200	21
35 U.S.C. § 202(a).....	19
35 U.S.C. § 202(c)(7).....	20
35 U.S.C. § 261	10, 18
35 U.S.C. § 262	11, 12, 23
RULES AND REGULATIONS	
Supreme Court R. 10.....	22
TREATISES	
3 Witkin, Summary of California Law, Agency § 150 (2005).....	23
Restatement (Third) of Agency § 5.04 cmt. b (2006).....	23
MISCELLANEOUS	
Massachusetts Institute of Technology, Inventions and Proprietary Information Agreement, <i>available at</i> http:// web.mit.edu/tlo/www/misc/forms.html# TECHNOLOGY	15
Williston, Transfers of After-Acquired Personal Property, 19 Harv. L. Rev. 557 (1906).....	18

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BRIEF IN OPPOSITION

INTRODUCTION

Stanford University's petition for certiorari is defective in numerous ways. First and foremost, this case does not present the very question on which Stanford seeks this Court's review. Contrary to its assertion, Stanford's rights in the patents-in-suit have not been "terminated" (Pet. i); rather, Stanford co-owns the patents through assignments from two of the three co-inventors. Nor does this case raise important issues bearing on Stanford's or the federal government's rights under the Bayh-Dole Act, 35 U.S.C. §§ 200 *et seq.* Rather, this case involves the factbound and splitless application of settled principles of contract interpretation to contract language

in an atypical factual situation, namely where an invention is conceived at a startup company and later confirmed by work done at a large university that receives federal funds. This fact pattern is unlikely to recur, notwithstanding the insistence of Stanford and its chorus of *amici*. In fact, this Court's review is unlikely to alter the outcome even in *this* case, as the district court held the patents invalid for obviousness, a fact Stanford does not even mention.

Moreover, Stanford's petition is meritless. As the court of appeals held, the Bayh-Dole Act nowhere alters an inventor's basic freedom to assign his own rights in an invention to a third party. The Act achieves its laudable goals by regulating the relationship between the federal government and entities that receive federal grant money. The inventor in this case assigned his rights as part of a collaboration between Stanford and a private company. Stanford shows no reason to believe that it can renege retroactively on contractual commitments voluntarily assumed by its agents. The petition should be denied.

STATEMENT

A. Cetus's Groundbreaking Research

This case has its roots in groundbreaking research conducted in the 1980s at Cetus Corporation, a startup company based in California. One Cetus employee, Dr. Kary Mullis, discovered an important technique known as polymerase chain reaction, or PCR, which allows scientists "to make billions of copies of specific sequences of DNA from a small number of starting molecules." Pet. App. 32a. The PCR technique also enables scientists to investigate and manipulate DNA. The technique is instrumental

in current medical and biological applications such as gene cloning, diagnosis of hereditary diseases, detection of infectious diseases and forensic crime scene analysis. For this discovery, Dr. Mullis won the 1993 Nobel Prize in Chemistry. *Id.*

B. Stanford Sends Its Scientists To Learn From Cetus

In 1985, Cetus scientists began looking for ways to use PCR to detect and quantify the presence of human immunodeficiency virus (HIV) in blood. Pet. App. 32a. Scientists at major universities sought out Cetus for its know-how and expertise in this area. One such scientist was Dr. Thomas Merigan, the director of the Center for AIDS Research at Stanford University. *Id.* Over the course of his collaboration with Cetus, involving investigation of HIV and the testing of experimental anti-HIV drugs, Dr. Merigan executed several “Materials Transfer Agreements” (MTAs) with Cetus that gave Dr. Merigan the right to use Cetus’s proprietary materials and information “in exchange for a non-exclusive, royalty-free license to Cetus for any intellectual property developed as a result of the MTA.” Pet. App. 33a. In February 1989, to support Dr. Merigan’s work in the HIV arena, Stanford (along with Dr. Merigan) signed a similar MTA agreement with Cetus, promising Cetus “the first option to an exclusive license, at a reasonable royalty to be negotiated in good faith . . . or at CETUS’ option, a nonexclusive license.” Pet. App. 34a.

