

No. 09-1159

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IN THE  
**Supreme Court of the United States**

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BOARD OF TRUSTEES OF THE LELAND STANFORD  
JUNIOR UNIVERSITY,

*Petitioner,*

*v.*

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

*Respondents.*

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

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**BRIEF FOR RESPONDENTS**

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## QUESTION PRESENTED

The Bayh-Dole Act limits the government's intellectual property rights by providing that federal contractors may "elect to retain title" to 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), 202(a).

In this case, a researcher obtained access to a private company's resources and expertise in exchange for a written assignment of his interest in any resulting invention. An invention was conceived while the researcher was at the company using its proprietary materials and know-how, thus triggering the assignment provision. Clinical trials involving the already-conceived invention later took place at Stanford University and, according to Stanford, proceeded under a funding agreement between Stanford and the National Institutes of Health.

The question presented is:

Whether the Bayh-Dole Act's provision allowing a federal contractor to "elect to retain title" to an "invention of the contractor" allows the contractor retroactively to take intellectual property rights that have been validly assigned to a third party that neither accepted nor benefitted from 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 Holdings, Inc.

## TABLE OF CONTENTS

	Page
QUESTION PRESENTED .....	i
CORPORATE DISCLOSURE STATEMENT.....	ii
TABLE OF AUTHORITIES .....	vi
INTRODUCTION .....	1
STATEMENT .....	3
A. Cetus’s Groundbreaking Discovery Of PCR And Its Application To Measur- ing HIV.....	3
B. Stanford Sends Holodniy To Cetus To Develop A PCR Assay For HIV .....	3
C. The Claimed Inventions Are Conceived At Cetus In 1989 Without Use Of Bayh-Dole Funding.....	5
D. Holodniy And Cetus Scientists Publish The Assay.....	7
E. Stanford Conducts Clinical Trials In 1990 And Applies For Patents .....	8
F. Roche Commercializes The Assay.....	10
G. District Court Proceedings.....	11
H. Court Of Appeals Proceedings.....	14
SUMMARY OF ARGUMENT.....	15
ARGUMENT.....	18
I. THE BAYH-DOLE ACT DOES NOT “VEST TITLE” .....	18
A. The Text Addresses Only Inventions That The Contractor Otherwise Owns .....	18

**TABLE OF CONTENTS—Continued**

	Page
1. “Invention of the contractor” .....	18
2. “Retain” .....	22
3. The absence of “vesting” language .....	23
<b>B. Other Provisions In The Act And Related Regulations Confirm Its Limited Application .....</b>	<b>26</b>
1. The Act’s implementation through contract confirms its application to contractors, not third parties .....	26
2. The Act’s procedural protections, which follow its substantive scope, apply only to contractors .....	28
3. Federal regulations and university policies demonstrate that title initially vests in the inventor .....	31
4. Stanford’s efforts to read the Act as a vesting statute fail .....	36
<b>C. Legislative History Does Not Help Stanford .....</b>	<b>39</b>
<b>D. Stanford’s Position Raises Serious Constitutional Questions The Court Should Avoid .....</b>	<b>43</b>
<b>E. Stanford’s Policy Arguments Miss The Mark .....</b>	<b>46</b>

**TABLE OF CONTENTS—Continued**

	Page
1. Inventions, both federally-funded and not, are successfully commercialized without divesting third parties of their intellectual property.....	47
2. Stanford’s reading would chill innovative collaboration and commercialization of inventions.....	50
3. The government’s rights are protected .....	52
II. STANFORD’S OTHER ARGUMENTS ARE NOT PROPERLY BEFORE THE COURT AND LACK MERIT.....	55
CONCLUSION .....	57

**TABLE OF AUTHORITIES**

**CASES**

	Page(s)
<i>Armstrong v. United States</i> , 364 U.S. 40 (1960) .....	27
<i>Barnhart v. Sigmon Coal Co.</i> , 534 U.S. 438 (2002) .....	37
<i>Biogen, Inc. v. Berlex Laboratories, Inc.</i> , 318 F.3d 1132 (Fed. Cir. 2003) .....	35
<i>Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.</i> , 563 F. Supp. 2d 1016 (N.D. Cal. 2008) .....	9, 14
<i>Calder v. Bull</i> , 3 U.S. (3 Dall.) 386 (1798) .....	44
<i>Campbell Plastics Engineering &amp; Manufactur- ing, Inc. v. Brownlee</i> , 389 F.3d 1243 (Fed. Cir. 2004).....	27, 28
<i>Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.</i> , 482 F.3d 1347 (Fed. Cir. 2007) .....	28
<i>Clark v. Martinez</i> , 543 U.S. 371 (2005) .....	43
<i>Connecticut National Bank v. Germain</i> , 503 U.S. 249 (1992) .....	38
<i>Curtis, Collins &amp; Holbrook Co. v. United States</i> , 262 U.S. 215 (1923) .....	49
<i>Dalzell v. Dueber Watch-Case Manufacturing Co.</i> , 149 U.S. 315 (1893) .....	19
<i>Diamond v. Chakrabarty</i> , 447 U.S. 303 (1980) .....	22
<i>Duncan v. Walker</i> , 533 U.S. 167 (2001).....	18, 21
<i>Eastern Enterprises v. Apfel</i> , 524 U.S. 498 (1998) .....	44

## TABLE OF AUTHORITIES—Continued

	Page(s)
<i>Ellis v. United States</i> , 206 U.S. 246 (1907) .....	18
<i>Fenn v. Yale University</i> , 393 F. Supp. 2d 133 (D. Conn. 2004).....	38, 48
<i>Fenn v. Yale University</i> , No. 396-CV-990, 2005 WL 327138 (D. Conn. Feb. 8, 2005).....	50
<i>FilmTec Corp. v. Allied-Signal Inc.</i> , 939 F.2d 1568 (Fed. Cir. 1991) .....	19, 32
<i>Hall St. Associates v. Mattel, Inc.</i> , 552 U.S. 576 (2008) .....	25
<i>Hapgood v. Hewitt</i> , 119 U.S. 226 (1886) .....	19, 20, 56
<i>Hughey v. United States</i> , 495 U.S. 411 (1990) .....	25
<i>Jacobs v. New York Foundling Hospital</i> , 577 F.3d 93 (2d Cir. 2009) .....	18
<i>Mead Corp. v. United States</i> , 652 F.2d 1050 (D.C. Cir. 1981) (per curiam) .....	28
<i>Mead Corp. v. United States</i> , 490 F. Supp. 405 (D.D.C. 1980) .....	32
<i>National Cable &amp; Telecommunications Ass'n</i> <i>v. Gulf Power Co.</i> , 534 U.S. 327 (2002) .....	18
<i>Perrin v. United States</i> , 444 U.S. 37 (1979) .....	22
<i>Pilley v. United States</i> , 74 Fed. Cl. 489 (2006).....	28
<i>Poe v. Seaborn</i> , 282 U.S. 101 (1930) .....	18
<i>Regan v. Wald</i> , 468 U.S. 222 (1984) .....	42
<i>Reiter v. Sonotone Corp.</i> , 442 U.S. 330 (1979).....	21
<i>Riegel v. Medtronic, Inc.</i> , 552 U.S. 312 (2008).....	55



## TABLE OF AUTHORITIES—Continued

	Page(s)
<i>Ruckelshaus v. Monsanto Co.</i> , 467 U.S. 986 (1984).....	20
<i>S.G. Borello &amp; Sons, Inc. v. Department of Industrial Relations</i> , 769 P.2d 399 (Cal. 1989) .....	51
<i>Samantar v. Yousuf</i> , 130 S. Ct. 2278 (2010) .....	20
<i>Solomons v. United States</i> , 137 U.S. 342 (1890) .....	44
<i>St. John’s University v. Bolton</i> , No. 08-CV- 5039, 2010 WL 5093347 (E.D.N.Y. Dec. 10, 2010) .....	50
<i>Standard Parts Co. v. Peck</i> , 264 U.S. 52 (1924) .....	19, 55
<i>Teets v. Chromalloy Gas Turbine Corp.</i> , 83 F.3d 403 (Fed. Cir. 1996) .....	20
<i>United States v. Dubilier Condenser Corp.</i> , 289 U.S. 178 (1933) .....	19, 20, 32
<i>University of Pittsburgh v. Townsend</i> , No. 04- CV-2912007, WL 2263079 (E.D. Tenn. Aug. 3, 2007), <i>aff’d</i> , 542 F.3d 513 (6th Cir. 2008) .....	52

## TABLE OF AUTHORITIES—Continued

	Page(s)
<b>STATUTES AND REGULATIONS</b>	
35 U.S.C.	
§ 101.....	1, 19, 24, 26, 33
§ 102.....	20, 26, 54
§ 115.....	24
§ 116.....	24, 26
§ 152.....	24
§ 201.....	2, 13, 18, 19, 45
§ 202.....	<i>passim</i>
§ 203.....	28, 37
§ 204.....	37, 38
§ 206.....	26
§ 210.....	24, 25
§ 212.....	7, 20, 29
§ 261.....	1, 19, 49
§ 262.....	54
42 U.S.C.	
§ 2182.....	23, 24
§ 2457.....	23, 24
§ 5908.....	23, 24
32 C.F.R. § 9-107.1 (1961).....	32
37 C.F.R.	
§ 3.73.....	19
§ 401.1.....	29, 30, 31
§ 401.4.....	29
§ 401.6.....	29
§ 401.10.....	33
§ 401.11.....	29
§ 401.12.....	29
§ 401.14.....	27, 42, 53, 54
§ 501.6.....	32

**TABLE OF AUTHORITIES—Continued**

	Page(s)
<b>LEGISLATIVE MATERIALS</b>	
H.R. Rep. No. 96-1307 (1980).....	40
S. Rep. No. 96-480 (1979).....	24, 39, 40, 41, 51
<i>Government Patent Policy Act of 1980: Hearing on H.R. 5715 Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong., 2d Sess. (1980).....</i>	42
126 Cong. Rec. 1796 (1980) (statement of Sen. Bayh) .....	40
126 Cong. Rec. 1799 (1980) (statement of Sen. Kennedy) .....	40
126 Cong. Rec. 1992 (1980) (statement of Sen. Dole) .....	40
126 Cong. Rec. 8739 (1980) (statement of Sen. Long) .....	40
126 Cong. Rec. 29,895 (1980) (statement of Rep. Kastenmeier).....	40
126 Cong. Rec. 30,364 (1980) (statement of Sen. Bayh) .....	40
126 Cong. Rec. 30,365-30,366 (1980) (statement of Sen. Dole) .....	40
<b>OTHER AUTHORITIES</b>	
Air Force Form 1279.....	32
Air Force Instruction 51-303 (Sept. 1, 1998), available at <a href="http://www.af.mil/shared/media/epubs/AFI51-303.pdf">http://www.af.mil/shared/media/epubs/AFI51-303.pdf</a> .....	32

**TABLE OF AUTHORITIES—Continued**

	Page(s)
<i>American Heritage Dictionary</i> (1969) .....	22, 23
California Institute of Technology Patent & Copyright Agreement (Dec. 30, 2003), <i>available at</i> <a href="https://www.ogc.caltech.edu/Forms/documents/patentagreement">https://www.ogc.caltech.edu/ Forms/documents/patentagreement</a> .....	48
Federal Council for Science and Technology, <i>Report on Government Patent Policy</i> (1976) .....	42
Iowa State University Intellectual Property Handbook, <i>available at</i> <a href="http://www.techtransfer.iastate.edu/documents/filelibrary/images/pdf/IP_Handbook_081104162623.pdf">http://www.tech transfer.iastate.edu/documents/filelibrary/ images/pdf/IP_Handbook_081104162623.pdf</a> (last visited Jan. 24, 2011) .....	34
MIT Patent Policy (Apr. 14, 2010), <i>available at</i> <a href="http://web.mit.edu/tlo/www/downloads/doc/IPIA.doc">http://web.mit.edu/tlo/www/downloads/doc/ IPIA.doc</a> .....	48
National Science Board, Science and Engineer- ing Indicators 2010 (2010) .....	47
<i>New American Roget's College Thesaurus</i> (1978) .....	23
NIH Grants Policy Statement, <i>available at</i> <a href="http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch8.htm#_Toc271264954">http://grants.nih.gov/grants/policy/nihgps_ 2010/nihgps_ch8.htm#_Toc271264954</a> .....	53
<i>Oxford English Dictionary</i> (1933) .....	22
Stanford Research Policy Handbook (July 15, 1999), <i>available at</i> <a href="http://rph.stanford.edu/5-1.html">http://rph.stanford.edu/ 5-1.html</a> .....	34, 39

## TABLE OF AUTHORITIES—Continued

	Page(s)
2A <i>Sutherland Statutory Construction</i> (7th ed. 2007) .....	25
University of Wisconsin Financial Administration Patent Policy (1985), <i>available at</i> <a href="http://www.uwsa.edu/fadmin/gapp/gapp34.htm">http://www.uwsa.edu/fadmin/gapp/gapp34.htm</a> .....	34
<i>Webster's New Collegiate Dictionary</i> (1979).....	22

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**BRIEF FOR RESPONDENTS**

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**INTRODUCTION**

The collaboration at the heart of this case rested on the principle that inventions and patents are owned by their inventor, subject to transfer by written assignment or other recognized means for conveying personal property. 35 U.S.C. §§ 101, 261. In exchange for access to Cetus Corporation's scientific expertise and proprietary materials, Dr. Mark Holodniy assigned any resulting inventions to Cetus. The inventions claimed in the patents-in-suit were conceived at Cetus during this collaboration. Under federal patent and state contract

law, title vested in Holodniy and was assigned to Cetus, giving both sides the benefit of their bargain.

