

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.

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

BRIEF OF AMICI CURIAE ASSOCIATION OF
AMERICAN UNIVERSITIES, AMERICAN
ASSOCIATION FOR THE ADVANCEMENT OF
SCIENCE, AMERICAN COUNCIL ON EDUCATION,
ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
ASSOCIATION OF INDEPENDENT RESEARCH
INSTITUTES, ASSOCIATION OF PUBLIC AND LAND-
GRANT UNIVERSITIES, THE ASSOCIATION OF
UNIVERSITY TECHNOLOGY MANAGERS, COUNCIL
ON GOVERNMENTAL RELATIONS,
IN SUPPORT OF PETITIONER

DOUGLAS HALLWARD-DRIEMEIER

Counsel of Record

JAMES R. MYERS

ROPES & GRAY LLP

One Metro Center

700 12th Street. N.W., Suite 900

Washington, D.C. 20005

(202) 508-4600

Douglas.Hallward-Driemeier@

ropesgray.com

*Counsel for Amici Other than The University of Texas at
Austin and Wisconsin Alumni Research Foundation
[Additional Counsel and Amici On Inside Cover]*

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(202) 508-4600

Douglas.Hallward-Driemeier@ropesgray.com

*Counsel for Amici other than The University of Texas
at Austin and Case Western Reserve University*

[Additional Counsel And *Amici* On Inside Cover]

ARIZONA STATE UNIVERSITY, THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, BRANDEIS UNIVERSITY, BROWN UNIVERSITY, CALIFORNIA INSTITUTE OF TECHNOLOGY, CARNEGIE MELLON UNIVERSITY, CASE WESTERN RESERVE UNIVERSITY, CORNELL UNIVERSITY, DUKE UNIVERSITY, EMORY UNIVERSITY, HARVARD UNIVERSITY, INDIANA UNIVERSITY, IOWA STATE UNIVERSITY, JOHNS HOPKINS UNIVERSITY, MICHIGAN STATE UNIVERSITY, NEW YORK UNIVERSITY, NORTHWESTERN UNIVERSITY, THE PENNSYLVANIA STATE UNIVERSITY, PURDUE UNIVERSITY, RICE UNIVERSITY, RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY, SYRACUSE UNIVERSITY, TEXAS A&M UNIVERSITY, TULANE UNIVERSITY, THE UNIVERSITY OF ARIZONA, THE UNIVERSITY OF CHICAGO, UNIVERSITY OF COLORADO, UNIVERSITY OF FLORIDA, THE UNIVERSITY OF KANSAS, UNIVERSITY OF MARYLAND, COLLEGE PARK, UNIVERSITY OF NEBRASKA-LINCOLN, THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL, UNIVERSITY OF PENNSYLVANIA, UNIVERSITY OF PITTSBURGH, UNIVERSITY OF ROCHESTER, UNIVERSITY OF SOUTHERN CALIFORNIA, THE UNIVERSITY OF TEXAS AT AUSTIN, UNIVERSITY OF VIRGINIA, UNIVERSITY OF WASHINGTON, UNIVERSITY SYSTEM OF MARYLAND, WASHINGTON UNIVERSITY IN ST. LOUIS, AND YALE UNIVERSITY

PATRICIA OHLENDORF
Vice President for
Legal Affairs
THE UNIVERSITY OF TEXAS
AT AUSTIN

*Counsel for The University
of Texas at Austin*

GARY KAPLAN
DEFOREST KOSCELNIK YOKITIS
KAPLAN & BERARDINELLI

*Counsel for Case Western
Reserve University*

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INTEREST OF *AMICI CURIAE*¹

Amici are leading research universities and associations of universities involved in the research and development of a wide range of technologies. *Amici* have thirty years of experience under the Bayh-Dole Act and are keenly aware of the threat the court of appeals' decision poses to the Act's success.

**SUMMARY OF ARGUMENT**

“[F]ederal support accounts for over half of the research conducted at colleges and universities in the United States.”² Even according to conservative estimates, university patent licensing has produced astounding economic benefits – from 1996 to 2007, university licensing contributed an estimated \$187 billion to U.S. gross domestic product, achieved a

¹ The parties have consented to the filing of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of *amici curiae*'s intention to file this brief. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission.

² Gov't Accountability Office, GAO-09-742, *Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions* 1 (2009) (hereinafter “GAO Report”).

\$457 billion impact on U.S. gross industrial output, and created 279,000 new jobs.³

The Bayh-Dole Act, 35 U.S.C. §§ 200-212, which provides the framework for commercialization of federally funded research at universities, stands as one of the most effective statutes ever passed by Congress. One commentator called the Act “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century” and suggested that “[m]ore than anything, this single policy measure helped to reverse America’s precipitous slide into industrial irrelevance.” *Innovation’s Golden Goose*, 365 *The Economist* 3, 3 (2002).

