

No. 091159 MAR 22 2010

OFFICE OF THE CLERK
In The
Supreme Court of the United States

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

v.

ROCHE MOLECULAR SYSTEMS, INC.,
ROCHE DIAGNOSTICS CORPORATION,
ROCHE DIAGNOSTICS OPERATIONS, INC.,
Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

RICARDO RODRIGUEZ
Counsel of Record
STEPHEN C. NEAL
LORI R.E. PLOEGER
MICHELLE S. RHYU
BENJAMIN G. DAMSTEDT
COOLEY GODWARD KRONISH LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, California 94306
(650) 843-5000
rr@cooley.com

March 22, 2010

Counsel for Petitioner

Blank Page



QUESTION PRESENTED

Whether a federal contractor university's statutory right under the Bayh-Dole Act, 35 U.S.C. §§ 200-212, in inventions arising from federally funded research can be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor's rights to a third party.

PARTIES TO THE PROCEEDING

Pursuant to Rule 14.1(b), the following list identifies all of the parties appearing here and before the United States Court of Appeals for the Federal Circuit:

The petitioner here and plaintiff/counterclaim defendant-appellant below is the Board of Trustees of the Leland Stanford Junior University.

The respondents here and defendants/counterclaimants-cross-appellants below are Roche Molecular Systems, Inc., Roche Diagnostics Corporation, and Roche Diagnostics Operations, Inc.

RULE 29.6 STATEMENT

The Board of Trustees of the Leland Stanford Junior University has no parent corporation and does not issue stock.

TABLE OF CONTENTS

QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING	ii
RULE 29.6 STATEMENT	iii
TABLE OF CONTENTS	iv
TABLE OF AUTHORITIES	viii
PETITION FOR A WRIT OF CERTIORARI	1
OPINIONS BELOW	1
STATEMENT OF JURISDICTION	1
STATUTORY PROVISIONS INVOLVED	2
INTRODUCTION	2
STATEMENT OF THE CASE	4
REASONS FOR GRANTING THE PETITION ...	8
I. The Bayh-Dole Act Provides a Framework for the Ownership of Inventions Made with Government Funding.	8
II. Under the Federal Circuit's Decision, an Individual Inventor Can Defeat a Research Institution's Right to Elect to Retain Title to a Federally Funded Invention, the Federal Government's	

	Rights Under the Bayh-Dole Act, and the Rights of Co-Inventors.	11
III.	The Federal Circuit’s Decision Will Cloud Title to Federally Funded Inventions and Impose Massive Costs on Research Institutions.	15
IV.	Universities Cannot “Contract Around” the Federal Circuit’s Decision.	17
V.	This Important Statutory Issue Should Be Addressed Now.	18
	CONCLUSION	21
	APPENDIX	
Appendix A:	Federal Circuit Decision (Sept. 30, 2009)	1a
Appendix B:	District Court Memorandum & Order re Cross-Motions for Summary Judgment (Apr. 16, 2007)	29a
Appendix C:	Federal Circuit Order re Rehearing (Dec. 22, 2009)	75a
Appendix D:	Federal Circuit Judgment (Dec. 29, 2009)	78a

Appendix E:	35 U.S.C. § 200. Policy and objective	80a
Appendix F:	35 U.S.C. § 201. Definitions	81a
Appendix G:	35 U.S.C. § 202. Disposition of rights	84a
Appendix H:	Declaration of Mark Holodniy, M.D.	92a
Appendix I:	Declaration of Luis R. Mejia	106a
Appendix J:	Supplemental Declaration of Luis R. Mejia	113a
Appendix K:	Copyright and Patent Agreement, Stanford University	118a
Appendix L:	Visitor's Confidentiality Agreement	122a
Appendix M:	Excerpts from Patent Number: US 5968730 . . .	125a
Appendix N:	Excerpts from Patent Number: US 6503705 B2 .	127a
Appendix O:	Certificate of Correction for Patent Number: US 6503705 B2	129a

Appendix P: Excerpts from Patent
Number: US 7129041 B2 . 131a

Appendix Q: Supplemental Declaration
of Michelle S. Rhyu 133a

TABLE OF AUTHORITIES

Cases

<i>Fenn v. Yale Univ.</i> , 184 F. App'x 21, 2006 WL 1408336 (2d Cir. 2006)	20
<i>Univ. of Pittsburgh v. Townsend</i> , 542 F.3d 513 (6th Cir. 2008)	20

