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.

*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]

AUBURN UNIVERSITY, ARIZONA STATE UNIVERSITY, BRANDEIS UNIVERSITY, BROWN UNIVERSITY, CALIFORNIA INSTITUTE OF TECHNOLOGY, CARNEGIE MELLON UNIVERSITY, CASE WESTERN RESERVE UNIVERSITY, CORNELL UNIVERSITY, CLEMSON UNIVERSITY, DUKE UNIVERSITY, EMORY UNIVERSITY, FLORIDA INTERNATIONAL UNIVERSITY, FLORIDA STATE UNIVERSITY, GEORGE MASON UNIVERSITY, HARVARD UNIVERSITY, INDIANA UNIVERSITY, IOWA STATE UNIVERSITY, JOHNS HOPKINS UNIVERSITY, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, MICHIGAN STATE UNIVERSITY, MONTANA STATE UNIVERSITY, NEW YORK UNIVERSITY, NORTHWESTERN UNIVERSITY, THE OHIO STATE UNIVERSITY, THE PENNSYLVANIA STATE UNIVERSITY, PURDUE UNIVERSITY, THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK, RICE UNIVERSITY, RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY, SAN DIEGO STATE UNIVERSITY, SOUTH DAKOTA STATE UNIVERSITY, SYRACUSE UNIVERSITY, TEXAS A&M UNIVERSITY, TULANE UNIVERSITY, UNIVERSITY OF ALABAMA, UNIVERSITY OF ALABAMA AT BIRMINGHAM, UNIVERSITY OF ALABAMA AT HUNTSVILLE, THE UNIVERSITY OF ARIZONA, REGENTS OF THE UNIVERSITY OF CALIFORNIA, UNIVERSITY OF CENTRAL FLORIDA, THE UNIVERSITY OF CHICAGO, UNIVERSITY OF COLORADO, UNIVERSITY OF FLORIDA, UNIVERSITY OF IDAHO, BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, THE UNIVERSITY OF KANSAS, THE UNIVERSITY OF LOUISVILLE, THE UNIVERSITY SYSTEM OF MARYLAND, UNIVERSITY OF MARYLAND AT COLLEGE PARK, UNIVERSITY OF MASSACHUSETTS AT AMHERST, UNIVERSITY OF MICHGAN, UNIVERSITY OF MINNESOTA,

UNIVERSITY OF NEBRASKA-LINCOLN, UNIVERSITY OF NEW HAMPSHIRE, THE BOARD OF REGENTS OF THE NEVADA SYSTEM OF HIGHER EDUCATION, ON BEHALF OF THE UNIVERSITY OF NEVADA, LAS VEGAS, THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL, UNIVERSITY OF NOTRE DAME, THE UNIVERSITY OF OKLAHOMA, UNIVERSITY OF PENNSYLVANIA, UNIVERSITY OF PITTSBURGH, UNIVERSITY OF ROCHESTER, UNIVERSITY OF RHODE ISLAND, UNIVERSITY OF SOUTHERN CALIFORNIA, UNIVERSITY OF TENNESSEE, KNOXVILLE, THE UNIVERSITY OF TEXAS AT AUSTIN, UNIVERSITY OF VIRGINIA, UNIVERSITY OF WASHINGTON, BOARD OF REGENTS OF THE UNIVERSITY OF WISCONSIN SYSTEM, WASHINGTON STATE UNIVERSITY, WAYNE STATE UNIVERSITY, WASHINGTON UNIVERSITY IN ST. LOUIS, WISCONSIN ALUMNI RESEARCH FOUNDATION, AND YALE UNIVERSITY

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

*Counsel for The University of Texas at Austin*

MICHAEL FALK
*General Counsel*
WISCONSIN ALUMNI RESEARCH FOUNDATION

*Counsel for Wisconsin Alumni Research Foundation*

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## INTEREST OF AMICI CURIAE

Amici are research universities, independent research institutes, and associations of researchers and research institutions that collectively account for the vast majority of federally funded research performed pursuant to the Bayh-Dole Act, 35 U.S.C. 200 *et seq.* Amici are keenly aware of the threat the court of appeals' decision poses to Bayh-Dole's success.[1]

## SUMMARY OF ARGUMENT

The Bayh-Dole Act, adopted in 1980, has for thirty years provided the basis for an immensely successful collaboration between the federal government, universities, and private industry whereby federally funded inventions are transformed into jobs and products that improve the lives of all Americans. The cornerstone of Bayh-Dole is the statutory policy granting universities the right to retain title to inventions conceived in the course of federally funded research programs.