The Act provides for the disposition of rights in a predictable and reliable way that allows universities and other nonprofit institutions to acquire clear title and license the inventions for development while at the same time reserving important rights for the federal government. The uniformity and clarity provided by the Act are among its principal achievements and are essential to the statutory purpose of promoting the advantageous utilization of inventions derived from federally funded research. See Council on Governmental Relations, *The Bayh-Dole Act: A Guide to the Law and Implementing Regulations* 9

³ See David Roessner *et al.*, *The Economic Impact of Licensed Commercialized Inventions Originating in University Research, 1996-2007* 7-8 (2009), available at [http://www.bio.org/ip/tech transfer/BIO_final_report_9_3_09_rev_2.pdf](http://www.bio.org/ip/tech%20transfer/BIO_final_report_9_3_09_rev_2.pdf).

(1999), available at <http://www.unm.edu/~counsel/files/DOC057.PDF> (“Certainty of title to inventions made under federal funding is perhaps the most important incentive for commercialization.”); GAO Report, *supra*, at 4. The statute has been so effective at efficiently disposing of patent rights that, until the decision of the court of appeals in this case, the Act has attracted little controversy, and consequently little judicial attention, despite its critical role in the most dynamic areas of the American economy.

The court of appeals’ opinion, if not corrected by this Court, threatens that success story by casting in doubt the rights of universities and the federal government alike to inventions arising from hundreds of billions of dollars in research. The decision of the court of appeals turns the statutory structure on its head, allowing rights in federally funded patents to be disposed of in obscure private contracts between researchers and third parties rather than according to Congress’s dictates. Bayh-Dole provides for a “[d]isposition of rights” in federally funded inventions, 35 U.S.C. § 202 (title), and establishes a presumption that ownership is allocated to the university or other nonprofit, 35 U.S.C. § 202(a). Individual researchers are allocated rights of ownership only if both the university and the federal agency providing the funding decline to take title. 35 U.S.C. § 202(d). The court of appeals, by contrast, held that the ownership rights of the university are subject to being defeated by the inventor, operating outside the statute.

By the same reasoning, the federal government's own rights and interests are subject to circumvention at the whim or by the inadvertence of an individual inventor. The court of appeals' refusal to enforce Bayh-Dole places at risk, for instance, the government's right under the statute to reserve title to itself in certain instances, to take title from a nonprofit that violates the Act's provisions, to receive a license to practice the invention, and to require the nonprofit to grant a license to a third party under circumstances specified in the Act. *See* 35 U.S.C. §§ 202(a), (c), 203, 204. It also undermines the strong federal interest in promoting commercialization through uniform, clear, and efficient allocation of title to federally funded inventions. *See* 35 U.S.C. § 200; S. Rep. No. 96-480, at 21 (1979).

The consequences of the court of appeals' decision are dramatic. Universities cannot simply rewrite assignment documents with all of their researchers going forward in time, because hundreds of billions of dollars in federally funded inventions will be entering the market during the next 10 to 15 years based on already-executed assignment documents. *See* GAO Report, *supra*, at 6-7. Private industry cannot be expected to invest billions of dollars over 10 to 15 years to transform fundamental breakthroughs at universities into commercial products (and jobs) without knowing that title to the inventions is free from reasonable question. Roche will likely urge the Court to wait until the consequences of clouded title are measured and weighed. But delay itself will have

a considerable detrimental effect on universities, federal funding agencies, and the U.S. economy. The Court should grant the petition for certiorari and correct the court of appeals' fundamentally flawed decision.

◆

ARGUMENT

I. OWNERSHIP OF FEDERALLY FUNDED INVENTIONS IS ALLOCATED ACCORDING TO BAYH-DOLE

The court of appeals erroneously analyzed this case as one of dueling contracts. The court first assessed the “chain of title” in the invention as a question of contract interpretation, *i.e.*, whether priority should be given to the assignment in the employment agreement between Stanford and its faculty researcher Dr. Holodniy (confirmed at the time of the patent application) or the assignment contained in a Visitor Confidentiality Agreement (“VCA”) between Holodniy and a third-party lab, Cetus. *See* Pet. App. 12a-15a.⁴ The court concluded that Stanford’s “agree to assign” framework creates only a promise to assign rights in the future whereas, under the VCA, “Cetus immediately gained equitable title to Holodniy’s inventions.” *Id.* at 13a-14a. Holodniy therefore “ha[d] nothing remaining to

⁴ Roche Molecular Systems, Inc. and related respondents (“Roche”) are successors to Cetus’s agreement with Holodniy.

assign” to Stanford at the time of its patent application. *Id.* at 14a (quoting *FilmTec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991)). Only after so concluding did the court consider the possible effect of Bayh-Dole, asking whether Stanford’s “election of title under Bayh-Dole had the power to void any prior, otherwise valid assignments of [Holodniy’s] patent rights.” *Id.* at 19a. Instead, the court should have started with Bayh-Dole and asked whether Holodniy could assign rights to Cetus in derogation of Stanford’s statutory rights.

