

No. 09-1159

IN THE
Supreme Court of the United States

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

v.

ROCHE MOLECULAR SYSTEMS, INC., ET AL.,
Respondents.

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

BRIEF OF PETITIONER

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QUESTION PRESENTED

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

PARTIES TO THE PROCEEDING

The parties to the proceeding in the Court of Appeals for the Federal Circuit were Petitioner Board of Trustees of the Leland Stanford Junior University and Respondents Roche Molecular Systems, Inc.; Roche Diagnostics Corporation; and Roche Diagnostics Operations, Inc.

CORPORATE DISCLOSURE STATEMENT

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

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OPINIONS BELOW

The decision of the United States Court of Appeals for the Federal Circuit, Pet. App. 1a-28a, is reported at 583 F.3d 832. The opinion of the United States District Court for the Northern District of California on the issue of Petitioner's standing to sue for patent infringement, Pet. App. 29a-74a, is reported at 487 F. Supp. 2d 1099.

JURISDICTION

The Court of Appeals issued its decision on September 30, 2009. The Petition for Panel Rehearing and Rehearing *En Banc* was denied on December 22, 2009. Pet. App. 75a-77a. The petition for a writ of certiorari was filed on March 22, 2010, and granted on November 1, 2010. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The text of the University and Small Business Patent Procedures Act of 1980, commonly known as the Bayh-Dole Act, 35 U.S.C. §§ 200-212, is set forth in the appendix to this brief.

STATEMENT

This case turns on construction of the Bayh-Dole Act's provisions governing ownership of inventions arising from federally funded research. That Act was the product of decades of experience with prior statutory regimes. It creates a uniform hierarchy in which federal contractor grantees are given the first right to perfect title in the invention. The federal Government holds explicit powers to enforce the statute's objectives, including itself receiving title if the contractor elects not to or defaults in ways specified in the statute. Individual inventors may get

title only in specified circumstances, if it is not retained by either the contracting institution or the Government.

A. The State of the Law Before the Bayh-Dole Act

1. Prior to passage of the Bayh-Dole Act in 1980, the Government had no uniform policy to determine the ownership of patents arising out of federally supported research. Instead, a “mélange of 26 different agency policies” governed who acquired title to Government-funded inventions. H.R. Rep. No. 96-1307, pt. 1, at 3 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6462.¹ Although each of the twenty-six policies differed in certain specifics, they generally followed one of two approaches. One approach favored vesting of title in the Government, and the second favored leaving title in the private entities that performed the federally funded research, subject to the Government’s retention of a license to itself practice the patent.

The title approach was motivated by a view that the public interest was best served by Government ownership of patents resulting from federally funded research. “Where patentable inventions are made in the course of performing a Government-financed contract for research and development, the public interest requires that all rights to such inventions be assigned to the Government and not left to the

¹ A breakdown of most agencies’ policies can be found in Subcomm. on Domestic and Int’l Scientific Planning and Analysis, H. Comm. on Sci. & Tech., 1 *Background Materials on Government Patent Policies: Presidential Statements, Executive Orders, and Statutory Provisions* 61-85 (1976).

private ownership of the contractor.” Francis Biddle, Att’y Gen., 1 *Investigation of Government Patent Practices and Policies: Report and Recommendations of the Attorney General to the President* 4 (1947). Several agencies followed such a title policy by statute or regulation. *See, e.g.*, Federal Non-nuclear Energy, Research, and Development Act (“FNERDA”) of 1974, Pub. L. 93-577, § 9, 88 Stat. 1878, 1887-88. According to the Federal Circuit, these statutes and regulations clearly “divested” inventors or other private entities “of all [their] interest.” *FilmTec Corp. v. Hydranautics*, 982 F.2d 1546, 1553 (Fed. Cir. 1992) (applying FNERDA to bar an inventor’s assignment).

The license approach stemmed from a preference that the Government acquire only those rights necessary to enable it to practice the invention rather than take full ownership of patents, on the view that leaving ownership with the contractor was the most effective way to advance innovation and achieve utilization and enforcement of patent rights. *See* Nat’l Patent Planning Comm’n, *Government-Owned Patents and Inventions of Government Employees and Contractors*, reprinted in 23 Chem. & Eng’g News 438, 442 (1945). For example, the Department of Defense followed a license policy, contending that it was the only way to ensure that the best contractors would participate in the development process. *See Science and Technology Research and Development Utilization Act: Hearing Before the Subcomm. on Sci., Tech., & Space, of the S. Comm. on Commerce, Sci. & Transp.*, 96th Cong. 364-65 (1979) (statement of Dale W. Church, Deputy Under Secretary of Defense for Acquisition Policy) (hereinafter “Church statement”). Still, the license

policy recognized the Government's ultimate control over inventions that resulted from federal funding, because it conferred title on the contracting entity, not the inventor, and demanded that the entity grant the Government an irrevocable paid-up license (*i.e.*, without payment of any additional federal funds) as a condition of retaining title. *See Mead Corp. v. United States*, 490 F. Supp. 405, 407-08 (D.D.C. 1980) (noting that the inventor only had title by virtue of the contractor's policies, *cf.* 32 C.F.R. § 9.107-2(b), ¶ (e) (1961)), *aff'd*, 652 F.2d 1050 (D.C. Cir. 1981).

While the policies differed in approach, each was premised upon the pre-eminent right of the Government to establish ownership of intellectual property created by public investment. They differed only on how best to use that right in furtherance of the public interest. Advocates of a title policy argued that the public was entitled to the fruits of its investment. *See Science and Technology Research and Development Utilization Act: Hearing Before the Subcomm. on Sci., Tech., & Space of the S. Comm. on Commerce, Sci. & Transp.*, 96th Cong. 397 (1979) (statement of Adm. Hyman G. Rickover, Deputy Commander for Nuclear Propulsion, Department of the Navy). Those in favor of a licensing policy contended that private ownership was necessary both to encourage industry to participate in research, and to ensure the commercialization and general availability of the research results. *See Church statement, supra*, at 368.

2. The debate over which approach to use continued for more than thirty years. From 1945 to 1980, numerous congressional reports studied the issues, and numerous bills were proposed to govern

who owned the intellectual property that resulted from federally funded research. *See* Subcomm. on Domestic and Int'l Scientific Planning and Analysis of the H. Comm. on Sci. & Tech., 2 *Background Materials on Government Patent Policy: Reports of Committees, Commissions, and Major Studies* (1976); James A. Dobkin, *Patent Policy in Government Research and Development Contracts*, 53 Va. L. Rev. 564, 630-46 (1967) (detailing four different bills debated, but not passed, from 1965 to 1966 alone). But no uniform policy was enacted at that time.

President Kennedy's Government Patent Policy Memorandum, adopted October 10, 1963, came closest to creating Government-wide uniformity. *See* Government Patent Policy, 28 Fed. Reg. 10,943 (Oct. 12, 1963). That Memorandum again recognized the pre-eminent "responsibility" of the Government "to foster the fullest exploitation of the inventions for the public benefit." *Id.*

Rather than choosing between a title policy or a license policy, President Kennedy attempted to accommodate both sides of the debate by encouraging agencies to tailor their approach to the invention at issue. The memorandum encouraged a title policy "where the nature of the work to be undertaken or the Government's past investment in the field of work favors full public access to resulting inventions." *Id.* A license policy, by contrast, was appropriate "where the contractor has an established non-governmental commercial position and where there is greater likelihood that the invention would be worked and put into civilian use than would be the case if the invention were made more freely available." *Id.*

3. The Department of Health, Education, and Welfare (“HEW”) followed the mixed title-license policy called for in the Kennedy Memorandum, and its experience is particularly relevant here for several reasons. First, HEW is the former parent department of the National Institutes of Health (“NIH”), whose funding underwrote the Stanford research at issue in this case. Second, the changes in how HEW applied its policies, which are detailed below, provided an important impetus for the enactment of the Bayh-Dole Act. Finally, Bayh-Dole is modeled, in part, on HEW’s Institutional Patent Agreements (“IPAs”), which are described below.

A single set of HEW regulations, with immaterial amendments, governed the agency’s patent policy from 1955 to 1979. *Compare* 45 C.F.R. Part 8 (1957 Cum. Supp.) *with id.* (1979). Those regulations, like President Kennedy’s Memorandum, asserted a pre-eminent public interest in all inventions created as the result of research supported by federal funds. “[T]he results of research supported by grants of public moneys should be utilized in the manner which would best serve the public interest.” *Id.* § 8.0(b).

Rather than adopting a title policy or a license policy to govern all funded research, the regulations generally reserved the decision of how to allocate patent rights until after invention. *Id.* § 8.1(a). Under this general approach, there was a rebuttable presumption that title would vest in the Government. *Id.* § 8.2(d). One limited exception to this after-the-fact determination created a license policy at the inception of the research if the agency determined that “the grantee’s established policies and

procedures” were “such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties.” *Id.* § 8.1(b). HEW implemented this limited exception by entering into IPAs with certain grantees to delineate the respective rights of the private but federally funded institution and HEW.

Even though HEW had the same general regulations for twenty-four years, the agency’s actual practices differed markedly within this time. Initially, HEW rarely used its regulatory authority to waive title to federally funded patents, either post-invention under § 8.2(a)-(b) or with IPAs under § 8.1(b). *See* Memorandum from James A. Shannon, Director of the National Institutes of Health, to the Surgeon General 1 (Aug. 14, 1964); Rebecca S. Eisenberg, *Public Research and Private Development*, 82 Va. L. Rev. 1663, 1682-83 (1996) (describing an expansion of HEW’s title policy in 1962).

In 1968, however, HEW changed its practices in response to criticism that it had not provided sufficient rights to grantees to ensure participation in federally funded research. *See* Harbridge House, Inc., 2 *Government Patent Policy Study* 2-40 (1968); Comptroller Gen., *Problem Areas Affecting Usefulness of Research of Government-Sponsored Research in Medicinal Chemistry* 31-32 (1968). HEW revamped and standardized its IPAs, which delegated to grantees authority to elect patent rights subject to a Governmental license pursuant to 45 C.F.R. § 8.1(b). Consistent with the license policy, the new form IPA gave grantees “a first option to retain principal rights in and to administer

inventions.” HEW, Institutional Patent Agreement: Revised Draft pmb. (July 11, 1968); *cf.* 45 C.F.R. § 8.1(b). Within a year, HEW entered into twenty-one such agreements, compared to only seventeen between 1955 and 1967. Manuel B. Hiller, HEW, *Government View*, in Nat’l Acad. of Eng’g, *Government Patent Policy* 9, 15 (1969). Additionally, post-invention “determinations were made to leave invention rights to grantee institutions in 13 cases in calendar year 1968 alone,” compared with “only five instances during the 12-year period from 1953 to 1965.” *Id.*; *cf.* 45 C.F.R. § 8.2(a)-(b).