Stanford, exercising its rights under Bayh-Dole, elected to retain ownership of an invention made by several Stanford researchers pursuant to research funding from the National Institutes of Health (NIH) for testing the effectiveness of anti-HIV therapies. The Federal Circuit held Stanford's exercise of its Bayh-Dole rights was ineffective to give it ownership of the

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[1] Pursuant to this Court's Rule 37.6, amici state that no counsel for any party authored this brief in whole or in part, and that no person or entity other than amici or their counsel made a monetary contribution to the preparation or submission of this brief. The parties have consented to the filing of this brief, and letters evidencing such consent have been filed with the Clerk of this Court, pursuant to this Court's Rule 37.3.

interests of one of the Stanford co-inventors, Mark Holodniy, because Holodniy had previously assigned his future inventions to a private firm, Cetus.

A. Roche defends the court of appeals' decision by asserting that there is a background presumption that researchers who make inventions with federal funding have a "basic freedom to assign" those inventions to third parties and that Bayh-Dole does not clearly displace that background norm. Br. in Opp. 2, 18. But the historical record is to the contrary. For at least 60 years, title to federally funded inventions has been disposed of by operation of law. Under an Executive Order, the inventions of federal employees are assigned by operation of law to the employing agency. Numerous statutes and regulatory frameworks, including several statutes specifically referenced in Bayh-Dole, also provide for disposition of rights in federally funded inventions by operation of law. Thus, when Congress adopted Bayh-Dole, it did so against a clear historical backdrop that rights in federally funded inventions could not be freely assigned by inventors, but were instead to be disposed of by operation of law.

B. Roche contends that a ruling in Stanford's favor would "confiscate [Cetus's] intellectual property" because the inventions were "conceived before Holodniy left Cetus." Roche Supp. Pet. Br. 2. Roche's assertion mischaracterizes the premise of the Federal Circuit's decision. The Federal Circuit made clear that its ruling applies *even if* Stanford's inventions were "conceived and reduced to practice" by Stanford inventors with federal funding *after* Holodniy left Cetus. Pet. App. 15a, 18a-21a. In other words, the Federal Circuit did not grant Cetus rights based upon its purported contribution to the invention. Rather, the Federal Circuit

established a categorical rule that would allow university researchers, whether intentionally or by oversight and without the university's awareness, to assign federally funded inventions to any third party, even one with no connection to the invention.

C. The Federal Circuit's decision casts doubt on the rights of universities and the federal government alike to inventions arising from hundreds of billions of dollars in federally funded research. By making ownership of federally funded inventions turn on assignments in undisclosed documents that may have been signed many years before the federally funded research in question, the court of appeals' decision makes it virtually impossible for universities or their prospective industry licensees to be certain that the university actually owns the invention in question. That uncertainty cannot be cured by changing the language of university researcher agreements. Hundreds of billions of research funding dollars have already been invested pursuant to existing contracts. By introducing uncertainty regarding university title, the decision below undermines Bayh-Dole's objective to facilitate the commercialization of federally funded inventions.