Bayh-Dole, not side-agreements between individual researchers and third parties, governs the allocation of rights in federally funded inventions. The Act specifies, for example, that nonprofits “acquire[] title under this chapter” of the U.S. Code, 35 U.S.C. § 203(a), and that inventors’ ownership rights, which must be approved by the federal agency, are “subject to the provisions of this Act,” 35 U.S.C. § 202(d). It is evident from a careful analysis of the statutory text and structure, as well as the broader legal context, that Holodniy could assign to Cetus only limited, contingent rights that could not defeat the superior rights allocated to Stanford and the federal government under the Act.

A.1. Section 202, entitled “Disposition of rights,” specifies the relative rights of the government, nonprofit contractors, and individual inventors in federally funded inventions. 35 U.S.C. § 202. Subsection (a) establishes the general rule that “[e]ach nonprofit organization or small business firm

may . . . elect to retain title to any subject invention.” 35 U.S.C. § 202(a); *see also* S. Rep. No. 96-480, at 36 (reprinting letter from the Congressional Budget Office) (“The bill would *automatically grant* small businesses and nonprofits *title* to inventions arising from Government-supported research unless the contracting agency could justify . . . holding title to the invention.”) (emphasis added). The same subsection permits the federal government to reserve title to itself in specified circumstances – for instance, when the funding contract concerns weapons-related programs or foreign intelligence activities. 35 U.S.C. § 202(a)(i)-(iv).

When, as is usually the case, title is allocated to the nonprofit, the nonprofit’s rights are “subject to the provisions of paragraph (c)” of § 202 and “the other provisions of” the Act, 35 U.S.C. § 202(a), that reserve important rights to the government and impose other restrictions on the nonprofit to “meet the needs of the Government and protect the public” interest in the federally funded invention, 35 U.S.C. § 200. Under those provisions, the government agency has discretion to take title to the invention if the contracting nonprofit fails timely to disclose the invention to the government, to elect title, or to file necessary patent applications. 35 U.S.C. § 202(c)(1)-(3); *see Campbell Plastics Eng’g & Mfg., Inc. v. Les Brownlee*, 389 F.3d 1243, 1249 (Fed. Cir. 2004) (failure to disclose invention properly resulted in forfeiture of patent ownership to the funding agency). The government also receives a non-exclusive,

non-transferable, irrevocable, paid-up license to practice the invention and may prohibit a nonprofit from assigning rights in the invention. 35 U.S.C. § 202(c)(4), (c)(7)(A). The contractor, for its part, is obligated to make reasonable efforts to achieve practical application of the invention and to report its efforts to the government, to give preference to small businesses and U.S. industry, to share royalties with the inventor, and to utilize excess royalties to fund further research or education. 35 U.S.C. §§ 202(c)(5), (c)(7)(B)-(D), 203, 204. In certain exceptional circumstances, the government is entitled to “march in” and require the contractor to grant a license to a third party. 35 U.S.C. § 203(a).

Section 202 also specifies the circumstances under which rights to a federally funded invention will be allocated to the inventor and the limitations on those rights. Subsection (d) provides that “[i]f a contractor does not elect to retain title to a subject invention . . . the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.” 35 U.S.C. § 202(d). Thus, the statutory text makes clear that an inventor can exercise ownership rights in the invention only if two circumstances are met: (1) the contractor does not exercise its superior right to take title and (2) the federal agency affirmatively grants a request by the inventor. *Ibid.*; *Fenn v. Yale Univ.*, 184 Fed. Appx. 21, 22 (2d Cir. 2006) (summary order) (“[A] federal agency . . .

may only grant an inventor's request to retain rights to an invention subject to the Act when the contractor . . . has elected not to retain [the] rights."). Moreover, even when permitted to take title, the inventor does so "subject to the provisions of this Act and regulations promulgated hereunder." 35 U.S.C. § 202(d). By regulation, the Secretary of Commerce has specified that an agency that allows the inventor to retain ownership rights pursuant to Section 202(d) "will impose" certain conditions upon the inventor. 37 C.F.R. § 401.9. Those conditions include requirements that the inventor convey title to the government if he fails timely to disclose the invention to the government or to prosecute or maintain the patent rights, and the government's right to compel licensing of the invention in certain circumstances in which the inventor has failed to utilize the invention or failed to secure an agreement that products embodying the invention will be produced in the United States. *Ibid.*; 37 C.F.R. § 401.14(a) (standard clause ¶¶ (d)(1), (d)(3), (i), (j)).