The 1968 policy changes achieved significant success in the scientific fields funded by HEW. “Since instituting the I.P.A. program a number of potentially important new drugs initially funded under HEW research have been delivered to the public through the involvement of private industry This program has been so successful that it has been copied by other agencies ... and was approved by the General Services Administration in 1978” S. Rep. No. 96-480, at 21 (1979); *cf.* Federal Procurement Regulations Amendment 187, 43 Fed. Reg. 4424 (Feb. 2, 1978).

“Ironically, HEW [returned] to its pre-1968 patent policies” under the Carter Administration. S. Rep. No. 96-480, at 21 (1979). In 1977, the new Secretary of HEW halted the routine approval of title waivers and IPAs. *See* Roberto Mazzoleni, *Patents and University-Industry Interactions in Pharmaceutical Research Before 1962*, 10 J. High Tech. L. 168, 183 (2010). This change “mobilized universities and other R&D contractors of the federal government in support of the Bayh-Dole Act, which is

widely credited for making its passing possible in 1980.” *Id.*; *cf.* S. Rep. No. 96-480, at 21 (1979).

4. HEW’s experience reflects some of the problems confronted under both the title and license policies. Title policies discouraged industrial participation, as HEW experienced before 1968. Moreover, even if inventions were made, the Government often was not able to commercialize them due to the additional costs necessary to develop an invention to the point of utilization. *See* S. Rep. No. 96-480, at 3 (1979) (noting that only 4% of Government-held patents were commercialized); 126 Cong. Rec. 29,896 (1980) (estimating the additional costs of development to be ten times as much as the original invention). Thus, under a title policy, patents gathered dust on Government shelves and industry was reluctant to undertake new research.

License policies avoided some of these problems but had their own defects. While contractor-held inventions were nine times more likely to be commercialized, *see* S. Rep. No. 96-480, at 3 (1979), the fact that the licensing policies were a matter of administrative grace, subject to change with each new administration, created uncertainty that dampened enthusiasm in the private sector. *Industrial Innovation and Patent and Copyright Law Amendments: Hearing Before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice, H. Comm. on the Judiciary, 96th Cong. 67* (1980) (statement of Dr. Roy P. Vagelos, President of Merck Sharp & Dohme Research Labs.); *see also* 126 Cong. Rec. 8739 (1980) (Sen. Dole).

The lack of statutory authority for the license policies posed an additional problem. One court invalidated licensing regulations as violating the constitutional prohibition on the disposition of Government property without congressional approval. *Public Citizen, Inc. v. Sampson*, 180 U.S.P.Q. 497 (D.D.C. 1974). While this holding was ultimately vacated for lack of standing, 515 F.2d 1018 (D.C. Cir. 1975), the suit nonetheless raised questions regarding the constitutionality of agency-initiated policies assigning title to the contractor. See Memorandum from Roger C. Cramton, Ass't Att'y Gen., Office of Legal Counsel, to Bruce B. Wilson, Deputy Ass't Att'y Gen., Antitrust Division, *Constitutionality of Proposed Regulations Granting Contractors Greater or Principal Rights Arising Out of Government Research and Development Contracts* (Oct. 10, 1972), reprinted in 119 Cong. Rec. 40,417-20 (1973).

Moreover, the existence of dueling license and title approaches, and over twenty-six different agency policies, posed additional administrative problems. "The mere complexity of these policies constitute[d] a very real hurdle to universities, nonprofit organizations, and small businesses who do not have large legal staffs to negotiate through this policy maze." S. Rep. No. 96-480, at 2-3 (1979). Further, when, as was often the case, funding came from multiple agencies, there was no clear rule as to which policy (or policies) should govern.

B. Bayh-Dole's Enactment: Purposes, Text, and Regulations

Against the confusion created by dozens of separate vesting statutes and divergent policies, Congress passed the Bayh-Dole Act in 1980, creating, for nonprofit organizations and small business firms, a uniform hierarchy of rights for inventions arising from Government-funded research. The Act gave private institutions a first right of refusal to receive title; the Government was the enforcer of the statute's requirements, with a full license and the possibility of itself receiving title in specified circumstances; and inventors were expressly given rights to royalties and the possibility of ultimately receiving title, subject to all of the Act's requirements, if it is concluded that title should not reside in either the private institution or the Government. Finally, uniform implementing regulations, detailing the Act's applicability to all funding arrangements, actuated Bayh-Dole's purposes and goals.

1. Section 200 of the Act details "the policy and objective of the Congress." 35 U.S.C. § 200. Most fundamentally, the Act reflects a statutory commitment to "use the patent system to promote the utilization of inventions arising from federally supported research or development" to foster the "public availability of inventions made in the United States by United States industry and labor." *Id.* In order to achieve this goal, that statute sought "to ensure that the Government obtains sufficient rights" not only to meet its own needs, but to "protect the public against nonuse or unreasonable use of inventions." *Id.* The Act also sought to "promote

collaboration between commercial concerns and nonprofit organizations, including universities,” “encourage maximum participation of small business firms” in Government research, “ensure” that inventions by such institutions “are used in a manner to promote free competition and enterprise,” and “minimize the costs of administering policies in this area.” *Id.*

2. The over-arching title of the Bayh-Dole Act, as enacted and as it appears in the United States Code, is “Patent Rights in Inventions Made With Federal Assistance.” 35 U.S.C. ch. 18. Section 202, the main operative provision, details the “[d]isposition of rights” to any “subject invention,” a term that the Act defines as “any invention of the contractor² conceived or first actually reduced to practice in the performance of work under a funding agreement.” *Id.* § 201(e). This disjunctive definition uses familiar terms that had been interpreted broadly during their use as part of the licensing approach of the Department of Defense. *See, e.g.,* Theodore Prahinski, *Interpretation of Term ‘First Actually Reduced to Practice’ Used in Patent Rights Clauses of Government Contracts*, 55 J. Pat. Off. Soc’y 107, 108 (1973). And, as the definition of “funding agreement” makes clear, Bayh-Dole’s operative provisions apply where the “research work [is] funded in whole or in part by the Federal Government.” 35 U.S.C. § 201(b).

Section 202(a) contains the critical right to take title at issue in this case: “[e]ach nonprofit

² “The term ‘contractor’ means any person, small business firm, or nonprofit organization that is a party to a funding agreement.” *Id.* § 201(c).

organization or small business firm may ... elect to retain title to any subject invention.” *Id.* § 202(a).³ In order to obtain this title, however, the institution must comply with a number of procedural requirements that § 202(c) directs must be set forth in the funding agreement: the institutions must “disclose each subject invention to the Federal agency within a reasonable time,” must “make a written election within two years after disclosure ... whether the contractor will retain title,” and must “file a patent application prior to any statutory bar date.” *Id.* § 202(c)(1)-(3). If the institution fails to comply with any one of these provisions, the statute specifically provides that “the Federal Government may receive title.” *Id.*

Where the contractor elects to retain title, it has several other obligations as well. It must report on the utilization of the subject invention as required by the federal agency, and must state in the patent specification that the invention was made with Government support, thereby putting the world on notice of the Government’s rights. *Id.* § 202(c)(5)-(6). The Act also limits the ability of a nonprofit organization to assign its rights to a subject invention, *id.* § 202(c)(7)(A), and requires that any net royalties or other income remaining with the

³ The contractor’s ability to retain title is subject to being restricted in the funding agreement, as discussed at length in 35 U.S.C. § 202(a). Among other stated grounds for including a provision in the agreement limiting the contractor’s right to retain title are “exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter.” *Id.* § 202(a)(ii).

contractor after it makes various required payments “be utilized for the support of scientific research or education.” *Id.* § 202(c)(7)(C). Also, the contractor is generally barred from granting an exclusive license absent agreement by the licensee that products under the license “will be manufactured substantially in the United States.” *Id.* § 204.

In addition to the Government’s ultimate right to itself “receive title” in the case of a contractor’s non-election or non-compliance with certain requirements, it retains important rights and powers even where title is successfully retained by the contractor. First, the Government agency “shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice ... [the] subject invention.” *Id.* § 202(c)(4). Second, related to the contractor’s duty to report on its progress in achieving utilization of the invention, *id.* § 202(c)(5), the agency has “[m]arch-in rights,” which entitle it, under certain circumstances, to grant, or require the contractor (or its assignee or exclusive licensee) to grant, a license to a responsible third party. *Id.* § 203.

The rights of inventors relating to a “subject invention” are expressly defined in the statute. The Act provides that, where the contractor is a non-profit organization, the funding agreement itself must require the contractor to “share royalties with the inventor.” *Id.* § 202(c)(7)(B). And where the “contractor does *not* elect to retain title,” the Government “may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated” under it. *Id.* § 202(d) (emphasis added). Receipt of such title by

the inventor, subject to all the same requirements as govern a contractor retaining title, would thus occur only where the Government decides not to “receive title” itself. *Id.* § 202(c)(2).

In sum, Bayh-Dole “entrusted” nonprofits and small businesses with patent ownership to act “as a steward of the public interest. Universities are expected to reasonably represent these interests, reaching ‘win-win’ deals with private sector developers.” Birch Bayh, Joseph P. Allen, and Howard W. Bremer, *Universities, Inventors and Bayh-Dole*, 79 Pat., Trademark & Copyright J. 167, 169 (2009).

3. Bayh-Dole’s first implementing regulations were promulgated within a year of the statute’s enactment.⁴ Issued as Bulletin 81-22, the regulations made clear that Bayh-Dole “coupled” the Government’s investment in research with “the incentive of invention ownership in small businesses, non-profits and universities.” Patents; Small Firms and Non-Profit Organizations, 46 Fed. Reg. 34,776, 34,776, ¶ 3 (July 2, 1981).