## ARGUMENT

### I. CONSISTENT WITH LONGSTANDING PRECEDENT, BAYH-DOLE DISPOSES OF RIGHTS IN FEDERALLY FUNDED INVENTIONS BY OPERATION OF LAW, AND INVENTORS ARE NOT "FREE TO ASSIGN" THEM TO THIRD PARTIES

Roche maintains that Bayh-Dole cannot provide the controlling framework for disposing of rights to the patents-in-suit because, in Roche's words, "the Bayh-Dole Act nowhere alters an inventor's basic freedom to assign his own rights in an invention to a third party." Br. in Opp. 2. See Roche Supp. Br. 12 n.6. Roche contends that there is a background presumption that researchers who make inventions with federal funding have a "basic freedom to assign" those inventions and that Bayh-Dole does not clearly displace that background norm. Br. in Opp. 2, 18.

The factual predicate for Roche's contention is mistaken. By statute, Executive Order, and regulation, the federal government has dictated the disposition of rights in federally funded inventions for at least 60 years, and individual inventors are not free to assign those inventions to third parties.

Like its predecessors, Bayh-Dole provides for the "[d]isposition of rights" in inventions made pursuant to federally funded research contracts. 35 U.S.C. 202 (title). The statute comprehensively addresses the rights of the federal government, university contractor, and individual inventor. Where, as here, a university elects to exercise its right under Bayh-Dole to retain title to an invention, the individual inventor cannot assign that invention to a third party because the invention is assigned, by operation of law, to the university.

### A. Federal Law Has Long Disposed Of Ownership To Federally Funded Inventions By Operation Of Law

For at least 60 years—30 years before Bayh-Dole was enacted—the federal government has, through various statutory and regulatory means, denied inventors the right to assign federally funded inventions to third parties. Those Bayh-Dole predecessors make clear that federal law may, and often does, provide for disposition of federally funded inventions by operation of law. An inventor's purported assignment of a federally funded invention to a third party is therefore ineffective to the extent it is inconsistent with superior rights of the federal government or federally funded contractor.

#### *1. Executive Order 10096 and numerous statutes provide for federal ownership of federally funded inventions*

Roche's contention that there is a background principle allowing inventors freely to assign federally funded inventions has not been accurate for at least 60 years. In 1950, President Truman issued Executive Order 10096 to establish "a uniform patent policy for the Government with respect to inventions made by Government employees." 35 U.S.C. 207 (note) (reproduced in an appendix hereto). The Order provides that when an invention is "made in consequence of the official duties of the inventor" the federal government "*shall obtain* the entire right, title, and interest" in the invention. App., *infra*, 1a (emphasis added). When the government decides not to "require[] assignment to" itself, it will nevertheless "reserv[e]" to itself a nonexclusive license. *Id.* at 1a-2a.

Beginning no later than 1954, in numerous statutes, Congress has likewise allocated to the federal government ownership of contractors' inventions made with federal funding. In the Atomic Energy Act of 1954, P.L. 83-703, § 152, 68 Stat. 944, Congress specifically provided that "[a]ny invention or discovery" conceived in the course of a contract with the Atomic Energy Commission "*shall be deemed to have been made or conceived by the Commission*," thereby "*entitling the Commission to take title to*" the resulting patent unless it "waive[s] its claim." *Ibid.* (emphasis added); see also P.L. 87-206, § 10, 75 Stat. 477 (amending AEA to affirm that such inventions "*shall be vested in, and be the property of*, the Commission") (codified at 42 U.S.C. 2182) (emphasis added); National Aeronautics and Space Act of 1958, P.L. 85-568, § 305, 72 Stat. 435 (NASA-funded inventions "shall be the exclusive property of the United States") (codified at 42 U.S.C. 2457(a)).

Executive Order 10096 and agency-specific vesting statutes were, moreover, fresh in the mind of the legislators who enacted Bayh-Dole in 1980. A Government Accounting Office report submitted to Senator Bayh in connection with Bayh-Dole's consideration noted that rights to inventions made by NASA employees are "determined by the agency pursuant to provision of Executive Order 10096" and that, under NASA's statute, "any invention conceived or first reduced to practice in the performance of work under a NASA contract becomes the exclusive property of the Government." *Science and Technology Research and Development Utilization Policy Act: Hearing Before the Subcomm. On Science, Technology, and Space*, 96th Cong. 211 (1979) (reprinting letter from Comptroller General).