It is therefore clear from the Act's text that Holodniy could not convey to Cetus rights that were superior to Stanford's. Under the Act, Holodniy could exercise rights in the invention *only* if Stanford chose not to exercise its right to assert ownership *and* the funding agency *granted* an application by Holodniy to retain ownership. Holodniy's rights, and all that he could assign to Cetus, were therefore doubly contingent. Because neither of the necessary contingencies occurred – Stanford elected title, and the agency did

not grant Holodniy permission to retain ownership (which Holodniy never requested) – Cetus could not have obtained any actual ownership rights by assignment from Holodniy.

2. The court of appeals, by contrast, regarded Bayh-Dole as “regulat[ing] relationships of small business and nonprofit grantees with the Government, not between grantees and the inventors who work for them.” Pet. App. 21a (quoting *Fenn v. Yale Univ.*, 393 F. Supp. 2d 133, 141-42 (D. Conn. 2004), *aff’d*, 184 Fed. Appx. 21 (2d Cir. 2006)). Thus, in the court’s view, before the Act could allocate rights between the government and Stanford, Stanford must first receive an assignment of rights from Holodniy, a question of state and Federal Circuit contract law. *Id.* at 12a, 21a. But that understanding cannot be squared with the text and structure of the Act. Under the Act, as discussed above, the inventor must apply for and receive permission from the federal agency before he can retain ownership rights in a federally funded invention. 35 U.S.C. § 202(d). Moreover, if the agency consents, it “will impose” conditions on the inventor’s rights. 37 C.F.R. §§ 401.9, 401.14(a) (standard clause ¶¶ (d)(1), (d)(3), (j)). The statute’s recognition of the agency’s discretion to “grant [inventor] requests for retention of rights” and the regulation’s “impos[ition]” of conditions on the inventor if the agency does grant a request necessarily presume that the inventor’s right to exercise ownership of the patent is conditioned by “the provisions of [the] Act.” 35 U.S.C. § 202(d); 37 C.F.R. § 401.9. The

court of appeals' view that Holodniy could assign ownership of a federally funded invention to a third party, thereby trumping Bayh-Dole's allocation of rights, contradicts the Act's text and structure.

B. The conclusion that rights in federally funded inventions are determined according to the Bayh-Dole framework, and not by side-agreements entered into (perhaps inadvertently) by individual researchers, is further supported by the larger legal context within which Bayh-Dole was adopted. The apparent assumption of the court of appeals that an individual inventor has unfettered discretion whether and how to assign rights in federally funded inventions is incorrect. As other federal funding statutes make clear, and the Federal Circuit has elsewhere recognized, Congress can allocate ownership in federally funded inventions, rendering invalid any contrary purported assignment by the inventor. Bayh-Dole did not grant to individual researchers the power – that did not previously exist – to frustrate federal policy by assigning federally funded inventions to third parties. The erroneous interpretation of the court of appeals in this case would allow just that.

1. Congress has the preeminent role in establishing the system for patenting inventions that derive from federally funded research. All patent rights ultimately derive from federal statute. The Constitution provides that “The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective

Writings and Discoveries.” U.S. Const. Art. I, § 8, cl. 8. Thus, the exclusive rights secured by patents owe their existence solely to the acts of Congress, and are therefore subject to such limitations as Congress imposes. Where Congress also provides the funding for the research from which an invention derives, its authority to control the disposition of patent rights in the invention is even clearer.

In numerous statutes that pre-dated Bayh-Dole, Congress allocated ownership of federally funded inventions to the federal government itself by force of law, independent of any assignment from the individual inventor. Several statutes specified that “title to such invention shall vest in the United States, and if patents on such invention are issued they shall be issued to the United States” unless waived. 42 U.S.C. § 5908(a) (1976) (Department of Energy);⁵ *see also* 42 U.S.C. § 2182 (1976) (“[a]ny invention or discovery . . . shall be vested in, and be the property of” the federal agency that funded the research unless the agency “waive[d] its claim”) (Nuclear Regulatory Commission); 42 U.S.C. § 2457(a) (1976) (NASA). Such statutes, without question, vested title in the United States unless the

⁵ Several additional statutes incorporated Section 5908 by reference. *See* 7 U.S.C. § 178j (Supp. II 1979); 42 U.S.C. § 5585(b) (Supp. II 1979); 42 U.S.C. § 6981(c)(3) (1976); 42 U.S.C. § 7879 (Supp. II 1979), *repealed by* Water Resources Research Act of 1984, Pub. L. No. 98-242, §§ 109-110(a), 98 Stat. 97, 101 (codified at 42 U.S.C. § 10308) (also incorporating Section 5908).