Statutes

28 U.S.C. § 1254(1)	1
28 U.S.C. § 1295	19
35 U.S.C. §§ 200-212	3, 6, 8
35 U.S.C. § 200	8
35 U.S.C. § 201(e)	2, 12
35 U.S.C. § 202(a)	2, 7, 9, 12
35 U.S.C. § 202(c)(1)	2, 11
35 U.S.C. § 202(c)(7)(A)	9, 13
35 U.S.C. § 202(c)(7)(C)	10
35 U.S.C. § 202(d)	2, 7, 13
35 U.S.C. § 204	9

Other Authorities

Birch Bayh, Joseph P. Allen, & Howard W. Bremer, <i>Universities, Inventors and Bayh-Dole</i> , 79 Pat., Trademark & Copyright J. (PTCJ) 167 (2009)	19
--	----

PETITION FOR A WRIT OF CERTIORARI

The Board of Trustees of the Leland Stanford Junior University (“Stanford”) respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit (App. 1a-28a) is reported at *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, 583 F.3d 832 (Fed. Cir. 2009). The Order of the U.S. Court of Appeals for Federal Circuit denying Stanford’s Petition for Panel Rehearing and Rehearing En Banc is not reported. App. 75a-77a.

The opinion of the United States District Court for the Northern District of California is reported at 487 F. Supp. 2d 1099 (N.D. Cal. 2007). App. 29-74a.

STATEMENT OF JURISDICTION

The Federal Circuit entered judgment on September 30, 2009. App. 78a-79a. The Federal Circuit denied Stanford’s Petition for Panel Rehearing and Rehearing En Banc on December 22, 2009. App. 75a-77a. This Court’s jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

“Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention.” 35 U.S.C. § 202(a).

“[T]he contractor [must] disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and [] the Federal Government may receive title to any subject invention not disclosed to it within such time.” 35 U.S.C. § 202(c)(1).

“If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.” 35 U.S.C. § 202(d).

“The term ‘subject invention’ means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.” 35 U.S.C. § 201(e).

INTRODUCTION

The impact of the Federal Circuit’s decision is without question: it immediately triggered a wave of discussion, commentary, and grave concern among the universities and other non-profits that have adhered to

the provisions of the Bayh-Dole Act, 35 U.S.C. §§ 200-212. At stake is the ownership of countless inventions made over the 30 years since the enactment of Bayh-Dole, as well as the expensive and onerous tasks that universities must now undertake in an attempt to manage the practical implications of the decision.

The Bayh-Dole Act establishes a comprehensive statutory scheme to allocate rights in “subject inventions” that arise from federally funded research. Prior to Bayh-Dole, the federal government generally held the rights to such inventions, which often went undeveloped. The Act establishes a framework under which “contractors,” such as universities and other non-profit institutions that receive federal funding for research, retain the rights to subject inventions and must exercise those rights in ways that protect the government’s and public’s interests. The Act also limits the patent rights for individual inventors involved in the contractors’ research, who may exercise rights in subject inventions only if the institution fails to exercise its statutory rights and, even then, only if the federal government consents following consultation with the institution.

Until the Federal Circuit’s decision, universities believed they could retain ownership of inventions they sponsored through federal grants by following the procedures set forth in Bayh-Dole. The Federal Circuit’s decision, however, allows for-profit companies to obtain shared ownership of these inventions simply by entering into a side-agreement with an inventor. Under the decision, a for-profit company does not need to follow any of the Bayh-Dole procedures to obtain this ownership, nor is it subject to any of the Bayh-

Dole restrictions, such as the use of royalties for further scientific research or education.

In arriving at its decision, the Federal Circuit ignored the clear mandate of the Bayh-Dole Act, choosing instead to rely on its own recent case law regarding the particular language that effects a “present assignment” of an invention. The Federal Circuit extended this case law to give a for-profit company a free and clear ownership interest in an invention made under the Bayh-Dole Act, even when it is aware of both the Bayh-Dole Act and the inventor’s association with a research university. The Federal Circuit decision places the burden of monitoring for such activity, and dealing with the aftermath of violations, solely with the university. The impossible, impractical, and unfair one-sided burdens imposed on universities by the Federal Circuit’s decision create an issue of enormous importance that should be addressed—and corrected—by this Court.