Also, in the immediately preceding years, Congress had adopted several additional statutes specifying that "title to such [federally funded] invention shall vest in the United States, and if patents on such invention are issued they shall be issued to the United States." Federal Nonnuclear Energy Research and Development Act of 1974, P.L. 93-577, § 9, 88 Stat. 1887 (FNRDA) (codified at 42 U.S.C. 5908(a)). See also 42 U.S.C. 6981(c)(3) (1976) (incorporating FNRDA); 7 U.S.C. 178j (Supp. II 1979) (same); 42 U.S.C. 5585(b) (Supp. II 1979) (same); 42 U.S.C. 7879 (Supp. II 1979) (same), *repealed by* Water Resources Research Act of 1984, P.L. 98-242, §§ 109-110(a), 98 Stat. 97, 101 (codified at 42 U.S.C. 10308). Indeed, Congress specifically referenced these statutes in Bayh-Dole. 35 U.S.C. 210(a).

Thus, it is clear that, by the time of Bayh-Dole's enactment, there was no established presumption that researchers who make inventions with federal funding retain a "freedom to assign" those inventions to third parties.

*2. Numerous courts have recognized that the government obtains title pursuant to Executive Order 10096 and agency-specific vesting statutes by operation of law*

As several courts have recognized, when the government obtains rights in a federal employee's invention pursuant to Executive Order 10096, the employee is deemed to have "assigned title and all other rights to such discover[y]" to the government "*by operation of law*." *Li* v. *Montgomery*, No. 99-5106, 2000 WL 815992, at *2 (D.C. Cir. May 15, 2000) (emphasis added). Even if the employee has not executed an assignment of title to the government, the government is nonetheless "the

owner of the" invention. *Heinemann* v. *United States*, 796 F.2d 451, 456 (Fed. Cir. 1986), cert. denied, 480 U.S. 930 (1987). In *Heinemann*, the Federal Circuit affirmed dismissal of a government-employee inventor's patent infringement suit, even though the inventor's formal assignment to the government was deemed invalid, because the invention "became the property of the Government," not the inventor, under the Executive Order. *Ibid.*

Similarly, it is clear that under the agency-specific vesting statutes, an inventor is unable to assign rights in a federally funded invention to a third party without the United States' consent. As the Federal Circuit recognized in a case involving a pre-Bayh-Dole funding agreement, these agency-specific statutes "clearly provide[] that title to any invention made or conceived under a [covered] contract 'shall vest' in the United States." *FilmTech Corp.* v. *Hydranautics*, 982 F.2d 1546, 1550 (Fed. Cir. 1992), cert. denied, 510 U.S. 824 (1993) (construing FNRDA (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 had "automatically vested in the United States" by "operation of law." *Ibid.*

Moreover, under these authorities, the government may apply for a patent as owner of the invention, even if the inventor refuses to sign an assignment in favor of the government. When an inventor "refus[es]" to "execute an assignment to the Government," the government may apply for the patent without the signed documents. *Boutros* v. *Boutros*, 231 U.S.P.Q. 829, 830 (Com'r Pat. & Trademarks July 10, 1986). By operation

of law, "the Government is considered to be the owner" of the invention. *Id.* at 830-831. See 37 C.F.R. 1.47(b) (allowing "person to whom an inventor has assigned or agreed in writing to assign the invention, *or who otherwise shows sufficient proprietary interest*" to apply for patent despite "the inventor['s] refus[al] to execute an application for patent") (emphasis added).

*3. NSF and NIH regulations also restricted an inventor's ability to assign federally funded inventions to third parties*

The regulatory programs put in place by the National Science Foundation (NSF) and NIH—then part of the Department of Health, Education, and Welfare (HEW)—before Bayh-Dole's enactment also made clear that federally funded researchers were not "free to assign" federally funded inventions to third parties. Although NIH and NSF adopted policies that favored leaving title to federally funded inventions in universities and similar nonprofit institutions, those policies did not leave to individual inventors the option to assign their federally funded inventions to third parties.