United States waived the rights in favor of the contractor or inventor.

As the Federal Circuit recognized in a case involving a pre-Bayh-Dole funding agreement, such pre-Bayh-Dole statutes “clearly provide[d] that title to any invention made or conceived under a [covered] contract ‘shall vest’ in the United States.” *FilmTec Corp. v. Hydranautics*, 982 F.2d 1546, 1550 (Fed. Cir. 1992) (construing 42 U.S.C. § 5908 (as incorporated by the Saline Water Conversion Act, 42 U.S.C. § 1959d note (1976) (repealed 1978))). Thus, the court held, the inventor’s purported assignee lacked standing to sue on the patent because the inventor “had no right to assign it.” *Id.* at 1553. Rather, “title to inventions made by an employee hired to perform [federally funded] research automatically vested in the United States” by “operation of law.” *Ibid.*

2. The court of appeals’ decision in this case creates an unwarranted inconsistency – individual inventors have the power to frustrate the federal government’s allocation of rights in federally funded inventions developed under contracts with nonprofits or small businesses, which are governed by Bayh-Dole, but have no such power with respect to inventions developed under contracts with other entities, such as large for-profit companies. Bayh-Dole displaces other statutes insofar as they relate to nonprofit organizations and small businesses by switching the presumption of ownership from the federal government to the nonprofit or small business. *See* 35 U.S.C. § 202(a); *id.* at § 210(a)

(providing that Bayh-Dole “shall take precedence over” any statute that “would require a disposition of rights” inconsistent with Bayh-Dole, including 21 listed statutes). However, the pre-Bayh-Dole statutes, such as Section 5908, continue to govern federally funded research with institutions other than non-profits and small businesses. *See* 35 U.S.C. § 210(b).⁶ *Hydranautics* makes clear that under such statutes, Holodniy’s purported assignment to Cetus in the VCA could not defeat the federal agency’s allocation of rights to Stanford. *See* 982 F.2d at 1548, 1553-54.

There is no indication that Congress intended Bayh-Dole to extend to individual inventors, in a dramatic departure from pre-Bayh-Dole statutes, the unilateral power to assign federally funded inventions outside the statutory structure. While Bayh-Dole marked an important policy shift vis-a-vis nonprofits and small businesses – adopting a presumption that they, rather than the federal government, would be allocated ownership of federally funded inventions – no significant change was contemplated with respect to the rights of inventors. To the contrary, although it differs in detail, Bayh-Dole, like its predecessors, permits “[d]isposition of

⁶ A Presidential Memorandum (endorsed by Congress, *see* 35 U.S.C. § 210(c)) has instructed federal agencies to use their waiver authority under the pre-Bayh-Dole statutes to extend Bayh-Dole’s benefits to other federal contractors as well. *See* Memorandum on Government Patent Policy, Pub. Papers 248 (Feb. 18, 1983).

rights” in such inventions to individual inventors only pursuant to affirmative agency action and “subject to the provisions of” the Act. 35 U.S.C. § 202(d).

As demonstrated above, the court of appeals’ view that Bayh-Dole concerns only the allocation of rights between the federal government and its contractors is therefore fundamentally flawed. The Act governs the disposition of rights among the federal government, nonprofit and small business contractors, *and* individual inventors. Holodniy could not assign to Cetus rights greater than those allocated to him under the Act. Because Holodniy’s rights were doubly contingent, and neither contingency occurred, Cetus did not obtain ownership rights in the invention, and the court of appeals’ judgment was in error.

II. THE COURT OF APPEALS’ DECISION UNDERMINES THE CLEAR TITLE THAT IS CENTRAL TO BAYH-DOLE

Prior to Bayh-Dole’s enactment, ownership of patent rights in federally funded research was governed by a convoluted combination of statutes, Executive Orders, federal regulations, funding agreements, assignment documents, and licenses. In general (subject to various exceptions), federal funding agencies acquired direct ownership of patents arising from federally funded research, unless the agency affirmatively decided to waive its rights. S. Rep. No. 96-480, at 2. It was nearly impossible, under that system, for nonprofits to obtain clear title to

inventions. As Congress ultimately concluded, that system failed to achieve the full promise of the research on which the federal government was spending so much money. Bayh-Dole establishes a uniform statutory framework under which nonprofits can obtain clear title to government funded inventions and attract private investment to commercialize the inventions. The Act has been immensely successful, but that success is cast in serious doubt by the court of appeals' decision, under which it is virtually impossible for universities to ensure clear title to their inventions.