Stanford claims, however, that established principles of ownership and assignment were swept aside by the Bayh-Dole Act, which it believes to be a “vesting” statute “automatically” granting “perfect” title to federal contractors if any amount of federal funding is involved at any point in the process—even if the invention would otherwise have been owned by a third party, such as an individual inventor or his assignee. The Act says nothing of the sort. Rather, it limits the *government’s* rights in inventions it helped to fund. The Act creates a system—implemented through bilateral funding agreements between the government and its contractors—under which a contractor may “retain title” to any “invention of the contractor” that is “conceived or first actually reduced to practice in the performance of work under a funding agreement.” 35 U.S.C. §§ 201(e), 202(a). As the words “invention of the contractor” confirm—and the remainder of the Act reinforces—the Act applies only to inventions that the contractor otherwise owns under established principles of law. It does not purport to alter those principles, much less do so *sub silentio*.

Stanford’s contrary arguments consist mostly of isolated passages of legislative history and misdirected policy arguments. Correctly viewed, none supports Stanford, nor would they justify rewriting the Act if they did. They certainly do not justify eliminating, retroactively and without notice or procedural protection, the intellectual property rights a third party receives in exchange for valuable contributions to an invention. The Court should affirm.

**STATEMENT****A. Cetus's Groundbreaking Discovery Of PCR And Its Application To Measuring HIV**

In the mid-1980s, Dr. Kary Mullis, a researcher at a small California startup called Cetus Corporation, discovered the polymerase chain reaction (PCR), a technique that allows scientists to make billions of copies of DNA sequences from a small number of starting molecules. Pet. App. 32a. PCR earned Dr. Mullis the Nobel Prize in Chemistry and is now a foundational tool of genetic and biological innovation. *Id.*

In 1985, Cetus began to examine the use of PCR to detect and quantify blood-borne levels of human immunodeficiency virus (HIV), which causes AIDS. Pet. App. 32a. In 1988, Cetus collaborated with Stanford University scientists Thomas Merigan and David Schwartz in the clinical trial of an AIDS drug, during which “the Cetus team used PCR to quantitate the HIV levels of the participating patients.” *Id.* 32a-33a.

**B. Stanford Sends Holodniy To Cetus To Develop A PCR Assay For HIV**

This case turns on work that Dr. Mark Holodniy performed at Cetus in 1989. Holodniy had joined Stanford in July 1988. After a “few months in clinical rotations,” Holodniy “began focusing on possible research projects.” Pet. App. 94a. He joined Merigan’s lab, and they determined that Holodniy should “direct [his] research to developing a better quantitative PCR-based assay for HIV.” *Id.*

Holodniy had no prior experience with quantitation assays or PCR. J.A. 49-52; Pet. App. 36a. Merigan and Schwartz likewise lacked substantial PCR experience, and—as Holodniy later wrote—the development of a



quantitation assay for HIV “proved to be difficult.” C.A.J.A. 4836. Merigan and Holodniy eventually “decided that it would be helpful to work with Cetus scientists to develop an HIV assay.” Pet. App. 95a.

Merigan, who sat on Cetus’s scientific advisory board, arranged for Holodniy to work at Cetus. Pet. App. 31a; J.A. 29, 87-88. Holodniy “began commuting daily to Cetus,” “was assigned a lab bench ... , and had access to Cetus personnel, materials, and equipment.” Pet. App. 35a. Holodniy spent approximately nine months at Cetus, “receiving technical information from Cetus scientists and proprietary physical materials.” *Id.* 36a. Holodniy went to Cetus “for access to certain reagents, certain equipment, [and] certain computer programs, ... to generate primers and to consult with members of Cetus on scientific issues.” J.A. 90.

As consideration for this access, Holodniy signed a “Visitor Confidentiality Agreement” (VCA), which assigned to Cetus Holodniy’s “right, title, and interest” in any invention made “as a consequence of [his] access” to Cetus facilities. Pet. App. 35a-36a (quoting VCA); J.A. 93. As both courts below ruled, the inventions at issue arose “as a consequence of” Holodniy’s access to Cetus, triggering the VCA’s assignment provision. Pet. App. 15a, 64a-65a. Although Stanford had previously required Holodniy to execute a “Copyright and Patent Agreement” (CPA), that document stated only that Holodniy “agree[d] to assign” his “inventions as required by Contracts or Grants” (*id.* 118a-119a)—language that merely obligated Holodniy to execute a *later* assignment of any covered invention (*id.* 13a). The VCA, by contrast, immediately assigned to Cetus any inventions within its scope upon their conception. *Id.* 14a. Because Holodniy went to Cetus as Stanford’s

agent, Stanford was chargeable with notice of Holodniy's execution of the VCA. *Id.* 16a-17a, 64a.

**C. The Claimed Inventions Are Conceived At Cetus In 1989 Without Use Of Bayh-Dole Funding**

The Cetus research “focused on quantitation of HIV-1 RNA in serum or plasma, using PCR techniques, in the hope that RNA levels would also correlate with the stage of HIV-1 disease and response to treatment.” C.A.J.A. 4837. “By early Fall of 1989,” *i.e.*, while Holodniy was still at Cetus, “a working assay for the quantitation of HIV RNA” had been constructed. J.A. 29. As the district court found, that assay consisted of five steps:

- (1) extracting HIV RNA;
- (2) producing a DNA molecule through reverse transcription;
- (3) using PCR to amplify the DNA using primers developed by Cetus;
- (4) detecting the amplified DNA; and
- (5) generating a standard curve used to calculate the amount of virus in a patient's blood using a cRNA standard (“quantitation”).

Pet. App. 36a. The district court ruled that the invention claimed in the patents-in-suit—the use of the PCR-based assay to quantitate HIV in patient blood and thereby track therapy or disease progression—was fully conceived while Holodniy was at Cetus. *Id.* 56a.

Holodniy did not develop the assay by himself; he worked with several Cetus scientists and learned “the techniques related to the cellular DNA and RNA quan-

titation and then the serum HIV RNA quantitation” from them. J.A. 69-71. Prior to visiting Cetus, Holodniy had never built a quantitation assay, run a PCR product, amplified or quantified HIV RNA, or even “done any previous work in that field.” J.A. 49, 55-57. Holodniy’s work at Cetus thus made use of “technical information from Cetus scientists and proprietary physical materials from Cetus.” Pet. App. 36a; *accord* J.A. 29-31, 58-63. Holodniy “sought the assistance of Cetus scientist Alice Wang to develop the quantitation portion of the assay.” Pet. App. 36a. The “cRNA standard” used in step (5) was developed by Cetus employee Clayton Casipit (and named CC2, using Casipit’s initials) and given to Holodniy in October 1989. *Id.* 36a-37a; J.A. 29. The primers used in the assay, known as SK38, SK39, and SK19-HRP, were developed by (and named after) Cetus employee Shirley Kwok. J.A. 74. Holodniy’s lab notebook reflects the many contributions that Cetus scientists made to his work, including his critical reliance on these materials and the fact that he received them from Cetus. J.A. 80-81; Supp. J.A. 7, 9, 11.

Stanford now suggests—for the first time—that Holodniy’s work before or during his time at Cetus was funded by Bayh-Dole money, but no evidence supports that claim. In fact, Stanford repeatedly asserted below that the Bayh-Dole Act was implicated through “federally funded clinical research at Stanford *beginning in July 1990*” (Stanford C.A. Reply 43), “after [Holodniy] was no longer a visitor at Cetus” (*id.* 12).<sup>1</sup> Stanford

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<sup>1</sup> See also Stanford C.A. Br. 2 (inventions “arose out of research conducted in the early 1990s”); Stanford C.A. Reply 7 (“clinical research giving rise to the claimed inventions” occurred “under at least two government grants” and “did not begin until

failed to produce the two NIH grant agreements on which it relies (J.A. 103), and it is undisputed that Holodniy's salary at Cetus was paid not by either grant, but by a National Research Service Award of the kind expressly exempted from the Bayh-Dole Act. J.A. 98 ¶13, 109-117; 35 U.S.C. § 212.

#### **D. Holodniy And Cetus Scientists Publish The Assay**

In December 1989, pursuant to his obligations under the VCA (Pet. App. 122a-123a), Holodniy sought Cetus's permission to publish the HIV assay in two conference abstracts (*id.* 37a). Cetus granted permission, but only after Holodniy added Cetus scientists as co-authors. *Id.*; *accord* J.A. 127-131, 132. Both abstracts not only described the steps of the quantitation assay, but noted that that “[q]uantitation of HIV-1 viral RNA in serum by PCR may be a useful marker for disease progression or monitoring antiviral therapy.” J.A. 32, 131; C.A.J.A. 769-770. Neither abstract suggested that the work was funded by any federal grant.

Again pursuant to his VCA obligations, Holodniy submitted an invention disclosure to Cetus in January 1990, attaching one of the abstracts. Supp. J.A. 14. Further contradicting Stanford's recent suggestion that the claimed invention was supported by work at Stanford in 1988, Holodniy made plain on this form that he began working on the invention in September 1989.

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July 1990, over seven months after Dr. Holodniy stopped visiting Cetus”); *id.* 58 (inventions made during clinical work “that began approximately nine months after Dr. Holodniy stopped visiting Cetus”).

*Id.* 15. This disclosure also referenced no grant support.

In July 1990, Holodniy and other Stanford and Cetus co-authors submitted an article to the *Journal of Infectious Diseases* entitled “Detection and Quantification of Human Immunodeficiency Virus RNA in Patient Serum by Use of the Polymerase Chain Reaction” (the “JID article”). J.A. 135. The article observed a correlation between “[s]erum HIV RNA detected by PCR” and “the presence of HIV-related symptoms or disease”; it also stated that HIV RNA quantitation through PCR “may be useful as a marker for disease progression or in monitoring antiviral therapy.” J.A. 136. The article concluded that “[s]erum PCR may provide an additional marker of disease progression and drug efficacy that could improve our ability to monitor the course of HIV infection. Further studies will be necessary to validate this approach.” J.A. 148-149. Katzenstein, one of the Stanford co-authors, confirmed that the JID article was the “fulfillment” of the idea of using PCR to measure HIV RNA in order to monitor therapy and/or disease progression. J.A. 86. Holodniy likewise wrote that his work with Cetus “culminated” in this publication “on the correlation between HIV-1 load and stage of HIV-1 disease.” C.A.J.A. 4837.