After the agency received public comments on the Bulletin, it promulgated Circular A-124 in 1982. *See* Patents—Small Firms and Non-Profit Organizations, 47 Fed. Reg. 7556 (Feb. 19, 1982). The Circular stated that Bayh-Dole “gives nonprofit organizations

⁴ *See* 35 U.S.C. § 206 (1982) (empowering the Office of Federal Procurement Policy to “issue regulations ... implementing the provisions of sections 202 through 204 of this chapter”), *amended by* Pub. L. 98-620, § 501(10), 98 Stat. 3335, 3367 (1984) (transferring regulatory authority to the Department of Commerce).

and small businesses ... a first right of refusal to title in inventions they have made in performance of Government grants and contracts.” *Id.* at 7559, ¶ 4.

The current regulations, issued by the Department of Commerce and codified at 37 C.F.R. Part 401, maintain this interpretation. Indeed, the bulk of the current regulations track, word-for-word, Circular A-124. *Compare, e.g.*, 37 C.F.R. § 401.1(a) (2010) *with, e.g.*, 47 Fed. Reg. at 7557.

C. Background of the Case

1. This dispute concerns the ownership of three patents claiming methods for evaluating the effectiveness of treatments for Human Immunodeficiency Virus (“HIV”), the virus that causes AIDS: U.S. Patent Nos. 5,968,730 (“the ‘730 Patent”); 6,503,705; and 7,129,041-B2. Three Stanford researchers—Drs. Merigan, Katzenstein, and Holodniy—developed these methods and are the named inventors. Pet. App. 125a-132a. Stanford is also named on the patents, as the inventors’ assignee. *Id.* Because two NIH grants for AIDS-related work provided partial funding for Stanford’s research, each patent states that “[t]his invention was made with Government support under contracts AI27762-04 and AI27766-07, awarded by the National Institutes of Health. The Government has certain rights in this invention.” *Id.* at 126a, 128a, 132a.

The ownership dispute arises from agreements signed by one of the named inventors, Dr. Holodniy. On joining Stanford’s Department of Infectious Disease in July of 1988, Dr. Holodniy signed Stanford’s standard Copyright and Patent Agreement. Pet. App. 94a. He specifically “agree[d]

to assign ... to Stanford” his intellectual property rights “as required by Contracts or Grants.” Pet. App. 119a. The Agreement prohibited Dr. Holodniy from “enter[ing] into any agreement creating copyright or patent obligations in conflict with this agreement.” Pet. App. 120a.

In the fall of 1988, Dr. Holodniy “joined the [Stanford] lab of Dr. Thomas Merigan” as a research fellow and assisted with research directed “to developing a better quantitative PCR-based assay⁵ for HIV than the one that existed at that time.” Pet. App. 94a. At the time Dr. Holodniy joined the lab, this work was already being supported by research funding from NIH. JA 95, 98. Dr. Holodniy’s initial work at Stanford experimented with PCR assays on HIV sequences, attempting to measure the amount of HIV DNA in a patient taking antiretroviral drugs in order to determine the effectiveness of the treatment.⁶ *See* Pet. App. 34a.

After Dr. Holodniy spent several months working on the federally funded research at Stanford, his supervisor suggested that he visit Cetus, a local

⁵ PCR, or polymerase chain reaction, is a technique that makes it easier to evaluate genetic material by creating millions of copies of DNA or RNA segments from a small sample.

⁶ HIV is a retrovirus, which means that it has an RNA genome rather than the DNA genome typical of most viruses. HIV virions bind to the CD4 protein on the surface of certain immune cells and inserts its contents, including its RNA genome, into the cells. The HIV RNA is converted to DNA, which is then integrated into the CD4 cell’s genomic DNA. This integrated, “proviral” DNA reprograms the CD4 cells to produce additional HIV particles, ultimately killing the infected CD4 cell and releasing more HIV virions.

biotechnology company. Pet. App. 35a. PCR had been invented at Cetus in the mid-1980s. JA 37. Cetus agreed, and Dr. Holodniy spent time both working at Stanford and visiting Cetus for approximately nine months in 1989. Pet. App. 95a-96a.

In connection with Dr. Holodniy's visits, Cetus asked him to sign a "Visitor's Confidentiality Agreement" ("VCA"). Pet. App. 122a-124a. In this agreement, Dr. Holodniy acknowledged that he might "acquire techniques, know-how, or other information of a confidential nature." Pet. App. 122a. As suggested by the Agreement's title, Dr. Holodniy promised "NOT [TO] DISCLOSE ANY SUCH INFORMATION TO ANY PERSON OR ENTITY ... WITHOUT CETUS' PRIOR WRITTEN CONSENT." Pet App. 123a.

A subsequent provision in the VCA stated that Dr. Holodniy "hereby assign[ed] to Cetus my right" to any inventions conceived or reduced to practice "as a consequence of my access to Cetus's facilities or information." Pet. App. 123a-124a. Dr. Holodniy "understood that the agreement concerned my obligations to Cetus' confidential information," but he also understood that nothing he ultimately learned at Cetus was of a confidential nature. Pet. App. 95a-97a.

2. Dr. Holodniy visited Cetus several days a week beginning in February 1989, while also continuing his work at Stanford. Pet App. 95a-96a. After the first several months at Cetus, Dr. Holodniy and his Stanford supervisors decided, "without any input from Cetus scientists," to shift to trying to

quantify HIV RNA in plasma, rather than HIV DNA in cells. Pet. App. 100a. Dr. Holodniy then developed a workable PCR assay to quantify HIV RNA. Pet. App. 98a-100a. While Cetus scientists helped Dr. Holodniy by providing, at his direction, assistance relating to the comparison standard for quantification, each of the PCR steps of the assay Dr. Holodniy developed was publicly available at the time. Pet. App. 97a-100a; JA 39-40.

To share his work, Dr. Holodniy—along with Stanford and Cetus co-authors—published an article describing it. The article noted that the research was funded in part by Stanford’s federal grants and expressed hope that “[s]erum PCR may provide an additional marker of disease progression.” Mark Holodniy *et al.*, *Detection and Quantification of Human Immunodeficiency Virus RNA in Patient Serum by Use of the Polymerase Chain Reaction*, 163 J. Infectious Diseases 862, 862, 865 (1991) [“JID Article”]; JA 135, 148-49. It concluded, however, by noting that “[f]urther studies will be necessary to validate this approach.” *Id.* at 865; JA 149. Cetus approved the JID Article for publication and did not file any patent application or otherwise seek ownership over the assay disclosed in the article. In fact, Cetus’s patent committee had given the work its lowest possible rating for patentability or commercial development. Pet. App. 38a.

When Dr. Holodniy ceased visiting Cetus and resumed full-time activity at Stanford in October or November of 1989, he and Drs. Merigan and Katzenstein performed extensive studies and clinical experiments, using real-life patient monitoring of persons taking anti-HIV therapy. Pet. App. 102a-

104a. This work was done without any further involvement or assistance from Cetus. *Id.* In their research, the Stanford team faced a number of significant challenges:

[T]here was widespread uncertainty at the time about whether the assay [could] be sufficiently sensitive and reproducible to measure HIV RNA changes over time in a clinical setting. It was unclear whether the variability of virus levels and changes in virus levels for different individuals would be detectable using this assay. There was much uncertainty in the field about whether nucleic acid levels in plasma could be used to predict the effectiveness of the therapy. There was also an overriding concern about whether the available treatments would be strong enough to produce changes that could be measured.

Pet. App. 103a. Additionally, “[t]he quantitative assay needed more refinement to improve sensitivity and reproducibility.” *Id.* Accordingly, the Stanford team performed numerous experiments and extensive statistical analyses to develop a therapeutically useful technique and protocol. Pet. App. 103a-104a.

Ultimately, in 1991, the Stanford team was able to develop a technique for monitoring the effectiveness of anti-HIV therapy based on the results of their clinical research. *Id.* The team published an article in the *Journal of Clinical Investigation*

detailing their results and acknowledging the Federal funding of the research. Mark Holodniy *et al.*, *Reduction in Plasma Human Immunodeficiency Virus Ribonucleic Acid After Dideoxynucleoside Therapy as Determined by the Polymerase Chain Reaction*, 88 J. Clinical Investigation 1755, 1759 (1991) ["JCI Article"]. Stanford filed a patent application on May 14, 1992. Pet. App. 108a.

Because the work done by the Stanford researchers was funded by the NIH, the resulting discovery was a "subject invention" governed by the Bayh-Dole Act. 35 U.S.C. § 201(e). Pursuant to the Act's provisions, Stanford timely submitted an invention disclosure form to the NIH in 1992 and confirmed the grant of a nonexclusive, nontransferable, irrevocable, paid-up license in the patent application to the Government as required. *See* Pet. App. 5a-6a; *see also* 35 U.S.C. § 202(c)(1), (4). In 1995, also pursuant to Bayh-Dole, Stanford timely perfected its rights to the patent by formally notifying the Government that it elected to retain title. Pet. App. 115a-116a.; *see also* 35 U.S.C. § 202(c)(2).⁷ It is undisputed that Stanford has satisfied all requirements of the Bayh-Dole Act to perfect its title to the subject inventions.

3. Cetus's PCR-related assets were acquired by Hoffmann-La Roche, Inc., a Swiss pharmaceutical company, in 1991. Pet. App. 42a. At no time prior to that acquisition did Cetus advise Stanford of the VCA

⁷ Shortly after making its election to retain title, Stanford recorded with the Patent and Trademark Office new assignments from Drs. Merigan, Katzenstein, and Holodniy relating specifically to this invention. Pet App. 41a, 112a.

or of any claim to own the inventions of the patents-in-suit. Nor did Roche make any filing relating to an interest in those inventions based on the VCA during the pendency of the patent applications pertaining to the patents-in-suit. Likewise, no such notice was given to Stanford or any involved party at or following the issuance of any of the patents, even though Roche learned of the first of these, the '730 patent-in-suit, soon after it issued in 1999. Pet. App. 41a.