In February 1989, Dr. Merigan sent his research fellow, Dr. Mark Holodniy, to Cetus “in order to explore the use of PCR techniques in his work.” Pet. App. 34a. Dr. Holodniy had no previous PCR experience. Pet. App. 34a-35a. In order to have access to

Cetus scientists and materials, Dr. Holodniy signed a Visitor Confidentiality Agreement (VCA), which provided:

If, as a consequence of my access to CETUS' facilities or information, I conceive of or make, alone or with others, ideas, inventions and improvements thereof or know-how related thereto that relate in any manner to the actual or anticipated business of CETUS, *I will assign and do hereby assign to CETUS*, my right, title, and interest in each of the ideas, inventions and improvements thereof described in this paragraph.

Pet. App. 35a-36a (quoting VCA) (emphasis added).

Dr. Holodniy had previously signed a Copyright and Patent Agreement (CPA) with Stanford. Pet. App. 4a. The CPA did not contain a present assignment of rights, but only stated: "*I agree to assign or confirm in writing to Stanford and/or Sponsors that right, title and interest in . . . such inventions as required by Contracts or Grants.*" Pet. App. 13a (emphasis added by court of appeals).

After signing the VCA, Dr. Holodniy "began commuting daily to Cetus," "was assigned a lab bench in Cetus' Clinical Group, and had access to Cetus personnel, materials, and equipment." Pet. App. 35a. Dr. Holodniy spent approximately nine months at Cetus, "receiving technical information from Cetus scientists and proprietary physical materials from Cetus." Pet. App. 36a.

C. The Inventive PCR Assay Is Conceived At Cetus

The invention at issue in this case is “an assay for quantitating HIV RNA using PCR” consisting of five steps. Pet. App. 36a. Dr. Holodniy admitted that he “had never performed any of the five steps of the PCR assay for HIV prior to working at Cetus.” Pet. App. 37a. In fact, Dr. Holodniy sought out the assistance of Cetus scientist Dr. Alice Wang to develop the methods needed to quantitate HIV. Pet. App. 36a. Cetus molecular biologist Clayton Casipit, working in Dr. Wang’s lab, developed the critical material — a cRNA standard — that was used to create a standard curve to quantify HIV. Pet. App. 36a-37a. The Cetus scientists provided the cRNA standard to Dr. Holodniy in October 1989. Pet. App. 37a. As the district court found, the inventive assay was conceived at Cetus while Dr. Holodniy was resident there. Pet. App. 37a, 39a, 41a. Dr. Holodniy requested permission from Cetus to publish the assay and its results in two abstracts; Cetus granted permission after Dr. Holodniy added the names of Dr. Wang, Casipit and another Cetus scientist who had contributed to the assay. Pet. App. 37a. In April 1991, an article in the *Journal of Infectious Diseases* disclosed the assay, naming Dr. Holodniy as lead author and scientists from Cetus and Stanford as co-authors. Pet. App. 38a-39a.

Although Stanford claimed in litigation that the inventive assay was conceived at Stanford (*see, e.g.*, Pet. 12), Stanford refused to disclose when it believed the invention had been conceived (Pet. App. 58a n.7). The district court rejected Stanford’s argument, finding as a matter of fact that the invention was

“conceived” and the assay “completed” before Dr. Holodniy left Cetus. Pet. App. 56a.

D. Stanford Continues The Research And Secretly Patents It

After Dr. Holodniy returned to Stanford, he, Dr. Merigan, and others continued to work on the PCR assay, conducting experiments “to correlate the detection of HIV nucleic acid levels via the PCR assays with the effectiveness of HIV treatment.” Pet. App. 39a. Stanford has contended that it received federal funds through the National Institutes of Health for its research. Pet. App. 5a. However, Stanford has never disclosed the federal funding agreement that allegedly covers this work, and it has never demonstrated how Dr. Holodniy’s work at Cetus, as well as the contributions of Cetus and its scientists, is connected to research grants awarded to Stanford.

In May 1992, Stanford filed a patent application entitled “Polymerase Chain Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the Treatment of Acquired Immunodeficiency Syndrome,” directed to “correlating measurements of HIV nucleic acids obtained via a PCR assay with determining whether or not a therapy is effective.” Pet. App. 31a. Stanford named as inventors Drs. Merigan and Michael Kozal, and later added Drs. Holodniy and David Katzenstein, all Stanford employees (Dr. Kozal was dropped from a continuation application). Pet. App. 3a-4a. Stanford did not name any Cetus scientists as co-inventors, nor did it inform Cetus that it had sought to patent the PCR assays. The application later led to issuance of the three related patents-in-suit, U.S. Patents Nos.