#### **E. Stanford Conducts Clinical Trials In 1990 And Applies For Patents**

Holodniy returned to Stanford in mid-October 1989. C.A.J.A. 4837. In July 1990, he and others began clinical trials using the PCR assay developed at Cetus and disclosed in the JID article. The purpose of these experiments was to “confirm[] the workability of the ... invention.” Dkt. 96, at 29. During that time, Holodniy

continued to use Cetus materials. *E.g.*, Supp. J.A. 11 (“primers received from Cetus” “picked up 7-11-90”).<sup>2</sup>

On May 14, 1992, Stanford filed the first of several patent applications for the inventions at issue. Although the original application listed only Merigan and Michael Kozal as inventors, Stanford filed a notice of correction of inventorship in November 1992 to add Holodniy and Katzenstein. Pet. App. 40a. As support for adding Holodniy as a co-inventor, Stanford’s patent counsel declared that Holodniy’s inventive contribution “principally concerns quantitation of HIV RNA in plasma of AIDS patients” (J.A. 154)—that is, the assay developed at Cetus.

In 1995, Stanford obtained written assignments from Holodniy, Merigan, and Katzenstein purporting to convey their interests in the pending patent applications. J.A. 42.

The first patent-in-suit (No. 5,968,730) issued in 1999; the two others issued in 2003 (No. 6,503,705) and 2006 (No. 7,129,041). All three are entitled “Polymerase Chain Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the Treatment of Acquired Immunodeficiency Syndrome.” Supp. J.A. 17, 39, 64. As Stanford conceded and the patents’ titles indicate, the asserted claims “include ... PCR assay steps like those disclosed in the JID arti-

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<sup>2</sup> Holodniy’s work at Stanford in 1990 could not have been more than confirmation. The assay was tested on HIV patients at Cetus to measure HIV levels, as reported in the JID article. J.A. 135-136. The article also reported the assay’s utility for assisting in monitoring disease. J.A. 85-86, 136, 148-149. The district court accordingly ruled that the article rendered the patents obvious. 563 F. Supp. 2d 1016, 1028 n.13 (N.D. Cal. 2008).

cle.” Stanford C.A. Reply 25. Claim 1 of the ’730 patent is representative and recites (1) “collecting” a plasma sample from an HIV patient, (2) “amplifying” the HIV-encoding nucleic acid in the sample using PCR; and (3) “testing for” the presence of HIV nucleic acids in the PCR product. Supp. J.A. 37. The claim then contains an additional limitation that, after the assay is performed, “the absence of detectable HIV-encoding nucleic acid correlates positively with the conclusion that the antiretroviral agent is therapeutically effective.” *Id.*<sup>3</sup> In other words, the patents claim the PCR-based HIV assay that the parties agree was developed at Cetus and disclosed in the JID article (*see supra* pp. 7-8), plus a step in which a doctor evaluates whether treatment was effective by determining whether HIV RNA is present and whether the amount has gone up or down.

#### **F. Roche Commercializes The Assay**

In 1991, Roche acquired all of Cetus’s PCR assets, including its rights under the VCA. Roche conducted clinical trials of a test kit for quantitating HIV RNA using PCR, including a trial on which Stanford’s named inventor Merigan was a principal investigator. C.A.J.A. 4811; Dkt. 109-2, at 11. Roche’s test kits went on sale in June 1996; Stanford University Hospital was among the first customers. C.A.J.A. 4815. Roche’s kits

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<sup>3</sup> *See also* Supp. J.A. 61 (’705 patent cl. 1) (adding additional steps of “comparing” the “HIV RNA copy numbers” over the course of treatment and “evaluating whether a statistically significant decline” exists), 86 (’041 patent cl. 1) (claiming a method of “correlating the presence or absence of detectable HIV-encoding nucleic acid in a plasma sample” with a standard, using the PCR assay).

are used in hospitals and AIDS clinics worldwide, facilitating treatment for millions of patients.

In 2000, Stanford asserted that Roche could not sell its kits without obtaining a license from Stanford and paying a royalty. Pet. App. 109a-110a. There is no evidence that Stanford has otherwise attempted to commercialize these patents or use them to benefit public health.

### G. District Court Proceedings

In 2005, Stanford sued Roche, asserting that the test kits Roche had been selling for nine years infringed the patents-in-suit. Roche asserted several affirmative defenses, including ownership and lack of standing based on Holodniy's assignment in the VCA. Dkt. 15 ¶¶27, 30. Roche also counterclaimed that at least one Cetus employee was a required co-inventor on the patents (*id.* ¶¶38, 43)—a claim that remains unresolved.<sup>4</sup>

Stanford first mentioned the Bayh-Dole Act when the parties cross-moved for summary judgment on Roche's claim of co-ownership. In response, Roche noted that Stanford had proffered neither the relevant grant agreements nor any evidence that the claimed inventions fell within their scope. Stanford's corporate designee testified that he "underst[oo]d" that the inventions "were all funded by at least two U.S. government grants" (Pet. App. 109a), but admitted that he

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<sup>4</sup> Stanford's assertion that Roche has "[a]t no point ... disputed inventorship to assert that a non-Stanford-employee was a co-inventor" (Pet. Br. 33) is baffling. Indeed, *Stanford* sought summary judgment on Roche's inventorship claim (Dkt. 295, at 1-6), a motion the district court deemed withdrawn when it held the patents invalid (Dkt. 314).



had “[n]ever seen those contracts” and could not find them (J.A. 103). Although Merigan asserted by declaration (15 years after the fact) that “Holodniy’s *research in my laboratory* was performed under two grants from [NIH]” (J.A. 98 (emphasis added)), that assertion both lacked support and failed even to suggest that Holodniy’s work on the relevant *inventions* was federally funded.<sup>5</sup>

The district court ruled that Roche’s ownership-related claims and affirmative defenses were time-barred. Pet. App. 49a, 51a. Nonetheless, “because the effect of the Holodniy VCA [was] raised and extensively argued,” the court addressed the issue. *Id.* 53a. After considering the evidence in detail, the court concluded that the “the specific method of using the assay to monitor HIV treatment was ... clear in the minds of Holodniy and the other Stanford scientists when the assay was completed at Cetus.” *Id.* 56a. The court thus ruled that “the invention was conceived during Holodniy’s consultancy at Cetus,” no later than October 1989. *Id.* 58a. Accordingly, “[t]he VCA effectively assigned any rights that Holodniy had in the patented inventions to Cetus.” *Id.* 59a.<sup>6</sup>

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<sup>5</sup> The invention disclosure form Merigan submitted to Stanford mentioned two NIH grants, but did not include Holodniy as a co-inventor. Dkt. 110-6. During his deposition, Merigan mentioned NIH grants to “renovate” Stanford’s facilities “to make it safer for managing viruses,” but did not suggest that they funded PCR research by anyone, much less Holodniy. Dkt. 95-1, at 3.

<sup>6</sup> Though Stanford insisted that the claimed inventions were conceived after Holodniy left Cetus, it refused to disclose the actual conception date reflected in its documentation. Pet. App. 58a n.7; Dkt. 110-6 (redacted invention disclosure form).

The district court then addressed Stanford's argument under the Bayh-Dole Act. The court recognized that the Act did not automatically vest title in Stanford and "does not alter the general rule that title to a patent vests in the inventor or the designated assignee." Pet. App. 60a. The court concluded, however, that "Holodniy's purported assignment to Cetus conflicted with the legal requirements of the Bayh-Dole Act" and that the "assignment provision in the VCA [was] therefore void" as to the patents-in-suit. *Id.* 62a.

The court made no finding and cited no evidence demonstrating that Holodniy's work on the claimed inventions fell "under a funding agreement." 35 U.S.C. § 201(e). Nor did it address the Act's limitation to "invention[s] of the contractor" (*id.*) or explain how that provision could encompass Holodniy's or Cetus's interest in the patents-in-suit.

The court separately ruled that, because Holodniy "was sent to Cetus by Merigan" and "signed the VCA in the course of Stanford's business," Stanford had notice of the VCA as a matter of law and (but for the Bayh-Dole Act) would have been bound by the assignment to Cetus. Pet. App. 64a. The court rejected Stanford's contention that the inventions fell outside the VCA's scope: they were "unambiguously" developed "as a consequence of" Holodniy's access to Cetus, because he "spent nine months working onsite at Cetus, using Cetus equipment and materials and obtaining advice from Cetus personnel, and ... developed the PCR assay with assistance from Cetus scientists while [he] was at Cetus." *Id.* 64a-65a (internal quotation marks omitted).

The district court accordingly granted Stanford's summary judgment motion in part and denied Roche's motion in its entirety.

The district court later held the asserted patent claims obvious because the JID article "discloses the same PCR HIV assay that is disclosed in the asserted patents." 563 F. Supp. 2d 1016, 1024 (N.D. Cal. 2008). The court ruled that the difference between the JID article and the asserted claims was "solely the correlation and evaluation steps in the patents." *Id.* at 1044. It found that those steps—many of which merely amounted to looking at the results of the assay and concluding that a given treatment was effective if HIV levels decreased—were known in the prior art and that their combination with the assay disclosed in the article would have been obvious. *Id.* at 1045-1049.

#### **H. Court Of Appeals Proceedings**

Stanford appealed the invalidity judgment, and Roche cross-appealed the grant of summary judgment on the ownership issues. The Federal Circuit, in rulings not challenged here, held that Roche's defense based on the VCA was not time-barred and that the inventions were covered by the VCA because they were developed "as a consequence' of [Holodniy's] access to Cetus." Pet. App. 9a-12a, 15a. The court also ruled that, under settled California law, "Stanford had at least constructive or inquiry notice of the VCA." *Id.* 16a; *see also id.* 17a ("For this purpose, there is no difference between constructive and actual notice." (quoting California law)). Although the Federal Circuit noted that the VCA would apply "[e]ven if Holodniy conceived and reduced to practice after departing Cetus" (*id.* 15a), it did not disturb the district court's

conclusion that the invention was conceived when the PCR assay was completed at Cetus.

With respect to the Bayh-Dole Act, the Federal Circuit observed that, “when the Bayh-Dole Act’s provisions are violated,” the government may take action, but nothing in the statute, regulations, or case law suggests that title is “automatically forfeited.” Pet. App. 18a-19a. The court left open the question whether Holodniy’s contracts or the Bayh-Dole Act gave the government or Stanford “some other legal recourse to recover Holodniy’s rights.” *Id.* 20a n.1.<sup>7</sup>

#### SUMMARY OF ARGUMENT

Nothing in the Bayh-Dole Act purports to upset the ordinary patent-law processes by which inventions are owned and assigned. The Act limits its application to “subject inventions,” defined as “inventions of the contractor”—*i.e.*, inventions the contractor *already* owns. The Act provides that the contractor may “retain”—*i.e.*, keep—those inventions, notwithstanding any claim the government might have to the results of research it sponsors. It says nothing about third-party assignees like Cetus that receive intellectual property rights through valid assignments for consideration and that neither accept nor benefit from federal funds themselves. Congress knew how to write provisions that “vest” title; the Bayh-Dole Act contains none.

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<sup>7</sup> The Federal Circuit made no finding that the claimed inventions, and particularly Holodniy’s inventive contributions to them, were funded by NIH, although it did state (without citation) that “Stanford received government funding for *its HIV research.*” Pet. App. 5a (emphasis added).

Beyond the plain language of its operative provisions, the Act is structured to regulate the relationship between the government and its contractors, not third-party rights. The Act is implemented through detailed provisions to be included in funding agreements—provisions that necessarily cannot bind non-contracting parties. The Act also contains scrupulous procedural protections designed to ensure that the government does not trench on the rights of contractors, yet it provides no protection at all for third parties—an understandable situation if the Act does not divest third parties of their rights, but a startling omission if it does. Under Stanford’s position, it can “take” title to a collaborative invention merely by *asserting*, without proving, that some undisclosed amount of federal funds under some undisclosed funding agreement was used to perform some undisclosed work at a time that, while itself undisclosed, came *after* the invention at issue was conceived using private funds. Such a result would be unsupported and constitutionally suspect.

The untoward results of Stanford’s reading vanish when the Act is correctly understood against the backdrop of established rules vesting title to inventions in inventors, subject to their assignments. The government itself presumes that federal employees own their inventions, subject to obligations to assign them in many (but not all) cases. Universities, including Stanford, have operated on that basis as well, requiring faculty to execute assignments of inventions, including federally-funded inventions—actions that would be superfluous if the Act were an automatic “vesting” provision.