NSF's generally applicable regulations were similar to Executive Order 10096. The regulations provided that NSF would "determine the disposition of the invention [made under the grant] and title to and rights under any patent application." 45 C.F.R. 650.4(b) (1977). The university was required to agree "for itself *and for its employees*" that "all documents will be executed and all other actions taken necessary or proper to carry out the determination of the Foundation." *Ibid.* (emphasis added). Thus, as with Executive Order 10096, if NSF determined that title to an NSF-funded invention should belong to the government, the indi-

vidual inventor was not free to assign the invention to a third party, but was instead obligated to execute the documents necessary to permit NSF to apply for a patent. Only if neither the government nor the university wished to take title could the individual inventor apply to retain rights, 45 C.F.R. 650.9(c)(4), and even then the inventor took ownership subject to a "reserv[ation]" of minimum rights to the government, 45 C.F.R. 650.9(c)(4), 650.10 (1977).

HEW's generally applicable regulations were similar to NSF's. They also provided that "disposition of all rights in and to" inventions made under research grants "shall be subject to determination" by the agency, which had the authority to "require that all domestic rights in the invention shall be assigned to the United States." 45 C.F.R. 8.1(a), 8.2(d) (1977).

As under the Executive Order and agency-specific vesting statutes, an inventor could not effectively assign his federally funded invention to a third party inconsistent with the disposition of rights provided by the applicable legal framework. In *VDI Technologies, Inc.* v. *Price*, No. Civ. 90-341, 1994 WL 485778 (D.N.H. Aug. 31, 1994), the court held that the inventors' purported assignment to a subcontractor of an invention made under an HEW contract failed to convey "enforceable title" to the patent because HEW was entitled to ownership under its pre-Bayh-Dole regulations. *Id.* at *1. The court reasoned that HEW's regulations "automatically vest[ed] in the government the exclusive right to determine who could obtain and exercise ownership rights and on what terms." *Id.* at *4. It did not matter that the subcontractor had received an assignment from the inventors because their "*interest … was necessarily circumscribed by the regulations reserving*

*to the government the right to determine ownership of the invention*." *Id.* at *6 (emphasis added).

Beginning in the late 1960s and lasting until the late 1970s, when the Carter administration reverted to a policy of government ownership, see S. Rep. No. 96-480, at 21 (1979) ("Senate Report"), both NSF and NIH adopted a policy that favored allowing nonprofit institutions to retain ownership of federally funded inventions. 45 C.F.R. 650.8(a) (1977); 45 C.F.R. 8.6(b) (1977). To qualify for an NSF Institutional Patent Agreement (IPA), nonprofit institutions were asked to "give assurance that employees are legally obligated to assign to the institution any inventions made by them in the course of or under awards." 45 C.F.R. 650.8(b)(2) (1977). NIH's IPAs similarly required that a university's employees assign to the university all inventions made under the NIH grant. See Federal Council for Science and Technology, *Report on Government Patent Policy* 330-331 (1976). And, as with the agencies' generally applicable regulations, NSF's and NIH's IPAs "reserve[d] to the Government" important rights. 45 C.F.R. 650.8(c)(1) (1977) (incorporating Section 650.10); 45 C.F.R. 8.3 (1977).

As the above demonstrates, while NSF's and NIH's precise policies regarding disposition of rights in federally funded inventions differed from those of Executive Order 10096 and the agency-specific vesting statutes, NSF's and NIH's regulations preserved the rights and interests of the public in the fruits of research conducted at public expense. Under none of these frameworks was an individual inventor "free to assign" his rights in a federally funded invention to a third party.

*4. The courts have upheld the government's authority to dispose of federally funded patents by operation of law against challenges based on inventors' "freedom to assign"*

By the time of Bayh-Dole's enactment, Executive Order 10096 had already been upheld against challenge by an inventor arguing, as Roche does here, that inventors are necessarily free to dispose of their federally funded inventions as they see fit. In *Kaplan* v. *Corcoran*, 545 F.2d 1073 (1976), the Seventh Circuit considered and rejected an argument that the Executive Order violated the Patent Clause of the Constitution, Art. I, § 8, cl. 8, *id.* at 1075-1077.