STATEMENT OF THE CASE

The Court of Appeals held that Stanford lacked standing to pursue its patent infringement claims against the Roche defendants based on the Roche defendants’ assertion of ownership rights in the patents-in-suit. App. 27a-28a.

Patents-in-Suit and Ownership Issues

The patents-in-suit relate to methods for evaluating the effectiveness of anti-HIV therapies. App. 125a-126a; 127a-128a; 131a-132a. Stanford researchers, including Dr. Mark Holodniy, developed these methods in the early 1990s. App. 102a-105a. Dr. Holodniy is one

of three Stanford researchers named as inventors on the three patents-in-suit. App. 125a; 127a; 129a. Stanford is the named assignee of all three patents. App. 125a; 127a; 129a.

The National Institutes of Health provided funding for the Stanford research project out of which the patents arose. App. 109a, ¶ 8; 114a-115a, ¶ 3. This clinical research was performed under at least two federal grants: one providing funding for AIDS-related clinical trials and another establishing Stanford as a Center for AIDS Research. *Id.*

Dr. Holodniy joined Stanford as a Research Fellow in the Department of Infectious Disease in 1988. App. 94a. Dr. Holodniy signed Stanford's standard Copyright and Patent Agreement (the "Stanford Agreement") when he began his work at Stanford in mid-1988. *See* App. 118a-121a. In the Stanford Agreement, Dr. Holodniy "agree[d] to assign" his inventions to Stanford. App. 119a, ¶ 2. Additionally, the Stanford Agreement prohibited Dr. Holodniy from creating "patent obligations in conflict with this agreement." App. 120a.

In 1989, Dr. Holodniy entered into a "Visitor's Confidentiality Agreement" ("VCA") with Cetus, a local biotechnology company. App. 122a-124a. Under the VCA, Dr. Holodniy agreed that he "will assign and do[es] hereby assign" his rights to Cetus to inventions conceived and/or reduced to practice as a consequence of his access to Cetus's information and facilities. App. 123a, ¶ 3. Cetus later transferred its interest in the VCA to Roche. *See* App. 5a.

After Dr. Holodniy ceased visiting Cetus, the Stanford inventors conceived and reduced to practice the clinical inventions of the patents-in-suit. *See* App. 102a-105a.

Stanford's inventions were "subject inventions" under the Bayh-Dole Act of 1980, because they were conceived or reduced to practice using federal funding. The Act generally provides that a university (as a nonprofit organization) may elect to retain title to any inventions that arise out of federally funded research projects.

On April 6, 1995, Stanford gave formal notice to the federal government that it intended to elect to retain title to the patents-in-suit under the Bayh-Dole Act, 35 U.S.C. §§ 200-212. *See* App. 115a-116a.

Decisions Below

The district court upheld Stanford's standing to bring patent infringement claims against Roche, based on (1) the agreement between Dr. Holodniy and Stanford, under which he agreed to assign his invention rights to Stanford and agreed not to enter into inconsistent agreements, (2) the Bayh-Dole Act, which gave Stanford ownership of the patents because they resulted from federally funded research, and (3) Stanford's recordation of its title at the U.S. Patent Office and the National Institutes of Health. App. 59a-62a.

The Federal Circuit reversed the district court's judgment as to the standing issue. App. 78a. The Court held that because of the VCA between Dr. Holodniy and Cetus, Roche had an ownership interest in the

patents that defeated Stanford's standing to sue Roche for infringement. App. 27a-28a.

The Court rejected Stanford's statutory argument based on the Bayh-Dole Act. App. 18a-21a. As provided by the Bayh-Dole Act, a university may "elect to retain title to any subject invention." 35 U.S.C. § 202(a), reproduced at App. 84a. If the university "does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor." 35 U.S.C. § 202(d). Relying on these provisions, Stanford argued that the Bayh-Dole Act limited Dr. Holodniy to a contingent right that would vest only if Stanford did not elect to retain title within a reasonable period of time. App. 18a-19a. As a result, even assuming that Dr. Holodniy transferred his contingent right to Cetus, that right was extinguished upon Stanford's election to retain title.