Treating the Act as regulating “inventions of the contractor”—rather than as transferring third-party rights to contractors without notice or opportunity to

protest—fully accords with Congress’s goal. The legislative history is replete with criticism of bureaucratic inefficiency and the desire to move inventions off *government* shelves. But Stanford identifies not one statement suggesting that Congress viewed *third-party* rights obtained through valid contractual assignments as problematic, much less that general assignment principles should be altered.

Stanford’s policy arguments are also deeply misdirected. Hundreds of billions of dollars of private investment flow annually to innovative research in this country without need for a federal statute “vesting” ownership in anyone but the inventor, and the Bayh-Dole Act itself has operated for 30 years without any suggestion (before this case) that it “vested” title. If anything, it is *Stanford’s* position that would harm innovation by upsetting contractual expectations and discouraging private firms from collaborating with the academy. Stanford’s hypotheticals regarding secret assignments, self-dealing professors, and conflicting contractual obligations can all be resolved under well-established patent and contract rules, as they are when they (rarely) arise in cases concerning privately-funded innovation.

Stanford ends its brief with an appeal to equity, a curious gambit given the facts of this case. Cetus did everything it could do to permit an open collaboration while protecting its intellectual property rights, and then taught Holodniy everything he knew about PCR. Roche, Cetus’s successor, uses the PCR assay in test kits that daily improve the treatment of patients afflicted with HIV. Stanford retains the right to practice or license the claimed inventions in competition with Roche. But Stanford does not want to compete; it wants to tax Roche’s commercial products solely for its

own benefit. Such a result is far from equitable, and Stanford has shown no reason why the Court should create such an obstacle to private enterprise by rewriting a statute intended to limit *the government's* intellectual property rights.

## ARGUMENT

### I. THE BAYH-DOLE ACT DOES NOT “VEST TITLE”

#### A. The Text Addresses Only Inventions That The Contractor Otherwise Owns

##### 1. “Invention of the contractor”

Construction of the Bayh-Dole Act “begin[s], as always, with the language of the statute.” *Duncan v. Walker*, 533 U.S. 167, 172 (2001). By its terms, the Act applies only to “subject inventions,” that is, “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) (emphasis added). This Court has ruled that “[t]he use of the word ‘of’ denotes ownership.” *Poe v. Seaborn*, 282 U.S. 101, 109 (1930); *see also Ellis v. United States*, 206 U.S. 246, 259 (1907) (Holmes, J.) (“[T]he most natural meaning of ‘of the United States’ is ‘belonging to the United States.’”); *Jacobs v. New York Foundling Hosp.*, 577 F.3d 93, 100 (2d Cir. 2009) (“[O]f is a word used to indicate belonging or a possessive relationship.”); *cf. National Cable & Telecomm. Ass’n v. Gulf Power Co.*, 534 U.S. 327, 335 (2002) (distinguishing “by” from “of”).

The Act sets forth no special rules for determining whether particular intellectual property is an “invention of the contractor.” That is unsurprising, because Congress has elsewhere enacted, and courts have long interpreted, detailed rules governing ownership and assignment of inventions. The Patent Act provides

that “[w]hoever invents or discovers a new and useful [invention] may obtain a patent therefor” and that patents and patent applications are “assignable in law by an instrument in writing.” 35 U.S.C. §§ 101, 261; *see also* 37 C.F.R. § 3.73 (“The inventor is presumed to be the owner of a patent application, and any patent that may issue therefrom, unless there is an assignment.”). As this Court has recognized for over a century, title to an invention thus vests in its inventor, subject to transfer by written assignment. *See, e.g., United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933); *Standard Parts Co. v. Peck*, 264 U.S. 52, 59 (1924); *Dalzell v. Dueber Watchcase Mfg. Co.*, 149 U.S. 315, 320 (1893); *Hapgood v. Hewitt*, 119 U.S. 226, 233 (1886). Expectant interests in inventions not yet in being may also be assigned in advance. *FilmTec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1572-1573 & n.8 (Fed. Cir. 1991).

The Bayh-Dole Act nowhere purports to upset these established principles, nor does it suggest that an invention’s status as an “invention of the contractor” is to be determined by any other means. Accordingly, the Act governs only rights that otherwise *belong to the contractor*, who may be the inventor himself (*see* 35 U.S.C. § 201(e) (contractor may be a “person”)) or his assignee or successor-in-interest. It does not affect rights “of” third parties that have not contracted with the federal government.

Stanford and its *amici* largely ignore the words “of the contractor,” frequently asserting—incorrectly—that the Act applies to all “inventions arising from federally funded research.” Pet. Br. 1, 11; *see also id.* 26 (quoting Section 201(e) but eliding the words “of the contractor”); U.S. Inv. Br. 4 (same). Stanford addresses “of the contractor” only once, arguing that



“[s]ince an institution can only *create* an invention through the actions of its employees, this language is naturally read to include all inventions *made by the contractor’s employees* with the aid of federal funding.” Pet. Br. 32 (emphasis added). Stanford’s argument is doubly mistaken.

First, “of the contractor” is not “naturally read” to mean “created by the contractor” because inventions are “created” by people, not institutions. *See* 35 U.S.C. § 102; APLA Br. 18-19. Where Congress meant to refer to the *making* of an invention, Congress used that verb expressly. *See* 35 U.S.C. § 212 (Act excludes inventions “made by the awardee” of an educational grant). The more natural reading of “invention of the contractor” is “belonging to the contractor,” not “made by one of the contractor’s employees without regard to any assignment.”

Second, contrary to Stanford’s assumption, employers do not automatically own employee inventions. Rather, “an invention presumptively belongs to its creator, ... even though the invention was conceived and/or reduced to practice during the course of employment.” *Teets v. Chromalloy Gas Turbine Corp.*, 83 F.3d 403, 407 (Fed. Cir. 1996) (citing *Hapgood*, 119 U.S. at 233-234). And as this Court has made clear, “title to [a patent] can pass only by assignment,” even as between employer and employee. *Dubilier*, 289 U.S. at 187. Once again, nothing in the Bayh-Dole Act purports to upset these longstanding principles; rather, the Act is “naturally read” as *consistent* with them. *Samantar v. Yousuf*, 130 S. Ct. 2278, 2289 n.13 (2010) (“[W]hen a statute covers an issue previously governed by the common law, we interpret the statute with the presumption that Congress intended to retain the substance of the common law.”); *Ruckelshaus v. Monsanto*

*Co.*, 467 U.S. 986, 1018 (1984) (“[W]here two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.” (internal quotation marks omitted)).

Stanford essentially reads the words “of the contractor” out of the Act, contrary to the canon that courts should “give effect, if possible, to every word Congress used.” *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979). It also radically transforms the Act. When “of the contractor” is given its ordinary meaning, the Act applies only to rights that federal contractors would otherwise hold, effectively expanding them by *giving away* any government title. Under Stanford’s reading, however, the statute also *takes away* third-party rights, abrogating all state and federal laws regarding contract and patent ownership in the process. Such a broad effect would be worrisome even if required by the express terms of the statute; there is no reason to achieve that result by ignoring the statutory limitation (“of the contractor”) that prevents it. *See Duncan*, 533 U.S. at 174 (the Court is “reluctant to treat statutory terms as surplusage in any setting” but is “especially unwilling to do so when the term occupies so pivotal a place in the statutory scheme” (internal quotation marks, citations, and alterations omitted)).<sup>8</sup>

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<sup>8</sup> In a footnote, Stanford suggests that the phrase “invention of the contractor” “excludes from the Act’s coverage inventions created by third parties without the assistance of federal funding, where the contractor’s employees had no role in its conception.” Pet. Br. 32 n.11. If that is correct, it appears to concede this case, because (as the district court found) the invention was fully conceived at Cetus by October 1989, at which point no Bayh-Dole grants were involved. *See supra* pp. 6-7 & n.1. If Stanford means

## 2. “Retain”

The Act separately requires that all federal funding agreements allow contractors to “elect to retain title to any subject invention.” 35 U.S.C. § 202(a). Of course, “unless otherwise defined, words will be interpreted as taking their ordinary, contemporary common meaning.” *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (quoting *Perrin v. United States*, 444 U.S. 37, 42 (1979)). The common meaning of “retain” is “to keep hold or possession of” or “to continue having or keeping.” *Oxford English Dictionary* 563 (1933); *accord Webster’s New Collegiate Dictionary* 980 (1979) (“to keep in possession or use”); *American Heritage Dictionary* 1109 (1969) (“to keep or hold in one’s possession”). The fact that the Act grants a right to “keep hold or possession” reinforces its limitation to inventions “of the contractor”—that is, inventions that the contractor already “hold[s] or possess[es].”

Stanford again rewrites the statute to suit its argument, introducing its first full quotation of Section 202(a) by recharacterizing the right to “retain title” as “the critical right to *take* title.” Pet. Br. 12-13 (emphasis added). It also describes Section 202(a) as “vest[ing] new title in the contractor” (*id.* 36; *see also id.* 27, 33), “giving” or “granting” title (*id.* 1, 30, 36, 44), and allowing contractors to “obtain,” “take,” or “perfect” title (*id.* 12, 13, 21, 39). But “take” and “retain” are not synonymous: to “retain” means to *keep* in one’s

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that Holodniy’s status as its *employee* turns inventions conceived “without the assistance of federal funding” into “inventions of the contractor,” then the contention is wrong because, as discussed in text, an employment relationship does not automatically vest the employer with ownership of employee inventions.

possession, whereas to “take”—like the other verbs Stanford prefers—means to “get into one’s possession.” *American Heritage Dictionary* 1311.<sup>9</sup>

### 3. The absence of “vesting” language

Congress’s failure to refer to “vesting” is particularly noteworthy given that it expressly used such language in some—but not all—of the statutes that the Act replaced. *See* 42 U.S.C. §§ 2182 (inventions relating to nuclear material or atomic energy “shall be vested in, and be the property of, the [Atomic Energy] Commission”), 2457 (inventions made under performance of certain contracts with NASA “shall be the exclusive property of the United States”), 5908 (title to inventions made under contracts with Department of Energy “shall vest in the United States”).

Those vesting statutes, which arise in specialized and sensitive areas, set forth unusual, reticulated procedures for patent issuance directly to the government. Two require any inventor working in the relevant *field* to file a special “statement under oath setting forth the full facts surrounding ... the invention or discovery ... and whether [it] was made or conceived” under a relevant contract. 42 U.S.C. §§ 2182, 2457(c). The agency must then be notified of the application and may “direct” that the patent issue directly to the agency if it believes that it was produced under a contract—a deci-

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<sup>9</sup> Elsewhere, Stanford proposes that “retain” be read as “synonymous with ‘obtain’” (Pet. Br. 39) or “as a synonym for ‘acquire’ or ‘receive’” (*id.* 37). While “obtain,” “acquire,” and “receive” are all synonyms for each other, none is a synonym for “retain.” *New American Roget’s College Thesaurus* 8 (1978) (acquire); *id.* at 425-426 (retain).

sion the inventor may appeal. *Id.* §§ 2182, 2457(d). The third provision likewise specifies that patents on covered inventions “shall be issued to the United States,” subject to certain enumerated waiver procedures and considerations. *Id.* § 5908(a), (d)(1)-(11). These carefully-detailed procedures for vesting title in a party other than the inventor have no analogue in the Bayh-Dole Act, further indicating that the Act does not operate as a vesting statute.

The government, unlike Stanford, acknowledges that the Patent Act grants title “to the inventor, who may assign that right.” U.S. Br. 16 (citing 35 U.S.C. §§ 101, 115, 116, 152). It contends, however, that that principle is displaced by 35 U.S.C. § 210(a), which provides that the Bayh-Dole Act “take[s] precedence over any other Act which would require a disposition of rights in subject inventions ... that is inconsistent with this chapter.” *Id.* But Section 210(a) relates only to “subject inventions”—inventions “of the contractor” conceived or reduced to practice with the aid of federal funds. Thus, the “inconsistent” “disposition[s] of rights” over which the Bayh-Dole Act takes precedence are specific provisions—like those enumerated in Section 210(a)—that would allocate ownership of “invention[s] of the contractor” as between contractors and government agencies. The Senate Judiciary Committee thus explained that the Act “takes precedence over a number of statutory provisions that currently control to varying degrees the *patent policies of some agencies*”—not that it repealed generally-applicable Patent Act provisions governing ownership and assignment. S. Rep. No. 96-480, at 35 (1979) (Senate Report) (emphasis added).