In 2000, Luis Mejia, a Senior Licensing Associate in Stanford's Office of Technology Licensing, traveled to Basel, Switzerland, to offer "Roche an exclusive license to the '730 patent and related Stanford patents." Pet. App. 109a-110a. Throughout the presentation, "it was clear that Stanford did not recognize that either Cetus or Roche had any ownership or license interest" in the '730 patent-in-suit. *Id.* Roche did not suggest otherwise: "no one from Roche ever indicated ... that Roche believed it had any right of ownership or license." *Id.* Instead, Roche negotiated with Stanford over a possible licensing arrangement for the next four years. Pet. App. 6a.

4. No licensing arrangement was reached. In 2005, Stanford sued Roche for infringement, based in part on Roche's sales of kits used to evaluate the effectiveness of anti-HIV therapy. Roche answered and counterclaimed, asserting, in relevant part, that it possessed an ownership interest in the patents because of Dr. Holodniy's assignment in the Visitor Confidentiality Agreement. *See, e.g.,* Defs.' Answer & Countercl. (D. Ct. Dkt. No. 15) 12, 18.

The district court bifurcated the ownership and infringement issues. On cross-motions for summary judgment, Judge Patel rejected Roche's ownership claims on several grounds, two of which are relevant here. First, she held that both California's four-year statute of limitations and the doctrine of laches barred Roche from asserting an ownership claim more than four years after it had learned of the patent. Pet. App. 48a-52a (“[b]ecause Roche's delay in suing to enforce its ownership interest is unreasonable and has at least caused substantial evidentiary prejudice to Stanford, Roche's ownership claims are barred by the doctrine of laches”).

As a second, independent ground for rejecting Roche's arguments, the district court held that “Holodniy's purported assignment to Cetus conflicted with the legal requirements of the Bayh-Dole Act, which mandated that Stanford be given a superior right to retain title to the patents.” Pet. App. 62a. Under Bayh-Dole, Dr. Holodniy “had no interest to assign.” *Id.*

After the Federal Circuit denied mandamus review of the ownership ruling, 513 F.3d 1003 (Fed. Cir. 2008), the district court granted Roche summary judgment on the infringement issue, holding that the patents were obvious, focusing primarily on Dr. Holodniy's JID Article. 563 F. Supp. 2d 1016 (N.D. Cal. 2008).

Stanford appealed the obviousness ruling, and Roche cross-appealed on the ownership claim. The Federal Circuit did not reach Stanford's appeal. Instead, while agreeing with the district court that Roche's affirmative claim of ownership was barred by

the statute of limitations, Pet. App. 9a, the court determined that Roche's lengthy delay did not bar it from asserting its ownership as a defense, and in particular from "assert[ing] its ownership interest as a bar to Stanford's standing." Pet. App. 12a.

The Federal Circuit further held that Cetus's VCA, acquired by Roche, trumped both Stanford's earlier Copyright and Patent Agreement and the later recorded assignment. Pet. App. 12a-14a. Reasoning that the "agree to assign" language of the earlier assignment to Stanford "reflects a mere promise to assign rights in the future," while the "do hereby assign" language of the VCA "effected a present assignment of Holodniy's future inventions to Cetus," the court concluded that "Cetus's equitable title converted to legal title no later than the parent application's filing date" in 1992, and takes priority over Stanford's earlier assignment agreement. Pet. App. 13a-14a.

The court also ruled that the premise of the VCA—that the invention be developed "as a consequence of [Dr. Holodniy's] access to CETUS' facilities or information"—was satisfied because Dr. Holodniy at Cetus received access to certain information, materials and equipment, which were used in the development of the invention.⁸ Pet. App. 15a, 123a. The Court made clear that its ruling rested simply on the fact that Cetus's information or facilities contributed in some way to the ultimate invention, and did not depend on any finding that

⁸ The court below does not suggest that anything received or used by Dr. Holodniy at Cetus was confidential, or that such confidentiality was necessary for the assignment to be effective.

property—*i.e.*, a patentable invention—had been created by the work Dr. Holodniy was involved in at Cetus. “Even if Holodniy conceived and reduced to practice after departing Cetus, ... his research was directly related to the collaboration with Cetus.” *Id.* at 15a.

In adopting this view, the court below expressly rejected the district court’s holding that the Bayh-Dole Act negated Dr. Holodniy’s assignment to Cetus because it empowered Stanford to take complete title to the inventions. The Federal Circuit concluded that the “statutory scheme did not automatically void the patent rights that Cetus received from Holodniy,” and therefore Cetus (and now Roche) had co-ownership of the patents by virtue of the VCA. Pet. App. 21a.

Finally, because standing principles preclude a patent suit by one co-owner without all other co-owners’ agreement and participation, the Federal Circuit determined that Stanford did not have standing, reversed the ownership decision, and vacated the obviousness holding. Pet. App. 27a-28a.

Stanford timely petitioned for *certiorari*, which this Court granted after inviting the views of the Solicitor General.

SUMMARY OF ARGUMENT

The right of a federally funded research institution to retain title to a subject invention under the Bayh-Dole Act derives from the Government’s pre-eminent interest in, and right to claim outright, the fruits of its research expenditures. Thus, the institution’s right to title does not depend on securing an assignment from the inventor.

Congress enacted the Act following decades during which Government-owned patents had gone largely unlicensed and undeveloped. To rectify this situation, the Act sought to “promote the utilization” and “commercialization” of Government-funded inventions by allowing research institutions such as Stanford that produce inventions with federal funding to retain title to those inventions. The statute was made applicable to all Government agencies and took precedence over existing statutes vesting in the Government title to funded inventions.

This case presents the question whether the title that a contractor is allowed to retain under the Bayh-Dole Act depends upon the contractor also securing effective assignments of rights from its inventors, so that title may be compromised by an inventor’s perhaps unknown assignment of his rights to a third party. The statute’s text, express purposes, legislative history, and regulations all confirm that the answer to that question is no.

The Act altered the default ownership of a federally funded patent as between the Government and the research institution. It did not make the ownership of either subordinate to rights of the inventor. The Act provides that a federally funded contractor may “retain title” to all “subject inventions”—those “conceived or first actually reduced to practice in the performance of work done under a funding agreement.” 35 U.S.C. § 201(e). To retain title, the contractor must satisfy a number of requirements, including, critically, actively pursuing the invention’s commercial development. *Id.* § 202(c)(5). If the contractor’s efforts fall short in some respect, the Government itself “may receive

title.” *Id.* § 202(c)(1)-(3). If the goal of commercial development is not realized, the funding agency retains the power to “march-in”—that is, to intervene and pursue the development of the invention. *Id.* § 203.

The Act’s provisions concerning inventors of a subject invention are markedly different. Where a contractor elects to retain title, the contractor must “share royalties with the inventor.” *Id.* § 202(c)(7)(B). Where the contractor does not so elect, “the Federal agency may consider ... requests for retention of rights by the inventor subject to” the Act’s provisions and regulations. *Id.* § 202(d). These distinctly subordinate rights of the inventor are incompatible with the decision below, holding that the inventor’s rights precede and ultimately may, as here, defeat the contractor’s statutory right to receive title that the Government itself had usually held in the past.

The legislative history and implementing regulations confirm that the title retained by the research institution rests on the Government’s pre-eminent interest based on its provision of funding, which most often in the past had resulted in outright Government ownership. Rather than the institution receiving title by an assignment from the inventor, Congress relinquished the Government’s own primary claim of title. It did this to encourage the involvement of private parties, with the goal of increasing the commercial development of Government funded inventions. The statute thus adopted a presumption that ownership of all patent rights in Government funded research will vest in any contractor, who must then comply with explicit

statutory requirements aimed at achieving the Act's purposes.

The implementing regulations have consistently echoed this purpose of the Act, using much of the same terminology, and require, *inter alia*, that funding agreements provide that the contractor may retain the entire right, title and interest throughout the world to each subject invention.

The Federal Circuit's decision is contrary to these authorities. If the contractor's title is only as good as the assignments it has received from its inventors, then title, as here, may always be called into doubt on the ground that an inventor may have made a prior assignment that could remain undisclosed for many years. This uncertainty, and the costs of seeking to uncover possible assignments, would substantially impede the commercialization that is the central objective of the Act. The uncertainty would also impede effective collaboration between commercial entities and federally funded research institutions. The contractual arrangements necessary to define the respective rights of the collaborating parties would be more, not less, difficult if the Federal Circuit's ruling were upheld.

The Federal Circuit's approach also undermines the integrity of the Government's own interest in federally funded inventions. If the contractor's title turned ultimately on the soundness of the assignment that it receives from the inventors, the Government's ability to itself take back title, as the statute under certain circumstances allows, would be severely compromised. So would the Government's ability to march-in and compel the contractor to

license, in order to advance commercial development, since the contractor's shared or uncertain ownership may not be of much commercial interest.

Finally, it is difficult to see how an inventor's co-ownership interest, arising outside of the provisions of the Act, could reasonably be subjected to the statutory conditions and requirements that are imposed by the funding agreement itself. Thus the achievement of the statute's stated goals demands a reading of the statute that recognizes the clear title of contractors who have elected to retain title and comply with the provisions of the Act.

It is also notable that this case implicates uniquely federal interests that reinforce the incorrectness of the decision below. The Bayh-Dole Act directly concerns the construction of United States Government research funding contracts, and their effectiveness in promoting public use of resulting inventions. The focus of those contracts is the determination of rights arising under patents, which subject is likewise one where state law must yield to the commandments of federal law. On the record here, including the fact that the claimed assignment was made after federal research funding had commenced, and respondent's sixteen-year delay in bringing the claimed assignment to light, equitable application of the law requires rejection of respondent's ownership claim, whatever precise construction one places on the Bayh-Dole Act.

ARGUMENT**I. THE BAYH-DOLE ACT GIVES TITLE TO CONTRACTORS LIKE STANFORD WITHOUT REGARD TO ASSIGNMENTS MADE BY INDIVIDUAL INVENTORS**

Prior to the Bayh-Dole Act, through numerous vesting statutes, the Government conditioned federal funding on Government ownership of inventions produced as a result of such funding.⁹ In the Bayh-Dole Act, Congress instead declared categorically that nonprofit and small-business grantees would step into the Government's shoes as owners of federally funded inventions, provided they follow certain procedures and subject to certain rights retained by the Government. In other words, a federal contractor who complies with the Act is allowed to "retain title" instead of having it go to the Government, and the contractor has the same title that the Government would have had in that event. Such title is not called into question by the action of a federally funded inventor who attempts to assign away title to another.