Roche never argued, and the Court did not find, that Stanford's statutory election to retain title was deficient in any way under the Act. Instead, the Court of Appeals' decision turned solely on a formalistic distinction between present and future assignments. The Court concluded that the language in the Stanford Agreement in which Dr. Holodniy "agree[d] to assign" his invention rights to Stanford constituted only a promise to assign those rights in the future. App. 13a. The Court further concluded that the later-in-time VCA included present "do[es] hereby assign" language that conveyed an ownership interest to Cetus immediately upon conception of the inventions. App. 14a.

Based on those conclusions and despite the Bayh-Dole Act, the Court awarded Roche title to Dr. Holodniy's ownership interests, holding that the "present" assignment language in the VCA trumped the "future" assignment language in the Stanford Agreement. App. 13a-14a.

REASONS FOR GRANTING THE PETITION

I. The Bayh-Dole Act Provides a Framework for the Ownership of Inventions Made with Government Funding.

Before the Bayh-Dole Act, ownership of federally funded inventions originally vested in the federal government. A patchwork of federal agencies made decisions about subsequent assignments and other ownership issues. Through the Bayh-Dole Act, Congress intended to end this uncertainty regarding title to federally funded inventions and thereby spur commercialization of federally funded inventions to the benefit of the American public.

Congress enacted the Bayh-Dole Act ("the Act"), *inter alia*, "to promote the utilization of inventions arising from federally sponsored research or development," "to promote the commercialization and public availability of inventions made in the United States by United States industry and labor," and "to promote collaboration between commercial concerns and nonprofit organizations, including universities." 35 U.S.C. § 200. Congress attempted to accomplish these goals by vesting ownership of "subject inventions" in "small business firms" and "nonprofit organizations," including universities such as Stanford, rather than the federal government. 35 U.S.C. §§ 200-212. "Subject

inventions” are defined to be inventions conceived or first reduced to practice in the performance of work under a federal funding agreement.

Under the Act, nonprofit organizations like Stanford have the right to “elect to retain title to any subject invention” except in limited circumstances not at issue in this case in which the federal government or individual inventors may retain title. 35 U.S.C. § 202(a).

The provisions of the Act do not allow unrestricted assignment of subject inventions by nonprofit organizations or individual inventors to commercial entities. Instead, the Act places careful restrictions on assignments, licenses, and use of royalties related to any subject inventions. For example, section 202(c)(7)(A) specifically requires all funding agreements to contain “*a prohibition* upon the assignment of rights to a subject invention in the United States without the approval of the federal agency.” 35 U.S.C. § 202(c)(7)(A) (emphasis added). Similarly, section 204 restricts a nonprofit organization from “grant[ing] to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured in the United States” unless a waiver is obtained. 35 U.S.C. § 204. As to royalties, the Bayh-Dole Act requires that the “balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the

support of scientific research or development.” 35 U.S.C. § 202(c)(7)(C).

Congress sought to achieve these ends by setting up an ownership structure in which title to federally funded inventions vests with the university so long as it makes an ownership election within a reasonable period of time after the invention is made. In return, those institutions agree to use their best efforts to commercialize those inventions for public benefit. By creating certainty as to the title of federally funded inventions, the Act encouraged collaboration between private companies and universities and other non-profit research institutions in a manner that would benefit the public.

Under the Federal Circuit’s decision, private, for-profit companies can obtain the benefits of federal research funding to create inventions, while avoiding the obligation to use royalties to benefit education and research and sidestepping the other conditions of federal funding under the Act. The Federal Circuit’s decision will also permit for-profit commercial entities to acquire invention rights for the purpose of “shelving” the technology to deprive their competitors of the use of the technology, contrary to the intent of the Bayh-Dole Act to foster commercialization of federally funded inventions.

The federal government has spent billions of dollars on federally funded research projects subject to the Bayh-Dole Act. Universities and other research institutions, through the commercialization of federally funded inventions intended by the Bayh-Dole Act, fund their further research and development

efforts through patent royalties, as contemplated by the Act.