5,968,730 (issued in 1999), 6,503,705 (issued in 2003) and 7,129,041 (issued in 2006).

In 1995, Drs. Holodniy, Katzenstein and Merigan executed written assignments purporting to convey their interests in the patent application to Stanford. Pet. App. 41a. Stanford also informed the government that it “elected to retain title” to the inventions under the Bayh-Dole Act, 35 U.S.C. §§ 200-212. Pet. App. 5a-6a. However, Dr. Holodniy’s interest in the patents had already been assigned to Cetus six years earlier through the VCA.

E. Stanford Sues Cetus’s Successor, Roche, To Prevent Commercialization Of The Invention

In 1991, Roche acquired Cetus’s PCR assets, including Cetus’s rights under transferred contracts and confidentiality agreements. Pet. App. 5a. Roche began manufacturing HIV test kits that employ the PCR assays conceived at Cetus; the kits quantify HIV in an infected patient’s blood and assist physicians in their treatment. *Id.* Roche first offered its test kits for sale in 1996, years before any of the patents-in-suit issued.

In 2005, after the patents-in-suit had issued and Roche’s products had been on the market for nine years, Stanford sued Roche for infringement. Roche answered and counterclaimed on numerous grounds, including invalidity, lack of standing, ownership, and license.

F. The District Court Decisions

The district court ruled that the patented inventions were “conceived” and the assay “completed” by the time Dr. Holodniy left Cetus and that the method

of using PCR to monitor HIV treatment was “clear in the minds of Holodniy and the other Stanford scientists when the assay was completed at Cetus.” Pet. App. 56a. The court found, however, that Roche’s claim to ownership of the patents was barred by the statute of limitations and by laches. Pet. App. 49a, 51a.

Nonetheless, because the parties had briefed the issue of ownership in detail, the district court addressed it in the alternative. The court held that the invention’s conception at Cetus “created an interest on the part of Holodniy in the patent applications” and that interest “was sufficient to trigger the assignment provision in the VCA.” Pet. App. 57a. Accordingly, “[t]he VCA effectively assigned any rights that Holodniy had in the patented invention to Cetus.” Pet. App. 59a.

The court stated, however, that the assignment “conflicted with the legal requirements of the Bayh-Dole Act, which mandated that Stanford be given a superior right to retain title to the patents.” Pet. App. 62a. Because Stanford had allegedly obtained funds from the National Institutes of Health in connection with its research, Dr. Holodniy’s assignment of the patents-in-suit was “void.” Pet. App. 62a. The court also held that the licenses given by Stanford and Dr. Merigan to Cetus in 1988 and 1989 could not be transferred to Roche without Stanford’s consent. Pet. App. 70a-72a.

The district court refused to certify its order for interlocutory appeal. Roche sought a writ of mandamus to vacate the district court’s ruling; the court of appeals denied the writ as premature by a 2-1 vote. *In re Roche Molecular Sys., Inc.*, 516 F.3d 1003 (Fed. Cir. 2008).

Roche then moved for summary judgment that the patent claims were invalid for obviousness over, *inter alia*, the *Journal of Infectious Diseases* article co-authored by Stanford and Cetus scientists in April 1991. In a separate decision not reproduced in the appendix to Stanford's petition for certiorari, the district court held the patents invalid. *Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 563 F. Supp. 2d 1016, 1049 (N.D. Cal. 2008).

G. The Court Of Appeals Decision

Stanford appealed the invalidity judgment to the Federal Circuit, and Roche cross-appealed the rejection of its ownership claim and its standing and license defenses. The court of appeals ruled that, although the district court had correctly dismissed Roche's counterclaim for patent ownership as time-barred, Roche was nonetheless allowed to assert ownership as a defense to infringement and to challenge Stanford's standing to sue. Pet. App. 11a-12a. The court of appeals noted that, under established principles of contract interpretation, the language "agree to assign" in Dr. Holodniy's CPA with Stanford reflected "a mere promise to assign rights in the future, not an immediate transfer of expectant interests." Pet. App. 13a (citing *IpVenture, Inc. v. Prostar Computer, Inc.*, 503 F.3d 1324, 1327 (Fed. Cir. 2007), and *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1580-81 (Fed. Cir. 1991)). Thus, while the CPA may have given Stanford "certain equitable rights against Holodniy," it did not give Stanford title to Dr. Holodniy's inventions. *Id.*

The VCA, by contrast, "effected a present assignment of Holodniy's future inventions to Cetus." Pet. App. 14a. Although Dr. Holodniy later effected a

present assignment to Stanford in 1995, “Cetus’s legal title vested first . . . negating his subsequent assignment to Stanford during patent prosecution.” *Id.* The court rejected Stanford’s argument that it was a bona fide purchaser without notice of Dr. Holodniy’s assignment (*see* 35 U.S.C. § 261), because Stanford was “charged with notice of its employees’ assignments.” Pet. App. 17a (citing authority under federal and California law); *see also* Pet. App. 64a (district court finding that Stanford had “imputed notice” of Dr. Holodniy’s assignment).