A. The Text and Structure of the Bayh-Dole Act Demonstrate That the Act Confers Clear Title to Inventions Directly Upon Funded Research Institutions

Against the backdrop of the many agency-specific statutes vesting title to federally funded inventions in the United States and the range of practices at

⁹ Such vesting statutes are still on the books, though they were expressly made subordinate to the provisions of the Bayh-Dole Act by § 210, which states that Bayh-Dole will take precedence over other statutes, including those enumerated there.

other agencies recognizing ownership interests in some private entities, *see supra* at 2-10, Congress enacted the Bayh-Dole Act in 1980 to provide a uniform set of rules for the “[d]isposition” of “Patent Rights in Inventions Made With Federal Assistance.” 35 U.S.C. ch. 18; § 202.

As this Court has consistently recognized, Congress has broad authority over intellectual property matters, and its actions in this realm are reviewed for “rational exercise,” with “substantial[]” deference to Congress’s judgment. *Eldred v. Ashcroft*, 537 U.S. 186, 204-05 (2003). In addition, the Spending Clause permits Congress to impose conditions on recipients of federal funds. *See United States v. Am. Library Ass’n*, 539 U.S. 194, 203 (2003) (“Congress has wide latitude to attach conditions to the receipt of federal assistance in order to further its policy objectives.”). Finally, Congress has the authority, “without limitation,” to dispose of public property in the “public interest.” *United States v. California*, 332 U.S. 19, 27 (1947); *Ashwander v. TVA*, 297 U.S. 288, 338 (1936).

In the Bayh-Dole Act, in order to “promote the utilization” and “commercialization” of Government-funded inventions, Congress expressly established that when inventions “aris[e] from federally supported research or development,” 35 U.S.C. § 200, the funded nonprofit institutions and small businesses may secure title in those inventions by complying with statutory procedures and requirements. There is no question in this case that the inventions at issue fall within the scope of the Act, or that Stanford, a qualified grantee, satisfied all the prescribed requirements to secure title.

1. The Act's operative provisions apply to "any subject invention," *id.* §§ 202(a), 203(a), 204, a term that the Act defines as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement." *Id.* § 201(e). Since an institution can only create an invention through the actions of its employees, this language is naturally read to include¹⁰ all inventions made by the contractor's employees with the aid of federal funding.¹¹ Also, the definition of "funding agreement" makes clear that the Act applies where the "research work is funded in whole or in part by the Federal Government," *id.* § 201(b), so the quantity of federal funding is not dispositive. Thus inventions made by the contractor's employees after the commencement of any federal funding are "subject inventions" covered by the Act, whether or not the individual inventors have expressly conveyed their rights in the invention to the contracting institution.

Here, the invention claimed by the patents-in-suit is clearly a "subject invention." It was both

¹⁰ This definition is not exhaustive. For example, an invention could also be "of the contractor" and covered by the Act where the institution has purchased the concept of an invention from an unfunded, non-employee inventor, and later actually reduces it to practice with the aid of federal funding.

¹¹ For an employee of the contractor to be an inventor, he or she must play some role in the conception of the invention. *E.g.*, *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460-61 (Fed. Cir. 1998). The statute's limitation to "invention[s] of the contractor" thus excludes from the Act's coverage inventions created by third parties without assistance of federal funding, where the contractor's employees had no role in its conception.

conceived *and* reduced to practice with the aid of federal funding that was in place no later than 1988, before Dr. Holodniy began visiting Cetus in 1989. *See supra* at 17.¹² And it was an “invention of the contractor” because the named inventors on the patents-in-suit—all of them—were researchers employed by Stanford. At no point has Cetus or Roche ever disputed inventorship to assert that a non-Stanford-employee was a co-inventor. It is far too late to do so now.¹³

2. Pursuant to the Act’s allocation of rights as between the Government, the contractor, and the inventor(s), title to the invention at issue here vested in Stanford. Subject to the Government’s ability to provide otherwise in the funding agreement, Section 202(a) states that “[e]ach nonprofit organization or small business firm may, within a reasonable time after disclosure [of the subject invention to the Government], elect to retain title to any subject invention.” 35 U.S.C. § 202(a). This right to retain title is conditioned on compliance with precisely

¹² Clearly, then, Dr. Holodniy’s execution of the VCA, on which Respondent’s purported ownership interest depends, occurred while the project he was working on at Stanford and Cetus was already receiving NIH funding that triggered application of the Act. *See* JA 95, 136. Such a prospective assignment by a researcher of the fruits of on-going, federally funded research obviously cannot stand, given Bayh-Dole’s express provisions defining a different disposition of any resulting inventions.

¹³ In addition, in ruling that Roche was a co-owner of the patents-in-suit, the Federal Circuit rested on the express assumption that Dr. “Holodniy [both] conceived and reduced to practice after departing Cetus”—an assumption contrary to any inventorship by Cetus. Pet. App. 15a; *see also* Pet. App. 102a-104a.

defined procedural requirements that seek to protect the Government's interests and, in the case of non-compliance, allow the Government in its discretion to "receive title" to the invention.

Stanford took all the steps required by the Act. First, Stanford made the required timely disclosure of the subject invention to the funding agency, without which "the Federal Government may receive title." *Id.* § 202(c)(1). *See* Pet. App. 5a-6a. Stanford also made the required timely written election to retain title, *id.* § 202(c)(2), and filed timely patent applications, *id.* § 202(c)(3), absent either of which the Government is likewise empowered to "receive title." *See* Pet. App. 5a-6a. Nor has any suggestion been made that Stanford has failed to honor any other requirements of the Act. *See supra* at 13-15.

By its terms, the Act sets out certain requirements for a contractor to secure "title" under the Act. Its omission of other prerequisites supports a strong inference that Congress did not intend to require contractors to take other steps—such as acquiring title to the invention from the contractor's employees—before being entitled to retain title. This routine application of the principle of *expressio unius est exclusio alterius*, *TRW Inc. v. Andrews*, 534 U.S. 19, 28-29 (2001), means that Stanford's title to the patents-in-suit should not be called into question where it has satisfied all the statutory prerequisites to securing title, on the ground that it failed to take other steps that are nowhere discussed there.

3. The relationship of Bayh-Dole to the previous regime that governed federally funded inventions confirms that it confers title upon funded contractors

that is not qualified or limited by competing ownership rights of inventor employees engaged in the funded research. Before the enactment of Bayh-Dole, numerous vesting statutes automatically vested title to federally funded inventions *in the Government*, irrespective of any agreements concerning title between the federal contractor and the individual inventor. *See, e.g.*, 42 U.S.C. § 2182 (“[a]ny invention ... made or conceived in the course of or under any contract [with the Atomic Energy Commission] ... shall be vested in, and be the property of, the Commission”); 42 U.S.C. § 2457 (“[w]henever any invention is made in the performance of any work under any contract of the [National Aeronautics and Space] Administration ... such invention shall be the exclusive property of the United States”); 42 U.S.C. § 5908(a) (“[w]henever any invention is made or conceived in the course of or under any contract of the Department [of Energy] ... title to such invention shall vest in the United States”).

The Bayh-Dole Act expressly displaced these earlier statutes, stating that its provisions addressing “[d]isposition of rights,” would henceforth “take precedence” over each of them. 35 U.S.C. § 210(a). Given the established practice of taking Government title to most federally funded inventions, it was natural to describe the change effectuated in the Bayh-Dole Act as allowing the contractor “to retain title.” § 202(a). Based on this prior history, the most reasonable understanding of the statute’s language is that it allows a contractor to “retain title,” as contrasted with having title vest or be taken entirely by the Government.

4. Separate provisions of the Act use the words “acquire” and “receive” as interchangeable with the word “retain” in § 202(a), thus confirming that the Act vests new title in the contractor and does not simply confirm title that the contractor previously acquired from someone else (such as the inventor). For example, in setting forth the circumstances under which the Government may compel a contractor to license a federally funded invention, § 203 states that the Government shall have such “march-in” rights “[w]ith respect to any subject invention in which a small business firm or nonprofit organization *has acquired title under this chapter.*” 35 U.S.C. § 203(a) (emphasis added). But § 202(a) is the *only* provision “under this chapter” (chapter 18) that specifies when a small business firm or nonprofit organization will have title to a subject invention. Thus, § 203(a) unambiguously recognizes that, in exercising its right to “retain” title under § 202(a), a contracting institution is “acquir[ing]” title—not merely holding onto preexisting title.

Similarly, § 204 refers to small business firms and nonprofit organizations that “receive[]” title to any subject invention. This provision likewise recognizes that § 202(a) operates as an affirmative grant of title to the contracting institution, and not simply as a confirmation of whatever title is already acquired through other means.

5. The Act’s provisions expressly allowing title to the subject invention to vest in the inventor under certain specified conditions further confirm that § 202(a)’s conferral of rights on the contractor is not subject to any pre-existing rights of, or transfers from, the inventor. Section 202(d) provides that “[i]f

a contractor does not elect to retain title to a subject invention,” the Government may “consider and after consultation with the contractor grant requests for retention of rights by the inventor, subject to the provisions of this Act and regulations promulgated hereunder.”

If, as Respondents would have it, the inventor’s rights in “subject inventions” under Bayh-Dole took precedence, such that the contractor gets only what the inventor has given it, then this provision recognizing a subordinated and hedged possibility of the inventor receiving title would make no sense. By contrast, if “retain” is read as a synonym for “acquire” or “receive,” then § 202(d) makes perfect sense. The inventor’s opportunity to take title is only a contingent possibility, and it does not exist unless the institutional contractor fails to retain title and the Government itself declines to “receive title.”

The position of the inventor is further illuminated by § 202(c)(7)(B), which requires a nonprofit organization that elects title to a subject invention to “share royalties” with the inventor.¹⁴ There would be little reason to confer such a statutory entitlement upon the inventor, if the premise of the statute were that the inventor already owns the patent until such time as he or she assigns it to someone else. The provision makes sense, by

¹⁴ Thus, it is probably not correct to say that an inventor working on federally funded research has no ability to assign away any rights in connection with it. Since the statute itself gives a right to royalties in future inventions to the inventors, § 202(c)(7)(B), perhaps an assignment of that right—specifically provided for by the statute—would be permissible.

contrast, when seen as an assurance of reasonable royalty payments to an inventor whose ownership rights in the patent were supplanted by the express terms of the statute, based on the pre-eminent federal interest that arises as a result of federal research funding.