II. Under the Federal Circuit's Decision, an Individual Inventor Can Defeat a Research Institution's Right to Elect to Retain Title to a Federally Funded Invention, the Federal Government's Rights Under the Bayh-Dole Act, and the Rights of Co-Inventors.

The Federal Circuit's decision radically upends the Bayh-Dole Act, a carefully balanced federal law intended to foster commercialization of federally funded inventions to the benefit of the American public. Under the decision, an individual inventor may prospectively assign to a for-profit, commercial entity the invention rights to a federally funded invention yet to be conceived, thereby circumventing the statutory rights of the nonprofit organization that received the federal funding. This result contravenes the plain language and structure of the Bayh-Dole Act, which contemplates that a nonprofit organization (such as a research institution or university) that receives federal research funds will have the right to elect ownership to resulting inventions except in cases where it fails to disclose the invention, or fails to file a timely patent application. If the nonprofit does not satisfy these requirements, then the federal government may receive title. 35 U.S.C. § 202(c)(1). The Bayh-Dole Act makes no provision for third-party commercial entities to take title if the nonprofit fails to take steps to retain or secure title.

The Federal Circuit's conclusion that Dr. Holodniy effectively assigned his rights to the patents-in-suit to Cetus necessarily and erroneously takes as its starting

point that Dr. Holodniy had a right to make an assignment that could extinguish Stanford's interests in the inventions. Under the Bayh-Dole Act, however, Stanford had a statutory right to make an ownership election within a reasonable period of time that could not be overridden by the inventor's agreement. The university's statutory right to title arises from the language and structure of the Bayh-Dole Act. Section 202(a) of the Bayh-Dole Act provides: "Each nonprofit organization . . . may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section . . . elect to retain title to any subject invention." 35 U.S.C. § 202(a). An inventor may not defeat the research institution's Section 202(a) right to elect retain title through a side agreement with a for-profit third party.

Further, the Act defines inventions that are subject to its provisions broadly. A subject invention under the Bayh-Dole Act is defined as one that is "*conceived or first actually reduced to practice* in the performance of work under a [federal] funding agreement." 35 U.S.C. § 201(e) (emphasis added). The Act thus expressly encompasses inventions that were either conceived or reduced to practice using government funding. This is significant because it contemplates that some inventions may have been conceived earlier without using government funding, but they are still subject to the Act if they were later reduced to practice for the first time using government funding. The Act does not exclude inventions from its coverage merely because some inventive work was accomplished without government funding. Here, Stanford presented substantial evidence showing that the patents in suit were *both* conceived and reduced to practice under federal grants.

The Act carefully restricts the circumstances in which an individual inventor may acquire an ownership interest in a federally funded invention. The inventor's ownership rights vest only if the research institution chooses not to exercise its statutory right to retain title *and* the federal government consents after consultation with the research institution. *See* 35 U.S.C. § 202(d). Section 202(c)(7)(A) also requires all funding agreements to contain "a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency." 35 U.S.C. § 202(c)(7)(A). The Stanford Agreement signed by Dr. Holodniy, before the execution of the VCA, contained just such a provision. App. 120a, ¶ 6.

Against this clear statutory backdrop, the Federal Circuit held that Dr. Holodniy's side agreement with Cetus gave Roche ownership rights in the patents-in-suit that defeated Stanford's infringement claims. Although Stanford had a prior agreement with Dr. Holodniy under which he "agreed to assign" his invention rights to Stanford, the Court held that this agreement did not effect a present assignment, but rather constituted a promise to assign those rights in the future. App. 13a. The Court concluded that Dr. Holodniy had, and effectively transferred to Cetus, patent ownership rights in the federally funded inventions. App. 14a. The Court deemed Stanford's later election to retain title under the Bayh-Dole Act to be subject to Dr. Holodniy's earlier private assignment agreement with Cetus. App. 19a-20a.