The court of appeals rejected Stanford’s reliance on the Bayh-Dole Act. The court observed that, while the Act allows the government to take title to federally-funded inventions, it does not indicate that title is “automatically forfeited.” Pet. App. 19a (quoting *Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1352-53 (Fed. Cir. 2007)) (internal quotation marks omitted). Rather, the Act provided the government with “at most, a discretionary option to [Dr. Holodniy’s] rights.” Pet. App. 19a. And nothing in the Act provided Stanford with the power to void a “prior, otherwise valid assignment[] of patent rights.” *Id.* Rather, Stanford was entitled to claim “whatever rights were still available after the Government declined to exercise its option, including the rights of co-inventors Merigan, Katzenstein, and Kozal.” *Id.* The court did not decide “whether Holodniy’s execution of the VCA violated any provisions of the Bayh-Dole Act, or whether the Act provides the Government or Stanford some other legal recourse to recover Holodniy’s rights.” Pet. App. 20a n.1.

Because Stanford could not establish ownership of Dr. Holodniy's interest in the patents-in-suit, it lacked standing to sue Roche for infringement. Pet. App. 27a-28a. The court of appeals accordingly did not address the merits of the district court's decision holding the patent invalid; it simply vacated the judgment below and remanded with instructions to dismiss the case. Pet. App. 28a. The court denied Stanford's petition for panel rehearing and rehearing en banc. Pet. App. 76a-77a.

REASONS FOR DENYING THE PETITION

I. THE PETITION DOES NOT WARRANT THIS COURT'S ATTENTION

A. The Case Does Not Present The Issue On Which Stanford Seeks Review

Stanford asks this Court to decide whether its rights to the patented invention have been "terminated unilaterally" through Dr. Holodniy's voluntary assignment of his patent rights to Cetus. Pet. i. That question simply is not presented in this case.

Stanford remains a co-owner of the patents-in-suit by virtue of the assigned rights of the other co-inventors, Drs. Merigan, Katzenstein, and Kozal. Pet. App. 41a. As a co-owner of the patents, Stanford retains all the rights of a patentholder, including the rights to "make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners." 35 U.S.C. § 262.

Stanford's insistence that there is a "cloud" on its title or that its rights are "uncertain" or "extinguish[ed]" (Pet. 12, 15-16, 18) is thus off-point, as are

the hyperbolic claims of its *amici*.¹ Leaving aside that the district court held the patents invalid as obvious (563 F. Supp. 2d 1016 (N.D. Cal. 2008)), Roche still could not sue Stanford for infringement. Stanford may freely practice the invention in conducting further research. If Stanford is concerned that Roche will not make the invention sufficiently available to the public, Stanford can license it; it can even license it for a pittance, or for free, “without accounting” to Roche. 35 U.S.C. § 262.

Stanford’s real objection, which only occasionally surfaces in its petition, seems to be that it is not the *exclusive* owner of the patent. Pet. 3 (bemoaning that Stanford’s ownership is “shared”). Stanford apparently wishes to exclude from the marketplace anyone who does not agree to pay Stanford a hefty royalty. Stanford’s desire for private monetary gain has nothing to do with clarity of title or bringing valuable scientific discoveries to the public. On the contrary, Stanford’s effort to exclude Roche from practicing the patented invention would *reduce* opportunities for the public to benefit from the invention, which was conceived at Cetus’s laboratory using Cetus’s own research materials and expertise. The Court should not be misled: Stanford’s petition does not seek clarification of Stanford’s right to commercialize the invention — a right Stanford already possesses — but rather to *restrain* competition by other parties who will not play by Stanford’s rules.²

¹ See, e.g., Wis. Alumni Research Found. *Amicus* Br. 16 (suggesting that an inventor could “leav[e] the research institution with no title”).