B. The History of the Bayh-Dole Act Reveals a Purpose to Promote Commercialization by Transferring to Research Institutions the Government's Right to Own Federally Funded Inventions

H.R. 6933, the bill that ultimately became the Bayh-Dole Act, was introduced on March 26, 1980, and contained in section six a new chapter of the Patent Code, Title 35, addressing the “Government Patent Policy.” *Id.* This bill, which tracked the structure and many of the provisions of the present Act, passed the House on November 17, 1980, and the Senate began debating it three days later. 126 Cong. Rec. 29,901 (1980); *id.* at 30,360.

In the Senate, certain language of the House bill was immediately altered by an amendment proposed by Senators Bayh and Dole “in the nature of a substitute.” *Id.* at 30,361 (Sen. Dole). Earlier in the year, the Senate had overwhelmingly passed a parallel bill, S. 414. *See id.* at 8746. When that bill was offered in the House as H.R. 2414, it failed to move forward, and the House instead acted on its own H.R. 6933. The Bayh-Dole substitute Amendment 1779 struck out section six of H.R. 6933 and replaced it with “the patent policy incorporated in S. 414.” *Id.* at 30,364 (Sen. Bayh).

While the original language of H.R. 6933 had stated that “[a] contractor that is a small business or a nonprofit organization *will acquire* title to its contract invention,” *see id.* at 29,891 (§ 383(a)) (emphasis added), the Senate bill allowed “[e]ach nonprofit organization or small business firm” to “*elect to retain* title to any subject invention.” *Id.* at 30,361 (§ 202(a)) (emphasis added).

The earlier Senate debates on S. 414, which included discussion of this latter language, indicate that this “[d]isposition of rights” was understood as “granting to the universities and small companies the right of first refusal for patents arising from their Federal grants or contracts.” *Id.* at 2007 (Sen. Weicker); *see id.* at 1991 (Sen. Dole). The debate made clear that the Government would “relinquish patent rights that would encourage and stimulate private industry to develop discoveries into products available to the public.” 126 Cong. Rec. 1796 (1980) (Sen. Bayh); *see also id.* at 1798 (Sen. Matthias) (“[o]ur bill would encourage the Federal Government to grant patent rights”).

No Senator in favor of S. 414 suggested that an assignment from the inventor was necessary for universities and small businesses to “retain” patent rights. To the contrary, statements from several Senators all confirm that “retain,” as used in § 202(a) of S. 414, is synonymous with “obtain,” *i.e.*, that “retain” was not used to suggest that some third party had a pre-existing right in the invention. *Id.* at 1796, 1798, 1799, 1991, 2002 (Sens. Bayh, Matthias, Kennedy, Dole, and Chafee).

Senate Judiciary Committee Report Number 96-480 contains “[t]he full legislative history” of S. 414. 126 Cong. Rec. 30,364 (1980) (Sen. Bayh). This Report indicates that the bill’s provisions, like H.R. 6933, were “designed to promote the utilization and commercialization of inventions made with Government support” and remedy the economic stagnation and crisis in innovation that the United States was experiencing. S. Rep. No. 96-480, at 1-3 (1979). These objectives were to be accomplished by “automatically grant[ing] small businesses and nonprofits title to inventions arising from Government-supported research.” *Id.* at 36.¹⁵

Following the Senate’s passage of H.R. 6933, as amended in the Senate, the House took up and passed the amended bill. 126 Cong. Rec. 30,556-60 (1980).¹⁶ In signing the Act into law, President

¹⁵ The meaning of the Act as ultimately passed is further illuminated by the House Report. In commenting on the slightly different language in the original House bill, the House Report noted that it “establishe[d] a presumption that ownership of all patent rights in government funded research will vest in any contractor who is a non-profit research institution or a small business.” H.R. Rep. No. 96-1307, pt. 1, at 5 (1980), *reprinted in* 1980 U.S.C.C.A.N. at 6464. While the “will acquire” language of the original House-passed version of H.R. 6933 differed slightly from that of S. 414, there is no indication that any legislator viewed the differences as significant or altering the substance of the legislation. Indeed, following the Senate’s substitution of “elect to retain” for “will acquire,” the sponsor of H.R. 6933, Representative Kastenmeier, stated that the Senate had left “intact” the provisions “relating to small businesses and universities.” 126 Cong. Rec. 30,560 (1980).

¹⁶ The primary objection raised to the bills in either the House or Senate was that they gave away too much of the Government’s rights, not that they interfered too much with the

Carter confirmed that the Act “enables small businesses and nonprofit organizations to *obtain* title to inventions made with Federal support.” Statement on Signing H.R. 6933 Into Law, 16 Weekly Com. Pres. Doc. 2803, 2804 (Dec. 12, 1980) (emphasis added).

After the enactment of Bayh-Dole, the Comptroller General’s first annual report confirmed that “Section 6 establishes a uniform policy for assigning title to inventions made by small business or nonprofit contractors during Government-sponsored research.” Comptroller Gen., *Patent and*

rights of inventors. *See, e.g.*, H.R. Rep. No. 96-1307, pt. 1, at 29 (1980), *reprinted in* 1980 U.S.C.C.A.N. at 6487 (dissenting views of Rep. Jack Brooks) (“The major problem I have with H.R. 6933 is that it violates a basic provision of the unwritten contract between the citizens of this country and their Government; namely that what the Government acquires through the expenditure of its citizens’ taxes, the Government owns.”); 126 Cong. Rec. 2002 (1980) (Sen. Long) (“When the public has paid for the research, the public is entitled to the benefit of it.”).

Sponsors of the legislation responded by noting that the public would not obtain any benefits absent the grant of title to contractors. *See, e.g.*, 126 Cong. Rec. 8739 (1980) (Sen. Dole) (“The incentive provision for private industry for the development of inventions, is designed to insure that the American public gets a return on the investment that has been made in research.”); *id.* (Sen. Bayh) (“But as long as that patent is not developed and made available in the marketplace, the public is receiving no benefits for the research money that has been expended in support of the invention.”); *id.* at 29,898 (Rep. Fuqua) (“I am aware of the criticism that granting contractors exclusive rights to Government-funded inventions enriches contractors at the expense of the taxpayer. However, I believe that without the grant of exclusive rights, virtually no economic benefits which would flow from commercialization would be realized.”).

Trademark Amendments of 1980 Set the Stage for Uniform Patent Practice by Federal Agencies (PAD-82-32) 1 (1982).

C. The Implementing Regulations Confirm Stanford's Reading of the Act

Bayh-Dole's implementing regulations, originally issued by the Office of Federal Procurement Policy¹⁷ and entitled to *Chevron* deference, confirm that Bayh-Dole "coupled" the Government's "large investment" in research with "the incentive of invention *ownership* in small businesses, non-profits and universities" for the purpose of "initiat[ing] a significant increase in the commercialization of inventions resulting from these programs." *See* Patents; Small Firms and Non-Profit Organizations, 46 Fed. Reg. 34,776, 34,776, ¶ 3 (July 2, 1981) (emphasis added).

The subsequently issued permanent regulations in Circular A-124 likewise clarify Bayh-Dole's disposition of rights. "This Act *gives* nonprofit organizations and small businesses, with limited exceptions, *a first right* of refusal *to title* in inventions they have made in performance of Government grants and contracts." Patents—Small Firms and Non-Profit Organizations, 47 Fed. Reg. 7556, 7559, ¶ 4 (Feb. 19, 1982) (emphases added); *cf.* 126 Cong. Rec. 2007 (1980) (Sen. Weicker). Thus, the agency charged with implementing Bayh-Dole

¹⁷ *See* 35 U.S.C. § 206 (1982), *amended* Pub. L. 98-620, § 501(10), 98 Stat. 3335, 3367 (1984).

interpreted § 202(a) as giving the contractor, and not the inventor, the first right to title.¹⁸

The current regulations, which were issued by the Department of Commerce after Public Law No. 98-620 transferred regulatory authority from the Office of Federal Procurement Policy in 1984, maintain this interpretation. Indeed, the bulk of the current regulations track, word-for-word, Circular A-124. *Compare, e.g.*, 37 C.F.R. § 401.1(a) (2010) *with, e.g.*, 47 Fed. Reg. at 7557. Two provisions of the current regulations are especially relevant in this case.

First, the regulations provide that “[t]he *Contractor* may retain the *entire* right, title, and interest throughout the world to each subject invention.” 37 C.F.R. § 401.14(a)(1), ¶ (b) (second emphasis added). Such a statement cannot be squared with a view that Bayh-Dole only determines the disposition of rights between the Government and the institution, and leaves the inventor with primary rights, yet to be addressed.

¹⁸ Circular A-124 also addressed Bayh-Dole’s applicability to collaborative research projects. 47 Fed. Reg. at 7557. The Act applies to cooperative projects “expediting or more comprehensively accomplishing the research objectives of the Government sponsored project.” *Id.* It does not apply, however, to inventions that are “related but separate” from the federally funded research. *Id.* The Circular gave an example of such closely related but separate projects: where one has “research objectives to expand scientific understanding in [a] field” and the second has “as its objectives the application of such new knowledge to develop usable new technology,” only the federally funded project is subject to Bayh-Dole. *Id.*

Second, contrary to any claim that Dr. Holodniy's use of Cetus's information and equipment entitled it to certain rights, § 401.1(a)(1) indicates that "the use of new fundamental knowledge from one [project] in the performance of the other [is] not [an] important determinant[] [of Bayh-Dole's applicability,] since most inventions rest on a knowledge base built up by numerous independent research efforts extending over many years." The fact that Dr. Holodniy may have obtained a better understanding of the then-publicly-known PCR technique from conducting some of his work at Cetus in no way suggests that Bayh-Dole does not apply to the resulting inventions. What matters is that the research by Dr. Holodniy and others, at Stanford and at Cetus, from 1988 on, was pursued with the help of grant money from NIH.