The Federal Circuit provided no reason why its present assignment case law should properly be extended to provide *clear* title even when it is subject

to an *earlier* promise to assign. There is no reason it should be applied such a manner. As a result of his earlier agreement with Stanford, the most that Dr. Holodniy could later assign—whether using the “present assignment” language or not—was an interest that was subject to his contract with Stanford. As that contract retained ownership for government funded inventions, Dr. Holodniy could not convey any ownership interest in the inventions of the patents-in-suit. *See App. 119a.*

Nor did the Federal Circuit’s decision explain why a present assignment could trump the Bayh Dole Act’s restrictions on how an inventor could claim title. Here, as explained above, the Bayh-Dole Act allowed Dr. Holodniy to obtain title only if Stanford declined to retain title. Nonetheless, the Federal Circuit’s decision held that the present assignment to Cetus can wholly evade this statutory framework and give to Cetus title through Dr. Holodniy even though Dr. Holodniy was precluded from obtaining that title for himself. *App. 13a-14a; 19a-20a.*

Additionally, when patents have multiple inventors, the Federal Circuit’s decision permits a single inventor to undermine the intellectual property rights of his or her co-inventors. It is very common that patents filed by research institutions result from the collaboration of multiple contributors, who may be named as co-inventors. This was the case with Dr. Holodniy. He was one of the three named inventors on the patents in question. *App. 125a; 127a; 129a; 131a.* Under the Federal Circuit’s decision, 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. The effect of

the Federal Circuit's decision is exacerbated when the contributing co-inventors are employed by separate research institutions. These inequities are expressly avoided by the Bayh-Dole Act, but are inevitable consequences of the Federal Circuit's decision.

If the Federal Circuit's decision is allowed to stand, the rights of contracting institutions, like Stanford, can be unilaterally terminated by the inventor. Further, applying the same reasoning, the federal government's rights under the statute in the invention would also be terminated unilaterally by the inventor if she or he assigns the rights to a third party. To the contrary, the Bayh-Dole Act plainly contemplates that inventors like Dr. Holodniy have rights only if the government consents (after consultation with the contractor). Thus, the Federal Circuit's holding means that the federal government has no rights unless the inventor consents. The Federal Circuit's decision stands the Bayh-Dole Act on its head. All of the statutory protections to the government and public under the statutory scheme, including the government's nonexclusive license, the made-in-America restrictions, the requirement to exploit the invention, and the requirement to invest royalties back into research would be eliminated.

III. The Federal Circuit's Decision Will Cloud Title to Federally Funded Inventions and Impose Massive Costs on Research Institutions.

The Federal Circuit's decision also eviscerates the certainty regarding title to federally funded inventions intended by Congress. It may no longer be safe for universities (or their commercial counterparts and

partners) to assume that the research institution will have the right to elect to retain title to federally funded inventions. Any individual inventor's side agreement could cloud the title for subject inventions made over the last 30 years.

Under the Federal Circuit's decision, before a research institution engages in the very technology transfer activities intended by the Act, it may be required to embark on wide-ranging investigations to ensure that no individual inventor on the project has purposefully or inadvertently entered into a side agreement that gives rights in the invention to a third party.

The need for this burdensome investigation is exacerbated by the Federal Circuit's holding that Stanford would be presumed to know of Dr. Holodniy's side agreement with Cetus under the legal fiction of "constructive or inquiry notice." App. 16a. There is no dispute that Stanford did not have actual knowledge of the agreement.

Requiring a research institution or university to police every agreement into which its researchers may enter would consume substantial resources and yet provide no assurances. Even with substantial investigation, a university may be unable to ascertain what rights have been transferred to third parties because university researchers have been entering into "side agreements" for decades, often without appreciating the import of those agreements. Individual researchers may well not have retained their side agreements or even remember that they have entered into such agreements.

The Federal Circuit's decision does not mention, much less consider, whether it was appropriate to require the university, rather than the for-profit company, to carry or share this enormous burden. Under the facts in the case, Cetus knew of Dr. Holodniy's association with Stanford when it entered into the consulting agreement. App. 122a-124a. Cetus was also aware of the Bayh-Dole Act. App. 136a-137a. Despite Cetus's actual knowledge, the Federal Circuit nonetheless chose to shift the burden to Stanford based on a "constructive knowledge" conclusion. Contrary to the Federal Circuit's decision, 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, particularly when it has actual knowledge that Bayh-Dole may be implicated.

The monumental one-sided burdens imposed by the Federal Circuit's decision significantly undermine the central goals of the Bayh-Dole Act, including commercialization of federally funded inventions for the benefit of the public.