² This case does not present the hypothetical scenario in which all inventors have assigned their rights to a non-funded entity. The sophistication of large universities and technology

Stanford offers no reason to think that the Bayh-Dole Act was designed to favor exclusive commercialization by private universities rather than shared commercialization with private industry. As Stanford and its *amici* rehearse at length, the Act was designed to remedy an inefficient system under which the *government* hoarded inventions in ways that made it difficult for the private sector (including universities *and* industry) to use them without navigating labyrinthine bureaucracy. *See, e.g.*, Pet. 8; Ass’n of Am. Univs. *Amicus* Br. 16-17. Nothing in this case raises that concern. Stanford may use the patent as it wishes; the only thing it cannot do is exclude its co-owners, a characteristic of the patent law that has been in place for decades. *See, e.g., Talbot v. Quaker-State Oil Refining Co.*, 104 F.2d 967, 968 (3d Cir. 1939) (co-owner may use invention without consent of co-owners or sharing of profits, even though that “unlimited right” “may, for all practical purposes, destroy the monopoly and so amount to an appropriation of the whole value of the patent”).

B. This Case Presents No Issue Of Government Patent Rights

Stanford urges that the Federal Circuit’s “reasoning” would “permit” an inventor “to terminate the government’s rights.” Pet. 20; *see also* Pet. 15 (“the Federal Circuit’s holding means that the federal government has no rights unless the inventor consents”); Wis. Alumni Research Found. *Amicus* Br. 16. Again, that concern is hypothetical at best.

One searches the Federal Circuit’s opinion in vain for any “reasoning” directed to government rights.

companies engaged in innovative discovery makes it highly unlikely that such a situation would ever arise.

The Federal Circuit was not asked to decide, and did not decide, what would happen if the government exercised its statutory option to take title to an invention subject to a prior assignment by an inventor. On the contrary, it expressly reserved the possibility that the Bayh-Dole Act might give the government “a discretionary option to [the inventor’s] rights.” Pet. App. 19a. It also did not rule out the possibility that the government might have remedies against Stanford or that Stanford might have remedies against Dr. Holodniy. Pet. App. 20a n.1.

Accordingly, the Court should not presume that this case will implicate any important federal interest. In the event a future case creates uncertainty as to the federal government’s rights, the government will doubtless make its views heard as a party.

C. Stanford’s Objection Is Splitless, Fact-Bound, And Highly Unusual

Stanford’s petition does not present any of the traditional indicia that would merit this Court’s attention. Unlike many cases involving patents, this case arises under the Bayh-Dole Act, over which the Federal Circuit concededly does not have exclusive jurisdiction. Pet. 19. Further percolation is thus not only possible but likely. Indeed, the Federal Circuit cited two other decisions raising issues similar to the one below. Pet. App. 20a-21a (citing *Univ. of Pittsburgh v. Townsend*, 2007 U.S. Dist. LEXIS 56860 (E.D. Tenn. Aug. 3, 2007), *aff’d*, 542 F.3d 513 (6th Cir. 2008), and *Fenn v. Yale Univ.*, 393 F. Supp. 2d 133, 141-42 (D. Conn. 2004)). Stanford does not even

discuss them, even though they demonstrate that there is no conflict among lower courts.³

In addition to being splitless, the decision below is highly fact-dependent, turning as it does on the particular language that Stanford and Cetus used in their respective agreements. As Stanford admits, universities can easily avoid the ruling below by “choos[ing] to revise their contracts with researchers and inventors” to grant immediate assignments, rather than simply “agree[ing] to assign” their inventions in the future. Pet. 17.

Although Stanford asserts that universities have used “agree to assign” language in their form agreements for 30 years (Pet. 18), it cites nothing to support that claim. Not one of Stanford’s many *amici* states that it has used such language. On the contrary, publicly-available form agreements of at least one of the *amici* reveal that they require employees to enter into immediate assignments, not mere agreements to assign. *See, e.g.*, Massachusetts Institute of Technology, Inventions and Proprietary Information Agreement, available at <http://web.mit.edu/tlo/www/misc/forms.html#TECHNOLOGY> (requiring all M.I.T. employees to agree that “I will disclose promptly to and assign to, *and I hereby assign to, M.I.T., all rights to all inventions*”) (emphasis added). Notably, Stanford previously boasted that its policies *differed* from those of “industry and many other universities” in that Stanford “allows all rights to remain with the inventor if

³ One of Stanford’s *amici* takes pains to distinguish the cases (Wis. Alumni Research Found. *Amicus* Br. 8 n.2), a counter-productive effort that, if successful, would prove only that this issue is so rare that it has arisen in exactly one case—this one—in the 30 years since the Bayh-Dole Act became law.

possible.” Pet. App. 13a (quoting Stanford’s Administrative Guide to “Inventions, Patents, and Licensing”); *see also* Pet. App. 19a.