A. Prior to Bayh-Dole's enactment, the lack of uniformity and clarity in the method for obtaining title to federally funded inventions presented a significant obstacle to the development of those inventions. See GAO Report, *supra*, at 4. Patent rights to government funded research were disposed of under twenty-six different regimes. *Ibid.*; H.R. Rep. No. 96-1307, pt. 1, at 3 (1980). This "potpourri" of policies "confus[ed] and discourage[d]" government contractors. Bradley Graham, *Patent Bill Seeks Shift to Bolster Innovation*, Wash. Post, Apr. 8, 1979, at M1. The Senate Report that accompanied Bayh-Dole recognized that uniformity and clarity were necessary to incentivize universities and small businesses to participate in government funding programs, as these private entities lacked the resources to cope with the existing maze of agency policies. See S. Rep. No. 96-480, at 2-3 (the complexity of "at least 24 different patent policies" that were "frequently contradictory")

“constitutes a very real hurdle to universities, non-profit organizations, and small businesses who do not have large legal staffs to negotiate through this policy maze”). The multiplicity of approaches also made it difficult to ascertain clear title to inventions. The Senate Report recognized “the onerous burden of trying to determine the ownership of patents arising from the agencies’ research and development grants and contracts.” *Id.* at 30.

Moreover, government ownership of federally funded inventions did not encourage the investment in development necessary to realize those inventions’ full potential. When Bayh-Dole was enacted, the federal government (through the individual funding agencies) owned between 25,000 and 30,000 patents. Graham, *supra*, at M2. Less than approximately 4% of those patents were developed for commercial use. *Ibid.*; *see also* GAO Report, *supra*, at 2.

Congress designed Bayh-Dole to “end this uncertainty [of patent ownership] and prevent these promising inventions from being suffocated under reams of unnecessary bureaucratic redtape.” S. Rep. No. 96-480, at 21; *see also* H.R. Rep. No. 96-1307, pt. 1, at 3. Bayh-Dole thus explicitly replaced the plethora of existing statutory regimes for disposing of patent rights in federally funded research with a “single, uniform national policy.” H.R. Rep. No. 96-1307, pt. 1, at 3; 35 U.S.C. § 210(a) (listing the replaced federal statutes). This new, uniform policy allowed “universities and nonprofit organizations,” which are “much more efficient in delivering these

important discoveries to the marketplace than are [government] agencies,” to “retain patent rights on these discoveries.” S. Rep. No. 96-480, at 29. At the same time, the new policy “adequately protect[ed] the legitimate rights of the funding agencies” in the inventions. *Id.* at 30; *see also* 35 U.S.C. § 200 (recognizing the need “to ensure that the Government obtains sufficient rights” in the inventions “to meet the needs of the Government and protect the public”).

B. Bayh-Dole has been incredibly successful in accomplishing Congress’s purposes. As of the end of FY 2008, 3,381 startup companies formed around university research are still in operation. Press Release, Ass’n of Univ. Tech. Managers, *New Survey Reveals Universities’ Impact on the U.S. Economy* (Feb. 2010). Of those startups, 595 were formed in FY 2008, with 72 percent of the new companies headquartered in the institution’s home state. *Ibid.* American universities “create more than two startup companies each working day,” and such startups “have longer life spans and raise more capital than non-university affiliated startups.” Arundeeep S. Pradhan, Op-Ed, *Defending the University Tech Transfer System*, *BusinessWeek*, Feb. 19, 2010.

Technologies licensed by academic research institutions have spawned new industries such as biotechnology and nanotechnology.⁷ “In the period

⁷ Ass’n of Univ. Tech. Managers, *Statement on the Role of Federally Funded Univ. Research in the Patent System* (2007), (Continued on following page)

2000-08, U.S. universities received 147,515 invention disclosures, filed 83,988 new patent applications, and signed 41,598 license and option agreements, of which 4,566 were with startup companies based on university research.” Pradhan, *supra*. Universities helped bring to market 4,338 new products between 1998 and 2006, or more than 1 new product every day. *The Role of Federally Funded University Research in the Patent System: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 118 (2007) (statement of Charles F. Louis, Vice Chancellor for Research, University of California, Riverside). Examples of new products arising from university research, include:

- Internet Explorer® (Mosaic) and Eudora Email (U. of Illinois)
- Google® (Stanford)
- Haemophilus B conjugate vaccine (U. of Rochester)
- Osteoporosis treatment (U. of Washington)
- Psoriasis treatment (Harvard)
- LYRICA® for fibromyalgia (Northwestern University)