This understanding of Section 210(a) is reinforced by its listing of 21 statutes, each of which is a specific

provision governing the relative ownership claims of the government and federal contractors with respect to sponsored inventions. *See* 35 U.S.C. § 210(a)(1)-(21). Not one is a general provision remotely similar to the Patent Act provisions dictating that title to inventions vests initially in inventors. The canon of *ejusdem generis*—like the plain text—thus suggests that the laws over which the Bayh-Dole Act takes precedence are those that create government claims to inventions “of the contractor,” not general provisions of patent law that determine whether an invention is “of the contractor” in the first place. *See Hughey v. United States*, 495 U.S. 411, 419 (1990).

The government contends that *ejusdem generis* does not apply because “Section 210 does not provide ‘a list of specific items followed by a general term.’” U.S. Br. 22 n.2 (citing *Hall St. Assocs. v. Mattel, Inc.*, 552 U.S. 576, 586 (2008)). That argument is hard to fathom; “any other Act” is a “general term,” and the list of 21 preempted provisions is a “list of specific items.” If the government is quibbling with the sequence, the objection is meritless; the canon limits a general term “in light of the specific terms that *surround* it.” *Hughey*, 495 U.S. at 419 (emphasis added); *see also* 2A *Sutherland Statutory Construction* § 47:17, at 362-365 (7th ed. 2007) (“Where the opposite sequence is found, i.e., specific words following general ones, the doctrine is equally applicable[.]”).

The government’s reading of Section 210(a) also admits of no limiting principle. It is the Patent Act that prevents inventors from filing applications that fail to name every inventor, that name individuals who are not inventors, that claim inventive but unpatentable subject matter, or that claim an invention first conceived by another (even if not yet disclosed). 35 U.S.C.

§§ 101, 102, 116. Each of these provisions—and especially the last—could result in a “disposition of rights” in a federally-funded invention that is arguably “inconsistent” with a contractor’s supposed right to take “perfect” title notwithstanding the otherwise valid claims of others. Yet the government presumably does not contend that the Bayh-Dole Act exempts federal contractors from those general patent-law principles.

In short, the text is plain. It grants contractors only the opportunity to “retain” rights to an “invention of the contractor”—rights that the contractor has obtained under other provisions of law—notwithstanding the fact that federal funding would otherwise give the government an interest in the invention. It does not “vest” title in a contractor or allow the contractor to “take” title from anyone.

## **B. Other Provisions In The Act And Related Regulations Confirm Its Limited Application**

### **1. The Act’s implementation through contract confirms its application to contractors, not third parties**

Further confirmation that the Act does not alter third-party rights lies in Congress’s judgment that the Act be implemented primarily through alterations in federal funding agreements between the government and its contractors. *See* 35 U.S.C. § 206 (directing implementation through “establish[ing the] standard funding agreement provisions required under this chapter”). Even the right to “elect to retain title” is subject to the terms of each particular agreement, which “may provide otherwise.” *Id.* § 202(a). The contractor’s responsibilities and the government’s residual rights are imposed not by the statute directly, but by a direction that they be included in “[e]ach funding

agreement with a small business firm or nonprofit organization.” *Id.* § 202(c)(1)-(8). In short, the Bayh-Dole Act regulates agreements between the government and funded entities; it does not affect the rights of strangers to such agreements.

Because the Act concerns contracts, the core regulation implementing the Act is a form *agreement* for use in federal research grants. 37 C.F.R. § 401.14. The language Stanford puts forward as allowing a contractor to retain “the entire right, title, and interest throughout the world to each subject invention” (Pet. Br. 43) appears in that form contract, not in a general interpretive regulation (37 C.F.R. § 401.14(a)). A bilateral contract is an appropriate vehicle for resolving ownership claims of two contracting parties; it cannot divest the rights of third parties not privy to the contract. *See Armstrong v. United States*, 364 U.S. 40, 45-46 (1960) (contract between government and federal contractor did not affect liens of persons “not parties to the contract”).<sup>10</sup>

Moreover, in cases in which the government has taken title to an invention that a contractor failed to disclose, it has done so under these regulations *as they are embodied in the contract*, not through any self-executing force of the Bayh-Dole Act or the regulations themselves. *See, e.g., Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee*, 389 F.3d 1243, 1247 (Fed. Cir. 2004)

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<sup>10</sup> Stanford’s plea for *Chevron* deference (Pet. Br. 44), not raised below or in the petition for certiorari, is meritless. Nothing in the regulations suggests that the Department of Commerce’s form agreement meant to address, much less abrogate, the rights of non-contracting third parties. The government’s brief notably does not support Stanford’s deference claim.



(interpreting right to retain in “Subsection 1.53 of Campbell Plastics’s contract”); *see also Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1352 n.4 (Fed. Cir. 2007) (government had discretionary right to take title based on “37 C.F.R. § 401.14, which was incorporated into the grant agreement between UC and NIH”); *Pilley v. United States*, 74 Fed. Cl. 489, 494-496 (2006) (contract between FAA and inventor gave government a “[l]icense under the [c]ontract” to subject inventions). In this respect, the Act’s regulations resemble preexisting agency-specific regulations, which were “not self-executing” and “require[d] only the inclusion of the patent rights clause in the [agency]’s research contracts.” *Mead Corp. v. United States*, 652 F.2d 1050, 1053 (D.C. Cir. 1981) (per curiam).

The only circumstance in which the Act envisions an actual taking of title to an invention is where a contractor *breaches* its obligations under a funding agreement, in which case the government may “receive title” from the breaching contractor. 35 U.S.C. § 202(c)(1)-(2); *Campbell Plastics*, 389 F.3d at 1249. The Act nowhere suggests that a contractor may simply take title from an innocent assignee like Cetus that did not even assume (let alone breach) any obligations to the government.

## **2. The Act’s procedural protections, which follow its substantive scope, apply only to contractors**

The Act is also notable in its concern for due process whenever the government seeks to limit a contractor’s rights, even though contractors have *already* benefitted from government funding. *See, e.g.*, 35 U.S.C. § 203(b) (extensive appeal rights where gov-

ernment exercises “march-in rights”); *id.* § 202(b)(3) (same appeal rights when agency imposes exceptions on contractor’s right to retain title). The implementing regulations further expand these protections (*e.g.*, 37 C.F.R. §§ 401.4, 401.6, 401.12) and grant even broader appeal rights regarding government determinations adverse to the contractor (*id.* § 401.11(b)).

The Act is even more careful about ensuring that the government not interfere with the contractor’s rights to inventions that are funded privately or by educational awards like the one that paid Holodniy’s salary while at Cetus. 35 U.S.C. § 202(f)(2) (agency can only require licensing of non-subject-inventions following agency adjudication subject to judicial review); *id.* § 212 (agency obtains no rights in inventions made under an award “primarily ... for educational purposes”); 37 C.F.R. § 401.1(a)(1) (“closely related [projects] fall[ing] outside the *planned and committed activities* of a government-funded project” are not covered by the Act (emphasis added)). If the government challenges a contractor’s designation that a given project was privately funded and not subject to the Act, the contractor may appeal. 37 C.F.R. §§ 401.1(a)(1), 401.11(d).

In stark contrast, the Act contains not a single procedural protection for third parties that have neither sought nor received federal funds. The Act does not allow third parties to challenge the contractor’s unilateral decision to designate discoveries as “subject inventions.” Indeed, as happened here, a contractor need not even inform a private entity that might have a valid claim of ownership that the contractor has elected to “retain title.” The failure to protect the rights of third parties is understandable in light of the Bayh-Dole Act’s limitation to “inventions of the contractor”: there is no need to protect third-party rights because the Act

affects only the rights of the government and the contractor. Stanford's reading of the Act, however, yields a situation in which Congress attended carefully to the property rights of contractors—who already benefit from government funding and can retain rights that otherwise might have been the government's—yet showed complete disregard for the property rights of third parties that received no federal funding and owed the government no obligation.

Treating the Bayh-Dole Act as a “vesting” statute is also highly problematic given how little a contractor need do to “retain” its rights beyond complying with obligations already in its funding agreement. Here, Stanford merely *averred* that the invention was federally funded, included that averment in its patent applications, and gave timely notice to the government. J.A. 42 ¶93. The district court required no further proof on summary judgment, notwithstanding Roche's objection that Stanford had failed to produce the relevant grant agreements or prove that they encompassed the claimed inventions. To this day, it remains unclear how the claimed inventions fall within the “planned and committed activities of a government-funded project.” 37 C.F.R. § 401.1(a)(1).

If the Act applies only to rights that the contractor otherwise owns (but for any government interest), it makes sense to trust the contractor's averment, since the contractor gains nothing by subjecting its own privately-funded inventions to the requirements of the Act. But if, as Stanford asserts, the Act grants it *greater* rights to a federally-funded invention than Stanford would have to an invention funded from its private endowment—namely, by vesting Stanford with “perfect” title to inventions that it might otherwise share with private parties like Cetus—then the absence

of a requirement that the contractor prove a connection between the funding and the invention permits contractors to assert complete title to inventions based on nothing more than their own say-so. Indeed, that is precisely what Stanford did here.<sup>11</sup>

This Court should be reluctant to adopt an interpretation that allows federal contractors to divest third parties of intellectual property rights based solely on unilateral assertions of federal funding in patent applications and government disclosure forms. Nor should it lightly presume that Congress authorized such an outcome without any procedural protection for the third party—especially in a statute that, on its face, is highly protective of private property rights.

### **3. Federal regulations and university policies demonstrate that title initially vests in the inventor**

Stanford attempts to read the Act against an “established practice of taking Government title to most federally funded inventions” (Pet. Br. 35), but in fact such practices were decidedly the exception. Stanford itself cites a case recognizing that the Department of Defense’s pre-Bayh-Dole-Act contracting policy did

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<sup>11</sup> Roche appealed the district court’s grant of summary judgment on this issue. *E.g.*, Roche C.A. Reply 15-16, 20-21. Taking the record in the light most favorable to Roche, as the district court was required to do, the evidence *at the very least* permits a reasonable jury to find that Stanford failed to show that the claimed inventions fell within the “planned and committed activities of a government-funded project.” 37 C.F.R. § 401.1(a)(1). The Federal Circuit did not need to address this argument, but the material factual dispute remains an open issue here and on any possible remand.

“not require that full title to the new inventions be assigned to the Government.” *Mead Corp. v. United States*, 490 F. Supp. 405, 408 (D.D.C. 1980) (quoting Armed Services Procurement Regulations, 32 C.F.R. § 9-107.1(a) (1961)), *aff’d*, 652 F.2d 1050 (D.C. Cir. 1981). When the government did seek title, it typically did so through assignment. *See FilmTec*, 939 F.2d at 1571 (federal contract contained “warrant[y] that [the contractor] will obligate inventors to assign their rights” to the contractor, which in turn assigned its rights to the government).

The same is true with respect to inventions of federal employees. This Court ruled in 1933 that the government has no automatic title to its employees’ inventions. *Dubilier*, 289 U.S. at 187-193. Under modern regulations and agency policies, there is likewise no automatic “vesting” of title except for unusual provisions that expressly use such language. *See supra* pp. 23-24. Rather, generally-applicable regulations contemplate that the government’s interest in an invention may be “insufficient equitably to justify a requirement of assignment to the Government of the entire right, title and interest in and to such invention.” 37 C.F.R. § 501.6(a)(2) (emphasis added). Government forms calling for the disclosure of inventions by employees thus allow the inventor-employee to *refuse* to assign the invention. *See, e.g.*, Air Force Form 1279 (Disclosure and Record of Invention), at 3 (allowing employee to answer “no” to the phrase “I agree to grant voluntarily to the Government the entire title to the invention”); Air Force Instruction 51-303 ¶7.1 (Sept. 1, 1998) (recognizing that an employee may “not agree to assign his or her entire right, title and interest in and to an invention to the Government”), *available at* <http://www.af.mil/shared/media/epubs/AFI51-303.pdf>. These provisions

likewise confirm that, when the government chooses to obtain title to employee inventions, it does so through the ordinary method of requiring the employee to execute an assignment.