Not only do these regulations confirm the plain-text reading of the statute, but they are also entitled to deference to the extent that the text admits of any ambiguity. *See Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984); *cf. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 477-82 (2001). The regulations, which link the grant of title to the contractor to the express purpose of achieving commercialization, have remained consistent for thirty years, thus "reflect[ing]" the agencies' "considered views." *See Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 171 (2007). These settled views are certainly not arbitrary. Rather they reflect the most reasonable interpretation of the text, history, and purposes of Bayh-Dole as detailed above, and have stood without challenge for nearly three decades.

D. The Federal Circuit's Construction of Bayh-Dole Undermines the Act's Express Purposes

1. Vesting title in contracting institutions is necessary in order to maximize commercial utilization of inventions resulting from federally funded research. In enacting the Bayh-Dole Act, Congress included within the statute itself a clear indication of the Act's purpose: "to use the patent system to promote the utilization of inventions arising from federally supported research." 35 U.S.C. § 200. To implement that statutory purpose, the Act "gives nonprofit organizations and small businesses ... a first right of refusal to title." 47 Fed. Reg. at 7559, ¶ 4. Congress recognized that giving such contractors clear title was necessary to spur the additional investment required to turn the initial invention into a commercially viable product. 125 Cong. Rec. 1796-98 (1980) (Sen. Bayh).

Congress's decision was a wise one. Since Bayh-Dole's passage, "American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2,200 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute \$40 billion annually to the American economy." *Innovation's Golden Goose*, *The Economist*, Dec. 14, 2002, at 3.

The Federal Circuit's decision in this case not only ignores the language and structure of the Act, but also ignores the statute's thirty-year period of consistent and successful application, and threatens this success by fundamentally undermining Bayh-Dole's framework. In contrast, giving primacy to § 202's explicit "[d]isposition of rights" provides

certainty that is essential if Bayh-Dole's developmental purpose is to continue to be fulfilled.

Under the decision below, even when a university or small business elects to retain title and complies with all of the requirements of the Bayh-Dole Act, it can never be sure that it has obtained clear title. Instead, title will remain clouded by the potential that an inventor, at some point, may have inadvertently or intentionally entered into an undisclosed agreement with an unknown third party years before a patent even issued. Such an unknown prior assignment by a named inventor may deny the institution any title at all (in the case of a single inventor) or may mean that the institution shares ownership with others, if some but not all co-inventors have assigned rights away. In the latter case, as here, the purported assignee of such rights can preclude the university and the other inventors from obtaining any royalties at all, prevent licensing to other parties, and thus stand in the way of the realization of the fruits of federal funding.

Such "uncertainties" create "artificial restraints" on the commercialization of inventions by inhibiting the additional investments necessary to reduce the invention to a commercially viable product. S. Rep. No. 96-480, at 19 (1979). Substantial investments must be made to convert a patented invention to a marketable commercial product, and the willingness of prudent investors to make such investments is greatly impaired when there is doubt about the nature of the rights that are being secured by a patent license.

Especially in the biotechnology area, where testing and governmental approvals are often enormously expensive and accompanied by long periods of delay, uncertainty about a patent holder's ability to convey an exclusive license can pose a major obstacle to successful commercial development of the innovation. *See* 126 Cong. Rec. 2007 (1980) (Sen. Weicker) ("A new drug, for example, frequently requires careful testing on laboratory animals. If successful, years of carefully controlled clinical trials will follow.... It is clear that a drug manufacturer will invest the time and money to bring the product to the marketplace only if there is a reasonable certainty that the investment will be recovered through sales.").

It is no answer to suggest that a contractor like Stanford can alleviate such uncertainties by combing through the files of each faculty member, graduate student, or employee who may be an inventor and seeking documents from all of the third parties with whom those people may have interacted. Even such due diligence cannot prove a negative. Absolute assurance that a contrary assignment does not exist is impossible. And performing such a wide-ranging inquiry on each "subject invention" would significantly increase the university's administrative costs, thus undermining Bayh-Dole's correlative objective of "minimiz[ing] the costs of administering policies in this area." 35 U.S.C. § 200.

By contrast, giving primacy to § 202's "[d]isposition of rights" avoids the need for a costly and wide-ranging due diligence inquiry, thus reducing administrative costs for universities. 35 U.S.C. § 200. It also "promote[s] the utilization of

inventions” by providing the clear title that is most likely to call forth the substantial additional investment usually required to turn the invention into a commercially viable product. *Id.*

2. The Federal Circuit’s ruling also undermines the Government’s significant interests in seeing that the research it funds serves the public interest. The statute’s first section states, as another central congressional objective, “ensur[ing] that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions.” 35 U.S.C. § 200. But, as the Solicitor General stated, the decision below “jeopardize[s]” the Government’s rights that are explicitly secured to it under the Act. CVSG Br. at 18.

The provisions that confer title upon contractors, subject to numerous statutory conditions, also empower the Government, upon failure of a number of those conditions, to itself “receive title” and/or “march-in” and confer rights upon another. §§ 202(c)(1), (2), (3), 203. If the contractor’s rights were only the contingent set recognized by the Federal Circuit, then the Government’s rights would be diminished as well. This would compromise the Government’s ability to protect the public interest and to take back clear title for itself. A university that does not obtain clear title cannot “convey to the Federal agency, upon written request, title to any subject invention,” even though such a conveyance may be required under Bayh-Dole and its implementing regulations. 37 C.F.R. § 401.14(a), ¶ d.

The Federal Circuit sought to avoid the consequences of its position by suggesting that, where the contracting institution does not already have title to an invention, the Act might nevertheless provide the Government with “a discretionary option to [the inventor’s] rights.” Pet. App. 18a-19a. But that illusory hope finds no support in the statute, and the Federal Circuit pointed to none. The Act provides that the title of the contractor reverts back to the Government when conditions triggering that result arise, § 202(c)(1), (2), (3), and thus the only “title” that the Government “may receive” is the same “title” that the contractor received pursuant to its election under § 202(a). Clear title cannot revert back if it did not exist in the first place.¹⁹

Similarly, the Government’s ability to exercise “march-in” rights in response to the contractor’s failure to achieve utilization of a subject invention can logically pertain only to the rights that the contractor in fact possessed. If an inventor’s earlier unauthorized assignment really is effective to confer a right to shared ownership in a federally funded patent, that assignee ownership interest would be beyond the reach of the Government when it later

¹⁹ Consider the hypothetical scenario in which, under the Federal Circuit’s reasoning, another university that received only partial title due to an earlier assignment by an inventor to Company A were to breach one of the conditions of § 202(c)(1)-(3), causing the Government to intercede and receive title. It is hard to imagine that the property rights of Company A, declared by the court below to be good as against that university and other third parties, could be voided at some future time based on governmental intervention due to the university’s perceived breach of its obligations under Bayh-Dole.

“marches in” because of the contractor’s failure to achieve commercial development. A contrary conclusion would amount to creating a bizarre type of assignee “ownership” that the Government is free to rescind, not due to any breach of duty by the assignee, but through a failing by another—here the contractor.

The language in the Bayh-Dole Act does not remotely suggest any such strange innovation. Nor does it contemplate a “march-in” process in which the Government’s pre-eminent interest in funded research may be rendered an impotent nullity, by an inventor’s quiet assignment of his rights. Straightforward application of the statute’s language defining the “[d]isposition of rights” in “subject inventions” avoids both of these problems.

3. The decision below diminishes the federal interest in funded research in another respect as well. It creates a huge loophole in Bayh-Dole’s statutorily created obligations with respect to inventions produced with federal funds. Undisclosed assignment agreements like that executed by Dr. Holodniy at Cetus are quite unlikely to embody any of the obligations that Bayh-Dole imposes with respect to a “subject invention.” These include reporting the invention to the Government, granting the Government a license, manufacturing the invention in the United States where practicable,²⁰ or

²⁰ See 35 U.S.C. § 204. Although Respondent happens to manufacture its products in the United States (Resp. Supp. Opp. 12), that mere fortuity is not required by the VCA. Under the Federal Circuit’s decision, Respondent, which is itself affiliated with a Swiss parent company, appears to be free at any time to move manufacturing to a foreign location.

granting the Government march-in rights. And this is true, notwithstanding that the statute and regulations expressly impose such obligations on inventors, where they receive title with agency permission, subject to an express procedure outlined in the Act. 35 U.S.C. §§ 202(d), 204; 37 C.F.R. § 401.9.

Thus, in this way as well, by allowing the Cetus VCA form to take precedence, rather than focusing on the statutory “[d]isposition of rights” in § 202, the Federal Circuit’s decision “calls into question the Government’s ability to manage federally funded inventions for the benefit of the public.” CVSG Br. at 18.

4. Honoring Stanford’s right of first refusal in the inventions also best advances Bayh-Dole’s purpose of “promot[ing] collaboration between commercial concerns and nonprofit organizations.” 35 U.S.C. § 200. Bayh-Dole provides a clear rule that federal contractors like Stanford can obtain full patent rights in subject inventions without regard to any unilateral acts by individual inventors. History, both leading up to the Bayh-Dole Act and in the thirty years since, teaches that collaborations both in innovation and in commercial development of Government-funded inventions, are best encouraged by this sort of clear rule about how ownership rights can be acquired and what those rights are. The Federal Circuit’s rule would undermine such collaboration.

Bayh-Dole expressly seeks “to promote collaboration between commercial concerns and nonprofit organizations, including universities.” 35

U.S.C. § 200. This policy reflects a clear intention that the entire process contemplated by the Act, involving both innovation and commercial development of resulting inventions, is to take place within the context of the free enterprise system, and to involve effective collaboration between the research institutions and private businesses. *See* 126 Cong. Rec. 1799 (1980) (Sen. Kennedy) (“[i]f [small businesses and universities] are able to obtain patent rights to inventions, they will be in much better positions to secure the venture capital necessary to reduce the inventions to commercial use”); *see also id.* at 1796, 2002, 8739 (Sens. Bayh, Chaffee, and Dole).