Moreover, the Federal Circuit’s interpretation of agreements to assign has been settled for nearly two decades. *See* Pet. App. 13a (citing, *e.g.*, *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1580-81 (Fed. Cir. 1991)). To the extent any universities continued to use mere agreements to assign, they did so at their peril and presumably for their own reasons.⁴

In addition to turning on specific contractual language, this case also arises in the unusual context in which a foundational invention was conceived not at a university receiving federal funds, but at a small company that did not receive federal funding (Cetus), and was only later incorporated into a federally funded project at a large university (Stanford). In the typical Bayh-Dole case, the groundbreaking research is all done at the same grantee institution and subsequently provided to a company for product development and marketing. The Court should view with skepticism Stanford’s claims about the frequency with which the facts of this case will recur.⁵

⁴ Stanford itself has articulated its policy of seeking to have inventors keep ownership of their own inventions “if possible.” Pet. App. 13a. There may be many reasons for such a policy, including creating incentives for top researchers to join a university’s faculty.

⁵ The fact that a decision “of first impression” generated “a flurry of commentary and concern” (Pet. 19) does not suggest that the issue is important or will come up often. Sophisticated academic institutions like Stanford and its *amici* frequently produce “flurr[ies] of commentary,” especially when they lose a case. And the only piece of “commentary” Stanford cites was co-authored by counsel for one of Stanford’s *amici*. Pet. 19 n.1

D. The Question Presented Will Not Be Outcome-Determinative

A further reason for this Court to deny review is that it is highly unlikely that this issue will have any impact even in *this* case. As pointed out above, a ruling that Dr. Holodniy's assignment did not "terminate" Stanford's patent rights would change nothing, as Stanford is already a co-owner of the patent. Moreover, Stanford's effort to hold Roche liable for infringing a patent is likely to fail on other independent grounds, notably that the district court has already held the patent invalid for obviousness. Pet. App. 2a (citing 563 F. Supp. 2d 1016 (N.D. Cal. 2008)). Roche also contended below that it can practice the patent due to the licenses Cetus received from Stanford and Dr. Merigan in 1988 and 1989. The Federal Circuit has not yet reached these issues, but each provides an independent ground to end the case in Roche's favor.

Accordingly, were this Court to grant review, there is every likelihood that its decision would not affect the outcome in this or any other case. If this ruling were truly the momentous sea change Stanford says it is, a case that actually turns on the issue should not be far behind.

(citing article co-written by Howard W. Bremer, emeritus patent counsel for Wisconsin Alumni Research Foundation); *see also* Wis. Alumni Research Found. *Amicus* Br. 9 n.3, 10 n.5, 12 n.7 (citing additional articles by Mr. Bremer written prior to the Federal Circuit's decision).

II. THE FEDERAL CIRCUIT'S DECISION IS CORRECT

Although the considerations discussed above are ample reason to deny review, Stanford's petition additionally lacks merit.

A. The Bayh-Dole Act Does Not Alter A Co-Inventor's Right To Assign His Shared Interests In An Invention

Inventors own their intellectual property unless and until it is assigned to another by an instrument in writing. *Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24, 35-37 (1923). The patent law gives an inventor an express statutory right to assign his interest in patents and patent applications. 35 U.S.C. § 261 ("Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing."). An assignment may occur between an invention's conception and the issuance of a patent, in which case legal title to the ensuing patent will pass to the assignee upon grant of the patent. *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 493 (1850). An inventor may also assign expectant interests in a future invention not yet in being, in which case the creation of the invention automatically transfers the inventor's rights in it to the assignee, without need of any further action. *FilmTec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1572-73 & n.8 (Fed. Cir. 1991) (citing Williston, *Transfers of After-Acquired Personal Property*, 19 Harv. L. Rev. 557 (1906)).