The Bayh-Dole Act itself recognizes that title to federal employee inventions does not vest automatically in the government: it envisions that a federal agency “may” acquire an employee’s invention. 35 U.S.C. § 202(e). Regulations implementing the Act are even plainer, providing that an agency “employing such co-inventor transfers or reassigns the right *it has acquired* in the subject invention *from its employee* to the contractor as authorized by 35 U.S.C. 202(e).” 37 C.F.R. § 401.10 (emphasis added). These provisions would be senseless under Stanford’s “vesting” rule.

Section 202(e) defeats Stanford’s argument in another way: it recognizes that title to a federally-funded invention may initially be *shared* among co-inventors employed by different entities, notably a contractor and a federal agency. In such a situation, Section 202(e) allows the agency to “consolidat[e] rights in the invention” in either the contractor or the agency. Again, that provision would make no sense if the Act presumptively vested “perfect” title in the contractor, since all rights would already be “consolidated” in the contractor (or, if the contractor elected not to “retain” its rights, in the government). But Section 202(e) makes perfect sense if the Act follows the ordinary rules of patent ownership: it allows the government to consolidate intellectual property rights that *initially vested in different co-inventors* under 35 U.S.C. § 101 and were subsequently assigned to the co-inventors’ respective employers.

University practices—including Stanford’s—also reflect the understanding that title to inventions, even federally-funded inventions, vests initially in the inventor, subject to assignment. *See, e.g.*, Pet. App. 119a (form agreement promising to assign to Stanford “such inventions as required by Contracts or Grants,” including federal grants); Stanford Research Policy Handbook 5.1.1.A.1 (July 15, 1999) (title to “inventions conceived or first reduced to practice in whole or in part by members of the faculty or staff ... shall be assigned to the University, *regardless of the source of funding*, if any” (emphasis added)), *available at* <http://rph.stanford.edu/5-1.html>; University of Wisconsin Financial Administration Patent Policy III.A.9 (1985) (“[T]he laws permit a university itself to accept assignment” of subject inventions under the Bayh-Dole Act, and the university must designate an office or organization that “will accept assignment of the invention”), *available at* <http://www.uwsa.edu/fadmin/gapp/gapp34.htm>; Iowa State University Intellectual Property Handbook 27 (“employees will be required to assign ownership” to the university where, *inter alia*, intellectual property “was funded in whole or in part by any agency of the federal government”), *available at* [http://www.techtransfer.iastate.edu/documents/filelibrary/images/pdf/IP\\_Handbook\\_081104162623.pdf](http://www.techtransfer.iastate.edu/documents/filelibrary/images/pdf/IP_Handbook_081104162623.pdf) (last visited Jan. 24, 2011).

Stanford’s claim to a vesting of “perfect” title is also refuted by its own practices. The public record discloses several instances in which Stanford collaborated with *Cetus co-inventors* on federally-funded inventions, after which the *Cetus co-inventors* assigned

their rights to Cetus.<sup>12</sup> Stanford also shares ownership with other private entities of numerous patents governed by the Bayh-Dole Act.<sup>13</sup> Even with respect to the patents at issue in this case, Stanford did not treat the invention as vesting directly in Stanford. Rather, it did what it always does: it sought assignments from the named co-inventors. J.A. 42.<sup>14</sup> None of these actions would make sense if the Bayh-Dole Act “vested” universities with “perfect” title.

Accordingly, Stanford’s university *amici* (unlike Stanford itself) concede that the Act does not displace the rights of private co-inventors who are not “conducting research under a federal funding agreement.” AAU Br. 23. That concession is irreconcilable with Stan-

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<sup>12</sup> *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1133 (Fed. Cir. 2003) (“The inventors are Francis P. McCormick and Michael A. Innis of Cetus Corporation, and Gordon M. Ringold of Stanford University. Berlex acquired the Cetus rights in 1991.”); *see also*, *e.g.*, U.S. Patents Nos. 4,684,623, 4,764,465 (listing Cetus and Stanford as assignees of inventions made using government funds).

<sup>13</sup> *See, e.g.*, U.S. Patent Nos. 7,778,386 (co-assigned to General Electric), 6,156,878 (co-assigned to Becton Dickinson).

<sup>14</sup> The same is true of the patents listed in notes 12 & 13 above: Stanford obtained assignments, recorded them in the Patent Office, and prosecuted the patent applications as an assignee of the inventors’ rights. When Stanford licensed the claimed invention to the government, it did so only in the name of the co-inventor(s) who assigned to Stanford, not the co-inventors who assigned to a private third party. *Compare, e.g.*, U.S. Patent No. 7,778,386 (identifying four co-inventors, three of whom assigned their interests to General Electric) *with* Stanford’s License to NIH of U.S. Patent No. 7,778,386 (listing only the one co-inventor who assigned his interests to Stanford). Respondents will request leave to lodge the relevant license and assignment documents under Rule 32(3).



ford’s argument that the Act “vests” perfect title to all federally-funded inventions in the contractor. It also suffices to affirm the judgment here because, when the invention was conceived at (and transferred to) Cetus, Holodniy was not “conducting research under a federal funding agreement” subject to the Act, even according to Stanford itself. *See supra* pp. 6-7 & n.1.<sup>15</sup>

#### 4. Stanford’s efforts to read the Act as a vesting statute fail

Stanford proposes three reasons for reading the Act as applying beyond “inventions of the contractor.” None is persuasive.

*First*, Stanford suggests (Pet. Br. 33-34) that because “th[e] right to retain title is conditioned on compliance with precisely defined procedural requirements,” the absence of other “prerequisites to securing title” can be inferred under *expressio unius*. Not so. The Act enumerates “precisely defined procedural requirements” for *retaining* title, permitting the inference that there are no other requirements for *retaining* title. But that simply begs the question what it means to “retain title,” a question not answered by replacing “retain” with “secur[e].” Pet. Br. 34. Just as Rule 23’s

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<sup>15</sup> AAU’s attempt to argue that this case proceeds “on the premise” that the invention was conceived after 1989 (AAU Br. 18) fails. Although the Federal Circuit believed that the terms of the VCA would have applied to inventions conceived after Holodniy left Cetus (Pet. App. 15a), it did not disturb the district court’s finding that the invention was “conceived during Holodniy’s consultancy at Cetus” (*id.* 58a). AAU’s effort to relitigate the timing of conception is particularly inappropriate given Stanford’s refusal to state when *it* believed the invention was conceived. *See* Pet. App. 58a n.7.

enumeration of precise requirements for maintaining a class action does not exempt a class plaintiff from compliance with the other Rules of Civil Procedure, the Bayh-Dole Act's enumeration of procedures to "retain" rights does not exempt a federal contractor from the ordinary steps required for obtaining whatever rights it wishes to "retain."

*Second*, Stanford suggests that because other sections of the Bayh-Dole Act use the words "acquire" and "receive," the right to retain in Section 202(a) should also be understood as a right to "acquire" or "receive" title. Pet. Br. 36. But ordinary canons of construction *discourage* attributing the same meaning to different phrases in different parts of the same statute. *See Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 454 (2002). Moreover, the other provisions extend beyond retention of title under Section 202(a). For instance, Section 203(a)'s provision that the government may "march-in" (*i.e.*, compel licensing) applies not only where rights have been "retained" under Section 202(a), but also where a contractor receives an assignment of an invention from a government co-inventor (§ 202(e)) or where, as Section 203(a) itself suggests, a small business or nonprofit is the "assignee or exclusive licensee of a subject invention." Section 203(a)'s reference to "acquir[ing] title under this chapter" thus ensures that the government's march-in rights apply in each situation.

Stanford's reliance on Section 204 (Pet. Br. 36) is similarly misplaced. Section 204 requires small businesses and nonprofits that "receive[]" title to a subject invention to employ U.S. industry in commercializing it. That provision applies even more broadly than Section 203(a) to subject inventions "receive[d]" in *any* way, not just "under this chapter" and certainly not just through retention under Section 202(a). Thus, rights

received through assignment, constructive trust, corporate succession, bankruptcy, bequest, or other means are still subject to the requirements of Section 204 if “receive[d]” by a nonprofit or small business. The use of a broader term is thus natural and meaningful and in no way suggests that a right to “retain” title to an “invention of the contractor” means anything other than what it says. *See Connecticut Nat’l Bank v. Germain*, 503 U.S. 249, 253-254 (1992) (the “cardinal canon” of statutory interpretation is “that a legislature says in a statute what it means and means in a statute what it says there”).

*Third*, Stanford argues that the contractor’s right to “retain title” must really be a right to “take title” because Section 202(d) supposedly places inventors at the “back of the line” when it comes to ownership rights. Once again, however, Stanford ignores both the text and context of the statute. Section 202(d) does place inventors at the back of the line, but only as to inventions “of the contractor,” *i.e.*, inventions that have *already been assigned* by the inventor to the contractor pursuant to established principles, most likely under a patent policy or an employment agreement that effectuates such an assignment. *See supra* p. 34. Section 202(d) nowhere suggests that the Act governs the rights of inventors as to inventions that have not become inventions “of the contractor.” *See, e.g., Fenn v. Yale Univ.*, 393 F. Supp. 2d 133, 141-142 (D. Conn. 2004) (“[T]he 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.”).

Section 202(d) simply provides that the government may, on occasion, allow an inventor to retain title after the contractor-assignee has disclaimed its rights.

Section 202(d) governs the rather ordinary case in which a contractor is uninterested in an invention and so allows the rights it obtained to revert to the assigning inventor-employee—a result contemplated by Stanford’s own policies. *See* Stanford Research Policy Handbook 5.1.1.A.4 (“If the University cannot, or decides not to, proceed in a timely manner to patent and/or license an invention, it may *reassign ownership* to the inventors upon request to the extent possible under the terms of any agreements that supported or related to the work.” (emphasis added)). The provision requiring the sharing of royalties with inventors (35 U.S.C. § 202(c)(7)(B)) is similarly understandable in the context of “inventions of the contractor,” as to which the inventor has already assigned away his ownership right and, *a fortiori*, his right to a royalty; Section 202(c)(7)(B) restores that right in part.

### C. Legislative History Does Not Help Stanford

Because neither the statutory text nor the facts of this case support its desired outcome, Stanford devotes fully one-fifth of its brief to legislative history. Pet. Br. 2-10, 38-42. But neither Stanford nor its *amici* identify a single statement addressing third-party rights, let alone suggesting that the Act automatically divests them. The lesson from this history is simple: Congress intended no such result.

The legislative record repeatedly voices concern over the “ineffective patent policies” of *government agencies*, which together created a complicated jumble of statutes, regulations, and “reams of unnecessary bureaucratic redtape.” Senate Report 2, 21. Congress responded with “a uniform patent policy” that would “apply to all agencies.” *Id.* 15; *see also id.* 16, 26. In Stanford’s words, the legislative record “ma[kes] clear

that *the Government* would ‘relinquish patent rights that would encourage and stimulate private industry to develop discoveries into products available to the public.’” Pet. Br. 39 (quoting 126 Cong. Rec. 1796 (1980) (statement of Sen. Bayh)) (emphasis added).