IV. Universities Cannot "Contract Around" the Federal Circuit's Decision.

In response to the Federal Circuit's decision, universities may choose to revise their contracts with researchers and inventors to excise the use of the phrase "agrees to assign" language and instead use the word "assigns" or the phrase "hereby does assign."

In practice, however, this is no solution. For decades, universities like Stanford—including the University of California, Massachusetts Institute of Technology, the University of Wisconsin, and Yale

University—have included “agree to assign” language like that in the Stanford Agreement in their own contracts and policies. Indeed, in the nearly 30 years since Bayh-Dole’s passage, universities have entered into innumerable agreements with individual inventors using “agree to assign” language. Under the Federal Circuit’s decision, the title to decades of federally funded inventions may be thrown into doubt for decades to come.

Further, such an approach is, at best, only a partial solution and remains fraught with uncertainty. Using “present” assignment language may be ineffective under the Federal Circuit’s decision if the contractor has executed a contract like Dr. Holodniy’s VCA before signing the University’s contract. In such situations, far-reaching language in such a side agreement could be used by for-profit companies to argue they have rights to inventions that are subsequently made with federal funding. Moreover, title could also be unclear if the university and a third party held competing present assignments at the time of invention. This cloud on universities’ ownership of patent or other intellectual property rights will make it more difficult to license and commercialize intellectual property. Consequently, the intellectual property will be less widely disseminated and used. This uncertainty caused by the Federal Circuit’s decision undermines the Bayh-Dole Act.

V. This Important Statutory Issue Should Be Addressed Now.

There is an extraordinary public interest in a clear and immediate resolution of the question presented by Stanford’s petition. Although the Federal Circuit’s

decision addresses an issue of first impression, this is not a matter that should be permitted to “percolate” over time through the lower courts. The important federal interests promoted by the Bayh-Dole Act—including billions of dollars invested by the government annually into research—are presently and substantially compromised by the Federal Circuit’s decision. Likewise, universities and other research institutions face immediate and substantial administrative and financial burdens if the Federal Circuit’s decision is not addressed by this Court. Indeed, several universities joined with Stanford in asking the Federal Circuit to address the issue en banc. The Federal Circuit’s decision has triggered a flurry of commentary and concern, including commentary from one of the authors of the Bayh-Dole statute, Senator Bayh.¹

This Court should not wait for a circuit split before addressing this issue. Although the Federal Circuit does not have exclusive jurisdiction of ownership disputes under the Bayh-Dole Act, such disputes are most likely to arise in patent infringement cases, which are subject to the exclusive jurisdiction of the Federal Circuit under 28 U.S.C. § 1295. The Federal Circuit declined to rehear the case en banc and thus a different conclusion is not likely to be forthcoming from the Federal Circuit. Other Circuits have decided only a very small handful of cases even tangentially

¹ Birch Bayh, Joseph P. Allen, & Howard W. Bremer, *Universities, Inventors and Bayh-Dole*, 79 Pat., Trademark & Copyright J. (PTCJ) 167 (2009).

involving the Bayh-Dole Act,² and there is no way to predict how, when, and whether another Circuit may reach the statutory ownership issues raised squarely in this case.

The Federal Circuit's decision implicates substantial federal interests for the additional reason that the Federal Circuit's reasoning would also permit an individual inventor to terminate the *government's* rights with regard to the federally funded invention. Moreover, permitting unilateral assignment by an individual inventor to circumvent the statutory scheme deprives the government and the public of the benefits intended under the Act, including requirements that the invention be made in the United States and that royalties be invested back into research.

Immediate review is necessary to resolve this important federal question.

² See, e.g., *Univ. of Pittsburgh v. Townsend*, 542 F.3d 513 (6th Cir. 2008); *Fenn v. Yale Univ.*, 184 F. App'x 21, 2006 WL 1408336 (2d Cir. 2006).

CONCLUSION

For these reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

RICARDO RODRIGUEZ

Counsel of Record

STEPHEN C. NEAL

LORI R.E. PLOEGER

MICHELLE S. RHYU

BENJAMIN G. DAMSTEDT

COOLEY GODWARD KRONISH LLP

Five Palo Alto Square,

3000 El Camino Real

Palo Alto, California 94306

(650) 843-5000

rr@cooley.com

Counsel for Petitioners

March 22, 2010

Blank Page