The Bayh-Dole Act did not amend or alter these longstanding principles. Where, as here, the government has not exercised its discretionary right to take title, "title remains with the named inventors

or their assignees. Nothing in the [Bayh-Dole] statute, regulations, or . . . caselaw indicates that title is automatically forfeited.” *Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1352-53 (Fed. Cir. 2007).

Stanford contends that the Act provides that ownership “vests with the university so long as it makes an ownership election within a reasonable period of time.” Pet. 10. The Act says nothing of the kind. Rather, the Act sets forth steps that a federally-funded institution must take in order to “retain title” as against the government. 35 U.S.C. § 202(a) (emphasis added). The Act therefore presumes that the funded institution that would otherwise *have* title (but for governmental interests) may elect to “retain” it. Here, as the court of appeals recognized, Stanford retained the title it would otherwise have had: the title acquired from the co-inventors other than Dr. Holodniy. *See* Pet. App. 19a. But nothing in the Act forbids Dr. Holodniy’s assignee from sharing in title, nor does the Act permit Stanford to sue the assignee for infringement. As courts have recognized, “the primary purpose of the Bayh-Dole Act is to regulate relationships of small business and nonprofit grantees with the Government, not between grantees and the inventors who work for them.” *Fenn v. Yale Univ.*, 393 F. Supp. 2d 133, 141-42 (D. Conn. 2004); *see also Therien v. Trs. of Univ. of Pa.*, 2006 WL 83448, at *3 (E.D. Pa. Jan. 10, 2006).

Stanford cites several provisions that delineate the respective rights and obligations between institutions or companies that *receive* federal funds on the one hand and the federal government itself on the other. Pet. 9. Those provisions remain applicable as between Stanford and the government, and nothing

in Dr. Holodniy's assignment alters them. The court of appeals accordingly left open the possibility that Dr. Holodniy's assignment to Cetus might have violated his or Stanford's obligations under 35 U.S.C. § 202(c)(7) or that Stanford or the federal government might have other remedies under the Act. Pet. App. 20a n.1. However, nothing in the Act operates to abrogate the rights of Cetus (or its successor, Roche), which did not receive any federal funding for its groundbreaking research.

Stanford essentially reads the Bayh-Dole Act as giving it a confiscatory power over the intellectual property of entities with which it collaborates. Indeed, Stanford argues that it can even undo valid assignments *retroactively* by obtaining federal funds with respect to inventions *already conceived and assigned*. See Pet. 12 (arguing that the Act encompasses inventions that were "conceived earlier without using government funding" and only "*later* reduced to practice . . . using government funding" (emphasis added)). Stanford's position would allow it to promise a collaborating entity shared rights to any invention conceived during the collaboration, but then avoid its promise by subsequently obtaining federal funds.

Despite numerous requests, Stanford has never produced the actual funding agreement with the federal government that allegedly bears upon the inventions at issue in this case. Nor has Stanford demonstrated how Dr. Holodniy's work at Cetus or the contributions of Cetus and its scientists are connected to research grants awarded to Stanford. Having obtained the benefit of Dr. Holodniy's residence at a private company, Stanford's failure to produce the applicable funding agreement and prove

that the Cetus material, reagents, and expertise were subject to it suggests that Stanford is trying to whipsaw Cetus (now Roche) and take property rights away from the company.⁶

The goals of the Bayh-Dole Act are advanced by allowing Cetus/Roche to continue to produce the HIV test kits that have allowed physicians to use the PCR assay to quantify and treat HIV in hundreds of thousands of patients worldwide. It is that development work, not Stanford's desire to suppress it or obtain an undeserved windfall, that will "promote the commercialization and public availability of inventions made in the United States by United States industry and labor." 35 U.S.C. § 200. Nothing in the Bayh-Dole Act or its underlying policies supports allowing Stanford to use federal funding as an offensive weapon to avoid contractual obligations. *See Univ. of Pittsburgh v. Townsend*, 2007 U.S. Dist. LEXIS 56860, at *60-61 (E.D. Tenn. Aug. 3, 2007) (inventor's assignment to third party was unaffected by university's election to retain title under the Bayh-Dole Act where "the University's ostensible exercise of its right to title . . . occurred after Dr. Townsend's assignment"), *aff'd*, 542 F.3d 513 (6th Cir. 2008).

⁶ Stanford asserts that it "presented substantial evidence" that the patents-in-suit were conceived under federal grants. Pet. 12. Conspicuously absent is proof that Dr. Holodniy's work at Cetus and the information obtained from Cetus was subject to federal research grants. The district court held that the invention was "conceived" and the assay "completed" before Dr. Holodniy left Cetus (Pet. App. 56a); Stanford refused to provide any asserted date of conception (Pet. App. 58a n.7).