The Act accordingly limited the circumstances in which *the government* claimed rights in inventions that otherwise belonged to the contractor. By “reduc[ing] Government interference,” Congress aimed to foster greater public/private cooperation. 126 Cong. Rec. 1992 (statement of Sen. Dole) (internal quotation marks omitted); *see also id.* 29,895 (statement of Rep. Kastenmeier), 30,364 (statement of Sen. Bayh), 30,365-30,366 (statement of Sen. Dole); Senate Report 22, 24, 29-30. Those in favor of the Act endeavored to turn an “adversarial” relationship between government and contractor into a productive, cooperative one. 126 Cong. Rec. 1992 (statement of Sen. Dole). Opponents saw it as a “radical, far-reaching giveaway[.]” of public property to private entities. *Id.* 8739 (statement of Sen. Long); *accord* H.R. Rep. No. 96-1307, at 29 (1980) (dissenting views of Rep. Brooks). But no legislator suggested that the statute would affect the ordinary laws of ownership and assignment that determine the rights of third parties not receiving government funds.<sup>16</sup>

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<sup>16</sup> Stanford cites a statement by Senator Kennedy that nowhere indicates a belief that small businesses and universities need “undivided” or “indisputable” title as against other *private* entities to secure venture capital. 126 Cong. Rec. 1799 (cited at Pet. Br. 52). Rather, like all other legislators who commented on the Act, Senator Kennedy focused on the benefits of giving small businesses and universities increased rights as against the *government*. *Id.*

Thus, while some legislative materials contain broad language referring to “automatically grant[ing] small businesses and nonprofits title to inventions” (Senate Report 36), there is no basis to conclude that such statements were made with an eye toward the scenario presented by this case. Rather, Congress’s concern was for inventions that already otherwise belonged to the contractor. Indeed, the Senate Report’s section-by-section analysis clarifies that, under Section 202(a), funded entities may elect “ownership of *their inventions*,” *i.e.*, inventions “of the contractor.” Senate Report 31 (emphasis added).

Stanford may be correct that “[n]o Senator in favor of S. 414 suggested that an assignment from the inventor was necessary for universities and small businesses to ‘retain’ patent rights” (Pet. Br. 39), but the point is that no legislator mentioned inventor assignments *at all*. If any inference can be drawn from this silence, it is that no legislator saw a need to reassert a basic point of law that nobody proposed to change. Rather, the legislation addressed solely whether the contractor could “retain” rights *already obtained* against claims by the federal government.

Relying on written testimony from a single witness from the National Science Foundation, the government asserts that, under the preexisting regime, “[a]n institution’s failure to obtain an effective assignment of rights from the researcher ... could compromise the allocation of rights and obligations under [an Institutional Patent Agreement (IPA)]” and that “Congress enacted the Bayh-Dole Act to address these shortcomings.” U.S. Br. 4-5. The testimony does not support the government’s argument. The NSF witness testified that “NSF has negotiated recoupment agreements in a limited number of instances when patent rights were left

with an individual inventor rather than a grantee institution.” *Government Patent Policy Act of 1980: Hearing on H.R. 5715 Before the Subcomm. on Science, Research and Technology of the H. Comm. on Science and Technology*, 96th Cong., 2d Sess. 80 (1980). The witness did not explain why patent rights “were left with an individual inventor” or that the witness (to say nothing of Congress) even viewed that as problematic, let alone a “shortcoming” in the pre-Bayh-Dole regime that the Act was intended to cure. One ambiguous statement by one witness before one subcommittee of one Chamber of Congress in no way suggests that Congress as a whole intended fundamentally to recast the rules of patent ownership. *See Regan v. Wald*, 468 U.S. 222, 237 (1984).

In fact, the Bayh-Dole Act incorporated many aspects of the IPA regime because, as Senator Bayh makes clear (Bayh Br. 7), “[t]he IPA programs proved extremely successful.” The form agreement for federal grants under the Act is strikingly similar to IPA clauses that obligated grantees to require non-clerical workers “promptly [to] report and assign all subject inventions.” Federal Council for Science and Technology, *Report on Government Patent Policy* 330-332, 342-343 (1976); *cf.* 37 C.F.R. § 401.14(f)(2) (obliging contractors to “require, by written agreement, ... employees, other than clerical and nontechnical employees, to ... execute all papers necessary to file patent applications on subject inventions and to establish the government's rights”). There is no reason to presume, as the government does, that Congress viewed inventor assignments as a problem with the IPA system, rather than part of a “successful” program that the Act took as accepted background in crafting a strikingly similar system. Bayh Br. 7; AIPLA Br. 7-18. The rational infer-

ence is that, to the extent Congress was aware of the requirement for inventor assignments to contractors, it left that requirement in place.

In the end, as another of Stanford's *amici* admits, the issues that Stanford raises here are simply "different" from those that "existed in the pre-Bayh-Dole regime": namely, "whether the Government, on the one hand, or the federally funded contractor, on the other hand, would ultimately obtain title to the invention." BayhDole25 Br. 7. Congress addressed *that* concern by creating a framework for settling the respective rights of government and contractor. Nothing in the Act or its legislative history suggests that Congress sought to address the "different" issue of third-party rights obtained through inventor assignment.

#### **D. Stanford's Position Raises Serious Constitutional Questions The Court Should Avoid**

The constitutional avoidance canon provides another reason to reject Stanford's attempt to rewrite the Act. "If one of [two plausible constructions] would raise a multitude of constitutional problems, the other should prevail." *Clark v. Martinez*, 543 U.S. 371, 380-381 (2005). This rule rests upon the "reasonable presumption that Congress did not intend the alternative which raises serious constitutional doubts," and it is properly invoked to avoid consideration of the constitutional question. *Id.* at 381. Stanford's reading of the Bayh-Dole Act raises two related and substantial constitutional questions: (1) whether the Act works an uncompensated taking; and (2) whether the Act provides sufficient process to ensure that no such taking occurs.

The takings problem raised by a right to "take title" is manifest. "The government has no more power



to appropriate a man's property invested in a patent than it has to take his property invested in real estate; nor does the mere fact that an inventor is, at the time of his invention, in the employ of the government transfer to it any title to or interest therein." *Solomons v. United States*, 137 U.S. 342, 346 (1890). Thus, as in the case of a federal employee, the mere fact that some federal funding is involved does not allow the government to divest a third party of its otherwise valid right to an invention, much less transfer it to a different private party.

The facts of this case demonstrate the seriousness of the constitutional problem. Cetus gave Holodniy valuable scientific expertise and proprietary materials in exchange for an assignment of any resulting invention. When the claimed invention was conceived in October 1989, the settled effect of the VCA was to pass title to Cetus. Pet. App. 18a, 59a. Had nothing else occurred, there would be no question as to Cetus's and Roche's right to practice the invention. Stanford's argument—that a federal statute transforms what was validly owned by Cetus one day into a possession of Stanford's the next, without any compensation to Cetus—is the essence of a takings violation. See *Eastern Enters. v. Apfel*, 524 U.S. 498, 523 (1998) (“It is against all reason and justice’ to presume that the legislature has been entrusted with the power to enact ‘a law that takes *property* from A. and gives it to B[.]” (quoting *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) (Chase, J.))).

It is no answer to say, as the government does, that the property never belonged to Cetus because Holodniy could only transfer a contingent right. U.S. Br. 19. In October 1989, by which time the invention was conceived and assigned to Cetus (Pet. App. 57a-58a), it

could not have been a “subject invention” under any reading of the Act because it had not been “conceived or first actually reduced to practice *in the performance of work under a funding agreement*” (35 U.S.C. § 201(e) (emphasis added)). Rather, all the work was done at Cetus without use of Bayh-Dole grants. To say that Cetus’s title at that time was “contingent” on whether Stanford *subsequently* used federal funds in clinical trials and *even later* made a Bayh-Dole election simply reinforces the constitutional difficulty of a retroactive divestiture of private property through Stanford’s discretionary acts.

Perhaps recognizing this unacceptable consequence of its argument, Stanford asserts, in very careful phrasing, that Holodniy worked on “the federally funded research” before going to Cetus. Pet. Br. 17. But it cites no evidence of work on *the inventions at issue* before Holodniy arrived at Cetus, and there is none. In fact, Holodniy admitted that he only began working on the invention in September 1989 (Supp. J.A. 15) and that he had no experience “in th[e] field” of PCR-based quantitation before arriving at Cetus (J.A. 57). Below, Stanford insisted that federally-funded inventive work did not begin until July 1990. *See supra* pp. 6-7 & n.1. The government, for its part, takes no position on *when* Holodniy performed work funded by the “two federal grants.” U.S. Br. 17.

Because there is no evidence of any federally funded work until after the invention was conceived, nor of the amount of such funding, Stanford’s position must be that use of even \$1 of federal funding in reducing an invention to practice would work a retroactive confiscation of intellectual property conceived entirely using private funds and already assigned to a third party for valuable consideration. *See* Pet. 12 (arguing

that the Act applies to inventions “conceived earlier without using government funding” but “later reduced to practice ... using government funding”); Pet. Br. 32 (“[T]he quantity of federal funding is not dispositive.”). That outcome, threatened here, is at least constitutionally questionable.

Stanford’s reading also raises a serious question regarding due process, because it provides no means for a third party to challenge the contractor’s election. The Act envisions no notice to a third-party assignee—even if the contractor knows that the assignee exists, as Stanford’s agents Merigan, Holodniy, and Katzenstein knew of Cetus. Nor does it provide an opportunity to argue that an invention is not a “subject invention” covered by the Act. These questions are easily avoided by reading the statute to mean what it says: it grants contractors a right to “retain” inventions “of the contractor,” not a right to “take title” to inventions that belong to someone else under the ordinary rules of patent ownership.

#### **E. Stanford’s Policy Arguments Miss The Mark**

Stanford and its *amici* extol the wisdom of the Bayh-Dole Act at length, and Roche readily agrees. The pre-1980 system *was* ill-conceived: the government often ended up with rights to inventions it had neither the incentive nor the means to commercialize. The Bayh-Dole Act remedied that situation by extracting the government from the system almost entirely. *See* Pet. Br. 9 (Act addressed the problem that “patents gathered dust on *Government shelves*” (emphasis added)); U.S. Br. 25 (Congress viewed universities as “better positioned *than the federal agencies* to develop federally funded inventions” (emphasis added)).

Stanford goes astray, however, in suggesting that abrogating *third-party* ownership rights would advance Congress's policies. Of course, even if Stanford's policy arguments were well-taken, the Act must be limited to the scope that Congress gave it. But Stanford's arguments are not well-taken. The American system of intellectual property ownership functions smoothly under long-established rules of ownership and assignment, which apply whether an invention is federally-funded or not. The Court should refuse Stanford's effort to knock down and rebuild that system at its foundations based on a rule of "vesting."

**1. Inventions, both federally-funded and not, are successfully commercialized without divesting third parties of their intellectual property**

Stanford and its *amici* argue that, unless they prevail, commercialization of innovative products will be impeded by the hypothetical risk "that an inventor, at some point, may have inadvertently or intentionally entered into an undisclosed agreement with an unknown third party." Pet. Br. 46; *see also* U.S. Br. 30; AAU Br. 34. Stanford forgets that such risks are not unique to federal contractors, yet private investment in innovation continues apace, accounting for the bulk of the investment in research and development in this country. *See* National Science Board, Science and Engineering Indicators 2010, at 4-4 & 4-14 (2010) ("The business sector itself provided an estimated \$268 billion of funding for R&D in 2008, or 67% of the U.S. total."). That economic activity rests not on any special vesting statute or on disregarding settled rules of contract and patent law, but rather on enforcing them. AIPLA Br. 29-30.

Stanford's argument also rings hollow in light of the Act's undisputed success notwithstanding the common understanding that it does not affect rights of parties other than the government and federal contractors. *See, e.g., Fenn*, 393 F. Supp. 2d at 141-142. Universities have thus designed their patent policies on the assumption that inventions—even federally-funded inventions—vest in the inventor and must be assigned to the university in writing. *See supra* p. 34. And universities know how to obtain effective assignments of their employees' future, as-yet-unconceived inventions. *E.g.*, MIT Patent Policy (Apr. 14, 2010), *available at* <http://web.mit.edu/tlo/www/downloads/doc/IPIA.doc> (“I will disclose promptly to and assign to, and I hereby assign to, M.I.T. all rights to all inventions ... conceived, invented, reduced to practice, or authored by me, either solely or jointly with others.”); Cal. Inst. of Tech. Patent & Copyright Agreement (Dec. 30, 2003) (“I agree to assign, and hereby do assign, to the Institute all such inventions and copyrightable material[.]”), *available at* <https://www.ogc.caltech.edu/Forms/documents/patentagreement>. That Stanford failed to do so here does not suggest that the system is fraught with uncertainty. On the contrary, it shows that universities are in firm control of their assignment policies. Their incentive to write effective contracts, combined with researchers' incentive to deal cautiously with their employers, has produced virtually no litigation of this type in 30 years of experience under the Act. The Act's continued success is not contingent on the Court rewriting it now.<sup>17</sup>

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<sup>17</sup> It is hard to know what to make of AAU's protest that, “if Roche's advice is followed” and universities obtain effective as-

Indeed, the fear of secret assignments dating back “years” (Pet. Br. 28; U.S. Br. 30) has long been addressed—for privately-funded and federally-funded inventions—by 35 U.S.C. § 261, which voids unrecorded assignments as against subsequent bona fide purchasers. Accordingly, even if a university cannot secure an effective assignment in advance, it can protect itself against any unknown and ancient assignments by recording a subsequent assignment for value. This rule functions perfectly well in private settings to provide the certainty of title necessary for licensing and commercialization. Stanford cites no reason why federally-funded inventions require a different regime.