- TRUSOPT® ophthalmic drops used for glaucoma (University of Florida)⁸

Moreover, Bayh-Dole spurs research and innovation beyond the inventions that arise from federal funding. Pursuant to 35 U.S.C. § 202(c)(7)(C), the balance of any patent royalties after expenses and payments to inventors must be used to fund further university research or education. Universities, hospitals, and research institutions received \$3.4 billion in patent royalties in 2008, revenue that augments the direct federal investment in research and education.⁹

C. The court of appeals' decision threatens Bayh-Dole's success by undermining the statute's clear and efficient allocation of rights in federally funded inventions. By focusing its analysis, not on the statute, but on dueling contracts that individual researchers might have signed decades ago, the court

⁸ Ass'n of Univ. Tech. Managers, *Technology Transfer Stories: 25 Innovations That Changed the World* 40-42, 94-96, 106-08 (2006); Council on Governmental Relations, *supra*, at 8; Press Release, Ass'n of Univ. Tech. Managers, *supra*; Pradhan, *supra*; Jo Thomas, *Satisfaction in Job Well Done Is Only Reward for E-Mail Software Inventor*, N.Y. Times, Jan. 21, 1997, at A10; Sharita Forrest, *NCSA Web Browser 'Mosaic' Was Catalyst for Internet Growth*, Inside Illinois (Apr. 17, 2003), available at <http://news.illinois.edu/II/03/0417/index.html>; Press Release, Nw. Univ. (Dec. 18, 2007), <http://www.northwestern.edu/newscenter/stories/2007/12/lyrica.html>.

⁹ AAAS Policy Alert (Feb. 25, 2010), <http://www.aaas.org/spp/policyalert/policyalert20100225.html>.

has created the very confusion and discouragement of development that Congress sought to eliminate.

The court of appeals' decision severely undermines the clarity of title ownership that is essential to incentivizing commercialization. Under the court's analysis, title at any given time could depend on the language of documents signed many years before and of which the university and any prospective industry collaborator are almost certainly unaware. Under such a system a university and its industry collaborator, believing that title rested in the university, could invest in a technology for over 15 years only to face a title challenge at the time of commercialization. *See* GAO Report, *supra*, at 6-7, 10 (recognizing that it can take 10 to 15 years for an invention to reach the market). In this very case, Stanford invested in the subject technology (supported by NIH funds) and worked to protect patent rights in the claimed technology for 20 years before being told in 2009 that those patent rights (as of February 1989) belonged to Roche. Pet. App. 4a, 28a. Such uncertainty of title would, contrary to Bayh-Dole's purpose, discourage private entities from making the investments necessary to bring new products to market. *See* S. Rep. No. 96-480, at 19 (condemning "uncertainties" of patent ownership, which impose "artificial restraints" on commercialization). Indeed, the court of appeals' holding actually creates an incentive for third parties to search for past visitor agreements entered into by university researchers or to entice them to execute new assignments in the

hope of free-riding on the work of universities and their industry collaborators.

By imposing extraordinary burdens on determining patent ownership for federally funded inventions, the court's decision strikes at the heart of the statutory goal of efficient disposition of federally funded patent rights. The court of appeals charged Stanford with constructive or inquiry notice of the assignment in Holodniy's VCA. Pet. App. 16a-17a. Stanford received no actual notice of the purported assignment, which was not recorded in the Patent Office. *Ibid.* Thus, to prevent the loss of patent rights (or identify rights that are lost and truncate further investment), a university's or industry collaborator's lawyers must comb through every possibly relevant document, including seeking documents from any third parties with which the university's researchers might have interacted. Such futile searches would constitute a far worse waste of patent lawyer resources than existed under the regime that Bayh-Dole was intended to correct. *See* S. Rep. No. 96-480, at 30 (condemning the "onerous burden" on government attorneys "trying to determine the ownership of patents arising from the agencies' research and development grants and contracts").

Nor can universities easily remedy the problem through differently drafted faculty employment agreements providing for immediate assignment of any invention. As long as the question of ownership comes down to dueling assignment provisions, as the court of appeals held, universities can never know

whether their own contract will prevail. There can always be another, equally well drafted agreement executed prior to the university's. The only way to avoid the problem of the unknowable engendered by the court of appeals' decision is to make the statutory scheme the ultimate arbiter of interests in federally funded inventions. That is, as demonstrated above, precisely what Congress intended.