B. Stanford's Additional Objections Do Not Merit Review

In an effort to supplement its erroneous reading of the Bayh-Dole Act, Stanford raises three arguments that do not raise any substantial federal question and, at most, contend that the courts below made errors in factfinding or misapplied properly stated rules of law. Those arguments do not warrant review. *See* Supreme Court R. 10.

First, Stanford appears to quarrel with the court of appeals' interpretation of Dr. Holodniy's assignment agreement. Pet. 13-14 (arguing that the Federal Circuit should not have applied "its present assignment case law"). Stanford contends that Dr. Holodniy's Visitor Confidentiality Agreement should have been interpreted as conveying "an interest that was subject to his contract with Stanford." Pet. 14. But the court of appeals concluded that Dr. Holodniy's contract with Stanford was only an "agreement to assign" and, accordingly, had no effect on the present assignment to Cetus. Pet. App. 13a. Stanford's dissatisfaction with that interpretation is not a substantial issue of federal law. Rather, the Federal Circuit simply applied its established rulings regarding the effect of assignments of patent rights. *Id.* Indeed, Stanford offers no developed argument suggesting that the Federal Circuit's interpretation of the agreements was even incorrect. Pet. 13-14.

Second, Stanford objects to the fact that "a single inventor could alienate his rights for a fee, usurping the rights of co-inventors to share in any financial benefits from commercializing the intellectual property." Pet. 14. That principle flows not from the Federal Circuit's decision in this case, but from the patent law itself, which provides that a patent owner

may “make, use, offer to sell, or sell the patented invention . . . *without the consent of and without accounting to the other owners.*” 35 U.S.C. § 262 (emphasis added); *see also Talbot*, 104 F.2d at 968. This Court does not sit to revise Congress’s statutory enactments, even if Stanford believes them to be unwise.

Third, Stanford complains that it lacked “actual knowledge” of Dr. Holodniy’s agreement. Pet. 16. That is simply incorrect. Stanford does not dispute that Dr. Holodniy was acting as Stanford’s agent when he signed the VCA with Cetus. His work at Cetus “related directly to his infectious disease research” at Stanford, and indeed it was his supervisor at Stanford, Dr. Merigan, who “directed” Dr. Holodniy to spend nine months working at Cetus for that purpose. Pet. App. 16a-17a. Stanford’s complaint appears to be that it should not have been “presumed to know” of Dr. Holodniy’s assignment to Cetus. Pet. 16. But just as the opinion below did not invent 35 U.S.C. § 262, it also did not invent the doctrine that “a principal is charged with the knowledge of the agent acquired by the agent in the course of the principal’s business.” *Curtis, Collins & Holbrook Co. v. United States*, 262 U.S. 215, 222 (1923); *see also Santillan v. Roman Catholic Bishop of Fresno*, 163 Cal. App. 4th 4, 11 (2008) (“For this purpose, there is no difference between constructive and actual notice. The rule applies to employees, who are agents of their employers.”) (citation omitted); 3 Witkin, Summary of California Law, Agency § 150 (2005) (“[A] corporation may be charged with notice of matters known to its employees.”); Restatement (Third) of Agency § 5.04 cmt. b (2006) (“Ordinarily, an agent’s failure to disclose a material fact to a principal does not defeat imputation.”).

This Court is not the proper forum for Stanford's contention that it should be exempt from the common-law imputation of its agent's knowledge. Pet. 16. Stanford is free to approach the California Legislature with its view that "it would be far more efficient, and would better serve the public interest, to impose some or all of this burden on the for-profit company." Pet. 17. Suffice it to say, however, that Stanford has not shown that the court below erred in not requiring private research laboratories like Cetus to investigate and police the obligations of employees of a large university that has a sophisticated technology transfer office.

Stanford and its agents should be bound by the agreements that they sign. Stanford's claim that it was treated unfairly rings particularly hollow given that Stanford *itself* sought out the collaboration, that it never told Cetus that Stanford would try to take for itself the results of Dr. Holodniy's onsite work at Cetus and his unfettered access to Cetus expertise and equipment, and that it seeks not to protect its own unchallenged right to use the invention, but to prevent Cetus (and Roche) from doing the same.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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