Of course, Section 261 does not protect Stanford here because, as both courts below correctly held, Stanford had notice of Holodniy’s assignment, which he signed within the scope of his employment after being sent to Cetus by Merigan to do Stanford’s business. Pet. App. 17a, 63a-64a. Stanford’s hypotheticals (*e.g.*, Pet. Br. 46-47) are equitably compelling precisely because they lack this feature. This Court has not granted certiorari to review this state-law holding of notice, which is in any event consistent with federal law and reflects the application of standard agency principles. *Curtis, Collins & Holbrook Co. v. United States*, 262 U.S. 215, 222-223 (1923).

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signments from their employees, then “the next case with facts like this one” could be resolved in the university’s favor. AAU Br. 35. AAU seems to be bemoaning the fact that contractual language matters. It is in no way “opportunism” or lacking in “principle” (*id.*) to insist that contracts like the VCA and statutes like the Bayh-Dole Act be enforced according to their terms, while recognizing that a different case with different contracts might yield a different result.

Ultimately, Stanford's primary objection appears to be that it does not trust its own employees. But *every* employer runs the risk that an employee's actions may have undesired consequences. Nothing in the legislative history suggests that Congress sought to treat employees of federal contractors like children or thieves or to relieve contractors of the ordinary consequences of their agents' actions. Employers protect against such risks through employment contracts or, if need be, through suits for breach of fiduciary duty, unjust enrichment, or other tort or equitable claims. At least two universities have brought such claims against former researchers. See *St. John's Univ. v. Bolton*, 2010 WL 5093347, \*40-41 (E.D.N.Y. Dec. 10, 2010) (denying motion to dismiss university's contract and tort claims against former researchers); *Fenn v. Yale Univ.*, 2005 WL 327138, \*6 (D. Conn. Feb. 8, 2005) (ruling that former faculty member obtained a patent "through fraud, civil theft, and breach of fiduciary duty" and ordering him to reassign the patent to Yale); AIPLA Br. 29.

## **2. Stanford's reading would chill innovative collaboration and commercialization of inventions**

Rather than creating certainty, Stanford's position would foster uncertainty by creating a highly unusual and unpredictable exception to ordinary ownership rules. Under Stanford's reading, any collaboration will raise a risk of loss of intellectual property rights if, unbeknownst to one collaborator, the other makes use of even a modicum of federal funds. The likely result would be that companies that were dissuaded from collaborating under the pre-Bayh-Dole regime due to fear that the *government* would take their intellectual prop-

erty will be similarly dissuaded by the identical fear that *universities* will do so. *See* Senate Report 21 (reporting that companies “are reluctant to use university research facilities because they fear that any resulting patent rights will be ‘tainted’ if the university is also receiving Federal support in related research”).

Stanford suggests that Cetus could have protected itself had it “approach[ed] Stanford” about the matter (Pet. Br. 53 n.21) rather than relying on Stanford’s agent Holodniy. But it is not clear that any agreement from Stanford would have protected Cetus under Stanford’s view of the law, in which contracts are swept away by force of a federal “vesting” statute that *forbids* universities from making assignments without government approval. *See* 35 U.S.C. § 202(c)(7)(A). It is hard to envision what contractual assurance would survive Stanford’s all-consuming vision of the Bayh-Dole Act. Stanford’s position would thus chill collaboration between industry and academy for fear of an unavoidable retroactive divestiture of intellectual property.

Moreover, contrary to Stanford’s assertion, there is no “certainty” to be had from a rule that automatically vests title to employee inventions in the contractor. Instead, the uncertainty would surface in questions about individual inventors’ employment status, a state-law question with easily as many “vagaries” as the “private contract law” Stanford derides. Pet. Br. 55. In California, employee status turns on a non-exhaustive eleven-factor test; written agreements are not determinative. *See S.G. Borello & Sons, Inc. v. Department of Indus. Relations*, 769 P.2d 399, 403-405 (Cal. 1989). Thus, one could not predict with “certainty” how Stanford’s “vesting” rule would apply to research by undergraduates, graduate students, faculty on sabbatical or leave of absence, volunteer researchers



with day jobs elsewhere, or university employees with outside employment or consulting arrangements. *See, e.g., University of Pittsburgh v. Townsend*, 2007 WL 2263079, \*2, 20 (E.D. Tenn. Aug. 3, 2007) (ruling that assignment in inventor's consulting agreements, not the Bayh-Dole Act, governed patent ownership), *aff'd*, 542 F.3d 513 (6th Cir. 2008).

Finally, as this case demonstrates, depriving a third party of its valid rights to practice an assigned invention would burden commercialization of innovative products. Stanford filed its parent application in May 1992, but apparently took no steps to commercialize the claimed inventions for the following eight years. There is no evidence that Stanford attempted to partner with private producers, raise venture capital, or license the invention. Roche, by contrast, developed, obtained FDA approval for, and commercialized a product that has helped millions of HIV patients and has been used in numerous U.S. hospitals and clinics—including Stanford University Hospital. In 2000, when Stanford threatened legal action if Roche continued to make and sell its products, Roche had already invested heavily in the product, creating manufacturing and distribution jobs in this country. Congress did not enact the Bayh-Dole Act to create a new class of non-practicing entities to tax commercial development by American industry and increase expenses to patients and the health-care system.

### **3. The government's rights are protected**

Stanford also suggests that the contractor must obtain clear, certain, and perfect title in order to protect the government's rights. Pet. Br. 48-54. But the government's expectations arising from federal grants are protected in the exact way expectations are always

protected when one party pays another for certain promises—*by contract*. The Bayh-Dole Act ensures that the government’s rights are protected through provisions in a funding agreement that are the *quid* for the federal grant *quo*. The Act does not impose obligations or responsibilities—much less forfeiture of intellectual property rights—on strangers to that agreement.

Accordingly, under the heading “Contractor Action to Protect the Government’s Interest,” the form contract in the Act’s implementing regulations contains an express promise by the contractor

to execute or to have executed and promptly deliver to the Federal agency all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the contractor elects to retain title, and (ii) convey title to the Federal agency when requested ... and to enable the government to obtain patent protection throughout the world in that subject invention.

37 C.F.R. § 401.14(f)(1). The contract also contains related obligations regarding contractor employees, including a promise that the contractor “require, by written agreement, its employees ... to execute all papers necessary to file patent applications on subject inventions and to establish the government’s rights in the subject inventions.” *Id.* § 401.14(f)(2). NIH guidance for grant recipients specifically directs grantees to “review existing agreements with third parties and revise them, as appropriate, to ensure they are consistent with the terms and conditions of their NIH grant awards.” NIH Grants Policy Statement ¶8.2.4, *avail-*

*able at [http://grants.nih.gov/grants/policy/nihgps\\_2010/nihgps\\_ch8.htm#\\_Toc271264954](http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch8.htm#_Toc271264954).*

The possibility that a contractor might fail to secure exclusive rights to an invention is no different from other possible actions by which a contractor might deprive the government of patent rights, including failure “to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent,” without telling the government. 37 C.F.R. § 401.14(f)(3). A contractor could also deprive the government of its rights by publishing the invention and failing to file a timely patent application. 35 U.S.C. § 102(b). In any such case, the remedy is not to reincarnate the patent that the contractor failed to secure, but for the government to sue for breach of contract including, if appropriate, reclaiming the amount funded to put the taxpayers in the same position they would have occupied had no funding been granted at all.

Of course, these issues are not presented here. Stanford retains the title it obtained from Merigan and Katzenstein, has delivered a paid-up license to the government, and remains an available target for march-in rights. Contrary to Stanford’s unsupported assertion, Roche cannot prevent Stanford from “licensing to other parties” (Pet. Br. 46); Stanford and the government can use and license the claimed inventions without accounting to Roche. 35 U.S.C. § 262. This provides only greater reason to prefer contract remedies to the “vesting” of “perfect” title in the contractor—in some cases, such as this one, vesting of title in the contractor would create no advantage for the public or government whatsoever.

## II. STANFORD'S OTHER ARGUMENTS ARE NOT PROPERLY BEFORE THE COURT AND LACK MERIT

Stanford closes with two arguments on which it did not seek certiorari and that are accordingly not before this Court. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). They lack merit in any event.

1. Stanford argues that the Bayh-Dole Act should be presumed to impose a status “analogous to the ‘hired to invent’ doctrine” on all Stanford employees—a status that, Stanford suggests, “vests [title] as an original matter in the employer.” Pet. Br. 57. This argument both misunderstands and misapplies the “hired to invent” doctrine.

First, as demonstrated by the very case Stanford cites, the “hired to invent” doctrine follows ordinary patent principles and vests title in the *inventor*, subject to an assignment. In *Standard Parts*, the question was whether the Court should require the inventor to “*assign and transfer* to the company the legal title to the letters patent” based on the inventor’s employment contract. 264 U.S. at 59 (emphasis added). After reviewing the terms of employment, the Court held that such an assignment was required because “the invention of a specific thing ... was the object and effect of Peck’s contract.” *Id.* at 57. The Court thus ruled only that the inventor was obliged to assign the title he was still holding to his employer; it neither suggested that title “vests as an original matter in the employer” nor determined the effect on any otherwise valid assignment to a third party.

Second, the “hired to invent” doctrine is only a default rule about the interpretation of employment contracts that contain no express terms regarding assignments of intellectual property. Accordingly, the out-

come can vary considerably based on the specific employment relationship. *See, e.g., Hapgood*, 119 U.S. at 229, 233 (even employee who agreed to “devote his time and services to devising improvements in, and getting up and perfecting, plows adapted to the general trade of the corporation” was not obligated to assign the invention to his employer). It makes no sense to apply the doctrine where—as here—the disposition of intellectual property is the subject of express agreements among the relevant parties. And in any event, the government’s contracts *with its own employees* do not vest title automatically in their employing agency. *See supra* pp. 31-33. Stanford does not explain why “unique federal interests” would impose a different rule on those supposedly “hired to invent” by Stanford compared to those supposedly “hired to invent” by the government itself.

2. Stanford also invokes “equities,” suggesting that Roche “slept” on its rights and that there are “questions about the enforceability” of Holodniy’s VCA. Pet. Br. 59. Any enforceability questions were resolved when both courts below rejected Stanford’s arguments under California law. Pet. App. 21a-22a, 54a-58a. And the “equities” of this case do not favor Stanford.

When Holodniy arrived at Cetus, he had—by his own admission—no skill whatsoever in the art of PCR. His development of the PCR-based HIV assay that constitutes his primary inventive contribution and that lies at the heart of the patents-in-suit relied crucially on the expertise of Cetus scientists and Cetus’s proprietary materials. In exchange, Holodniy signed the VCA in his capacity as an employee and agent of Stanford, giving Stanford notice thereof under California law. Nonetheless, when Stanford elected to claim title to the inventions for itself, it did not so much as notify Cetus;

its first notice of reliance on the Bayh-Dole Act was at summary judgment in this infringement suit. *See supra* pp. 3-8, 11-12.

Although Roche (unlike Stanford) did not seek a patent monopoly, it did not sleep on its rights. To the contrary, Roche has commercialized PCR-based HIV testing kits for fifteen years in the open market. It is hard to see anything “equitable” in the argument that a university may “take title” from—and then sue for infringement—a company that critically contributed to an invention, obtained an otherwise valid assignment of rights from the university’s agent, and then designed, manufactured, and distributed a product advancing medical treatment for many ailing Americans.

#### CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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