Collaborations, in the areas of pure and applied research, and also in product development, are extremely widespread today, and are almost universally governed by contractual understandings between the parties. *See* Erin Shinneman, Note, *Owning Global Knowledge: The Rise of Open Innovation and the Future of Patent Law*, 35 Brooklyn J. Int’l L. 935, 954-55 (2010). Such projects will carry not only a range of duties, but also a variety of definable and undefinable risks. Effective collaboration demands both trust and confidence in the ability to accomplish useful targeted ends, and assessment and allocation of the attendant risks. Uncertainty in the form of risks that might significantly jeopardize the collective undertaking is thus an obstacle with which collaborators must contend. *Id.*

Prior to Bayh-Dole, the jumble of varied procedures undermined effective collaboration. *See supra* at 9-10. Bayh-Dole, by contrast, established a single clear procedural path by which research

institutions can receive clear and indisputable title, subject to defined duties and specific residual rights in the Government. The Act's relative success in achieving commercial development of funded inventions is in no small part due to its clarity in defining the rights of respective parties.

The Federal Circuit's ruling threatens a return to the bad old days. Allowing a research institution's Bayh-Dole-derived title to be called into question based on an inventor's prospective transfer years earlier will be an impediment to effective collaboration. The complex collaboration agreements now used widely by sophisticated businesses and research institutions can reach a suitable bargain, provided that they have reasonable clarity about their starting place.²¹ What will make such bargains much more difficult, where the issue is whether and on what terms to acquire a license for the purpose of product development, is doubt about the nature of the ownership right that the licensor holds. And that is precisely the uncertainty that the decision below creates.

Respondent has argued, to the contrary, that the straightforward construction of the statute's words would "chill innovative collaboration," because a party in Cetus's position would have no effective way to "protect its intellectual property while

²¹ There is little doubt that Cetus and Stanford could have reached such an agreement in 1989, had Cetus simply been forthright in approaching Stanford if it wished some recompense for allowing Dr. Holodniy's use of their facilities in connection with his on-going federally funded research. And there is even less doubt today, when the complexity and sophistication of such arrangements has grown significantly.

collaborating with a university,” and thus, presumably, such collaborations would be greatly curtailed. Resp. Supp. Opp. 10, 13. Respondent’s contention rests on a mistaken premise about the limits on research institutions’ ability to strike agreements defining the terms of collaboration.

The Act’s “prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency,” § 202(c)(7)(A), only requires such consent with regard to an assignment to another of *full* title to a subject invention. Funded research institutions may, and frequently do, strike a variety of less categorical bargains to foster such collaboration. In fact, the very funding agency involved in this case, the NIH, has guidelines specifically permitting agreements that provide industrial collaborators with “preferential access and/or rights to intellectual property deriving from [funding] Recipient research results,” including agreements giving industrial collaborators a first option to become the university’s exclusive licensee for commercial development. *See* Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts, 59 Fed. Reg. 55,673, 55,675-76 (Nov. 8, 1994).²²

In short, clarity and certainty are the touchstones of successful collaboration because industry

²² On this point, the difference between an assignment, which transfers substantially all of the patent rights, and a license, which does not, becomes telling. *See AsymmetRx, Inc. v. Biocare Med., LLC*, 582 F.3d 1314, 1319-21 (Fed. Cir. 2009) (discussing the difference between an assignment and a license).

collaborators can contract around rights that are clearly defined. Adhering to the statute's "[d]isposition of rights" in "subject inventions" produces that clarity and certainty. Respondent's interpretation, by contrast, clouds title to such "subject inventions" and diminishes the prospects for collaboration as a result.

II. THE UNIQUE FEDERAL INTERESTS AT STAKE IN THIS CASE PROVIDE ADDITIONAL REASONS TO REVERSE THE DECISION BELOW

The conclusion that Stanford's rights in the patents in suit cannot depend on the vagaries of private contract law is strengthened because of the "uniquely federal interests at stake" in this case. *Boyle v. United Techs. Corp.*, 487 U.S. 500, 504 (1988). As in *Boyle*, cases arising under the Bayh-Dole Act "border[] upon two areas that [this Court] has found to involve such uniquely federal interests:" determination of rights under federal contracts and patent law. *Id.* (internal quotation marks omitted).

Bayh-Dole's express directives about ownership of inventions produced with federal funding means that this case differs materially from the mine run of patent cases, where determination of patent ownership may present questions of state law. *See Jim Arnold Corp. v. Hydrotech Sys., Inc.*, 109 F.3d 1567, 1572-77 (Fed. Cir. 1997) (discussing several decisions of this Court). Where "uniquely federal interests" are involved, otherwise applicable rules of state law may be "pre-empted and replaced, where necessary, by federal law of a content prescribed (absent explicit statutory directive) by the courts—so

called ‘federal common law’ See *Boyle*, 487 U.S. at 504 (1988) (internal quotation marks omitted).

Like *Boyle*, the Act directly involves obligations and rights arising under contracts to which the Government is a party. *Id.* At the same time, the provisions at issue involve rights arising under patents, an area in which “state regulation ... must yield to the extent that it clashes with the balance struck by Congress.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989) (invalidating Florida law protecting unpatented boat design); see *Lear, Inc. v. Adkins*, 395 U.S. 653, 673-74 (1969) (overriding state court enforcement of contractual royalty provisions during the pendency of a challenge to patent); *Brulotte v. Thys Co.*, 379 U.S. 29, 32 (1964) (overriding state court enforcement of contractual royalty provisions beyond the term of the patents). Given the pre-eminent federal interest in the ownership of patent rights arising from federal funding, including the need for certainty of title, a uniform body of federal law rather than a variety of state-law rules should govern the validity and priority of an employee-inventor’s attempts to assign title.

The Federal Circuit recognized that federal common law governs the question of who has title to the patents at issue here. See Pet. App. 12a. But it failed to draw the correct lesson from that point. It failed to weigh properly—or at all—the nature of the federal interest arising from governmental expenditure of billions of dollars of taxpayer funds to promote the public good through research and the commercial realization of resulting inventions.

As reflected in years of practice under the vesting statutes, the Government has an undisputed right to simply claim ownership of inventions developed as a result of federal funding. The decision reflected in the Act, instead to direct title to the funded research institution subject to express conditions, sought among other explicit goals to promote the commercial development of such funded inventions. If research funding is to bear fruit through the realization of that goal, the title that the research institution receives and attempts to license to others must be certain and reliable. Such certainty of title cannot be squared with an open-ended right in the inventor to assign away that ownership interest to some third party, even before it has come into existence.

The Bayh-Dole Act thus can reasonably be viewed as imposing, with regard to inventors working on federally funded research, a status analogous to that recognized by the “hired to invent” doctrine, previously recognized by this Court as a matter of pre-*Erie* general federal common law. This doctrine provides that where an employee is hired for the particular purpose of engaging in inventive activity for his employer, ownership of any inventions developed in the course of employment vests as an original matter in the employer. *See Standard Parts Co. v. Peck*, 264 U.S. 52, 59-60 (1924); *see generally* Catherine L. Fisk, *Removing the ‘Fuel of Interest’ from the ‘Fire of Genius’: Law and the Employee-Inventor, 1830-1930*, 65 U. Chi. L. Rev. 1127 (1998). Within the Bayh-Dole scheme, when similar reasoning is applied to employees engaged in federally funded research, it supports the conclusion that the Government’s funding gives it ultimate

control over the resulting inventions. This reasoning supplements and supports all the other grounds, discussed above, for refusing to allow frustration of the statute's objectives by purported assignment to third parties of an inventor's claimed interest in those inventions.

Moreover, with regard to patent law—the second area of uniquely federal interest on which this case touches—it is notable that rights arising under the patent laws have always involved equitable considerations.²³ The Federal Circuit, however, failed properly to take these equitable considerations into account when adjudicating title to the patents in this case.

²³ Under the original Patent Act, 1 Stat. 109, 111 § 4 (1790), the injunctive aspect of the patent right to exclude was secured in state courts through a suit at equity, and in federal courts only under diversity jurisdiction. See 5 Donald A. Chisum, *Chisum on Patents* § 20.02[1][a] (1995). In 1819, Congress conferred general equity jurisdiction over patent cases upon federal trial courts. *Stevens v. Gladding*, 58 U.S. (17 How.) 447, 455 (1855). This grant was expanded by the 1870 Patent Act, which gave federal equity courts the special power in patent cases to award damages. *E.g.*, *Clark v. Wooster*, 119 U.S. 322 (1886). While the current Patent Act, U.S. Code tit. 35, has altered this arrangement to some degree—most notably by eliminating the remedy of accounting, *see* Chisum, *supra*, at § 20.02[4]—equity still plays a large role in patent cases as evidenced by the injunctive remedy and the defenses of inequitable conduct, laches, and estoppel (whether equitable estoppel, assignor estoppel, or estoppel based on the patent prosecution history). *See generally* *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006); Leslie J. Lott, *Equitable Defenses in Patent Infringement Litigation*, 572 P.L.I. Pats., Copyright, Trademarks & Literary Prop. Course Handbook Ser. 1119 (Sept.-Nov. 1999).

In particular, the Federal Circuit paid no heed to equities when it breezed by the facts of this case and concluded that Roche could claim an ownership interest in the patents-in-suit. Roche and Cetus slept on their purported rights for over fifteen years, while Stanford, confident of its ownership because it had fulfilled the statute's requirements, continued to invest time, money, and effort in licensing and commercializing the patents as well as performing further research.

Several other factors raise additional serious questions about the enforceability of the VCA's purportedly very broad assignment of ownership rights on the facts of this case. Enforcement of such a prospective assignment of future rights is itself equitable in nature, *see Pomeroy on Equity Jurisprudence*, § 1288 (stud. ed. 1907), and thus deserves careful scrutiny. *See Ernest Bainbridge Lipscomb III, 5 Lipscomb's Walker on Patents* § 19:16 (3d ed. 1986). The Cetus agreement was signed at a time when Dr. Holodniy was already working pursuant to a federal research grant, and had already "agreed to assign" to Stanford any interest flowing from his current work, which during 1989 was pursued both at Stanford and at Cetus. Moreover, while the Cetus agreement was denominated a "confidentiality agreement," the provisions relevant here purporting to assign ownership interests do not require that the accessed, triggering information be confidential in nature. The Federal Circuit decision did not turn on whether the information learned at Cetus was confidential, Dr. Holodniy did not believe that it was, Pet. App. 96a, and that view is borne out by the fact that a detailed article was published in

1991 concerning the work done by Dr. Holodniy at Cetus. JA 135-149.

An interpretation of the Bayh-Dole Act that allows Stanford's claim of title and, more importantly, the rights and interests of the United States, to be frustrated by so dubious an assignment and so stale a claim cannot be correct.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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