III. THE DECISION BELOW SEVERELY IMPAIRS THE FEDERAL GOVERNMENT'S INTERESTS AS WELL AS UNIVERSITIES'

In a footnote, the court of appeals suggested that the federal government (and even Stanford) might have available other remedies by which to vindicate their rights under Bayh-Dole. *See* Pet. App. 20a n.1 (reserving the question "whether the Act provides the Government or Stanford some other legal recourse to recover Holodniy's rights"). But that suggestion flies in the face of the court of appeals' reasoning. Under the logic of its decision, Stanford cannot secure its rights under the Act because the court of appeals has effectively declared that those rights never arose in the first place, having been preempted by Holodniy's assignment to Cetus. The decision's logic will likely also control the resolution of future disputes over *the government's* rights, not just universities', because any suit involving the government's rights would likely be appealed to the Federal Circuit. *See* 28 U.S.C. §§ 1295(a)(1) and (3), 1338(a), 1491, 1498.

The court of appeals' refusal to enforce Stanford's rights under Bayh-Dole necessarily implies that an inventor is free to circumvent the government's rights as well, by assigning ownership to a third party of his choosing. The government, like universities, takes its rights in federally funded inventions only from Bayh-Dole – that statute alone provides the government with the right to deny ownership rights to an inventor or restrict those rights. *See* 35 U.S.C. § 202(d); 37 C.F.R. §§ 401.9, 401.14(a). Thus, the reasoning of the court of appeals' decision precludes the government, as it precludes universities, from asserting its statutory rights in order to protect the public interest in these inventions. *See supra* at 7-9 (discussing the government's march-in and other statutory rights relative to the inventions). For this reason, the court of appeals' footnote purporting to reserve the question of the government's rights is cold comfort to the myriad agencies that might seek to protect their interests in the inventions. *See* Pet. App. 20a n.1.

The court of appeals suggested that the decision in this case was consistent with its earlier decision in *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347 (Fed. Cir. 2007), in which it held that an inventor's violation of the government's rights under Bayh-Dole makes the inventor's rights voidable, but not automatically void. *See id.* at 1352-53. But the court's reliance on *Central Admixture* was misplaced. That decision in fact supports Stanford's position in the present case. In *Central Admixture*, the university

waived its right to retain title and the researcher applied for and received permission, with conditions, from the federal agency to pursue the patent application himself. *Id.* at 1351. The inventor violated a condition of the agency's consent, and the question arose whether the granted request was rendered void or merely voidable at the government's discretion. *Id.* at 1352. The court of appeals recognized that the statute and regulations give the agency discretion whether to take back title in such circumstances. *See* 35 U.S.C. § 202(c)(1)-(3) (agency "may receive title to any subject invention" if contractor fails to fulfill obligations) (emphasis added); 35 U.S.C. § 202(d) (if inventor's request is granted, rights are "subject to the provisions of this Act"). *Central Admixture* thus demonstrates the primacy of the statute. In this case, by contrast, Roche does not claim that Holodniy obtained rights pursuant to the statute (he never sought nor received the agency's approval to exercise ownership in the invention). If Holodniy has any rights to which Roche might have succeeded it is because, contrary to the primacy of Bayh-Dole, Holodniy possessed rights independent of any agency approval (or conditions on such approval).

The court of appeals hinted that Stanford and the government might have other remedies, such as suing Holodniy for breach of his contractual obligation to assign his rights in the invention to Stanford. It is far-fetched to think that a suit against an individual inventor, who received not one penny for signing the VCA, could compensate Stanford for

its investment in the invention or the royalties it lost as a result of Holodniy's breach.¹⁰ In any event, the federal government does not contract directly with individual inventors and would have even greater difficulty pressing a breach-of-contract claim against an inventor. Contract damages would not, in any event, be an adequate remedy for the government's loss of its important statutory rights, such as the right to insist that the contractor or inventor make efforts to commercialize the invention and license entities that will manufacture the product in the United States.

The federal government has an important interest in protecting the patent rights of federal funding agencies. Furthermore, the federal government has an important interest in preserving the Congressionally-mandated Bayh-Dole framework, which has served as an incredible engine for economic growth, innovation, and new technologies. *See* GAO Report, *supra*, at 1-2. As demonstrated above, those federal interests are substantially undermined by the court of appeals' decision and warrant this Court's review. If the Court has any question in that regard,

¹⁰ Although a state law cause of action against the inventor may be available to a university, such as by compelling assignment of a wrongfully obtained patent, *see, e.g., Fenn*, 393 F. Supp. 2d at 141-42, in circumstances like those of this case, such a remedy would be futile as a practical matter. Similarly, assuming state law might provide other theories of relief against Roche, the uncertain outcome of any such litigation itself impairs Bayh-Dole's objectives.

however, *amici* respectfully suggest that the Court invite the views of the United States.



CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

DOUGLAS HALLWARD-DRIEMEIER
JAMES R. MYERS
ROPES & GRAY LLP

April 26, 2010