In *Kaplan*, the inventor argued, on the basis of *United States* v. *Dubilier Condenser Corp.*, 289 U.S. 178 (1933), that the President lacked authority to compel transfer to the government of an invention made in the course of federal employment. The Seventh Circuit observed that, contrary to the inventor's contentions, *Dubilier* did not question whether federal law *could* trump an inventor's freedom to assign federally funded inventions. Rather, *Dubilier* had expressed the view that "formulation" of a policy concerning government ownership of federal employees' inventions "belongs solely to Congress," rather than the courts or an "unspecified" administrative officer. *Kaplan*, 545 F.2d at 1076 & n.2 (quoting *Dubilier*, 289 U.S. at 208-209). The court of appeals upheld Executive Order 10096 on the ground that Congress had given the President broad authority to promulgate regulations concerning federal employees and federal property. *Id.* at 1077 (citing 5 U.S.C. 301). Moreover, by the time of the *Kaplan* decision in 1976, Congress had, at the very least, acquiesced

in the Executive's longstanding policy of taking ownership of inventions made in the course of federal employment. *Ibid.* The Federal Circuit has endorsed *Kaplan*'s reasoning and likewise rejected a challenge to the Executive Order as unconstitutionally depriving federally funded inventors of property. See *Heinemann*, 796 F.2d at 455.

Courts have similarly upheld the constitutionality of the analogous "work-for-hire" doctrine of the Copyright Act of 1976, which provides that when "a work [is] prepared by an employee within the scope of his or her employment," "the employer ... is considered the author" of the work and owner of the copyright. See *Community for Creative Non-Violence* v. *Reid*, 490 U.S. 730, 737-738 (1989) (quoting 17 U.S.C. 101(1), 201(b)). This Court applied the doctrine in *Reid* without suggesting any doubt as to its constitutionality, *ibid.*, and the Second Circuit—the only court of appeals to consider a constitutional challenge to the doctrine—dismissed the challenge out of hand, *Childress* v. *Taylor*, 945 F.2d 500, 506-507 n.5 (2d Cir. 1991).

Congress's authority to protect copyrights derives from the same constitutional provision that grants Congress authority to protect patents. See U.S. Const. Art. I, § 8, cl. 8. Therefore, just as Congress can assign ownership of a copyright to a writer's employer, it can also assign ownership of a patent to an inventor's employer or to the government that funded the invention.

### B. Like The Statutes And Regulations That Preceded It, Bayh-Dole Controls Disposition Of Title To Federally Funded Inventions In Order To Promote The Public Interest

Bayh-Dole was adopted in order to establish a uniform national policy regarding ownership of inventions made by nonprofits or small businesses with funding from the federal government. Although Bayh-Dole's policy of allocating title to nonprofits or small businesses differs from the policy of federal ownership reflected in Executive Order 10096 and agency-specific vesting statutes, Bayh-Dole, like those predecessors, also provides for a "[d]isposition of rights" in federally funded inventions by operation of law. 35 U.S.C. 202 (title). There is no reason to believe, as Roche contends, that Congress would leave Bayh-Dole's important public policy objectives, affecting hundreds of billions of dollars in federal research funding, to be frustrated by individual inventors who assign their inventions to third parties.

1. Although Roche may argue that Bayh-Dole is different from the Executive Order and other statutes precisely because it allocates rights to the nonprofit or small business rather than to the federal government itself, that would not be correct. Bayh-Dole reserves to the federal government important rights that could be defeated if individual inventors were free to assign their inventions inconsistent with Bayh-Dole's framework.

Significantly, Bayh-Dole specifically permits the funding agency, in certain circumstances, to take full ownership of the invention. Section 202 creates a "right[] of the Government," 35 U.S.C. 202(b), to "eli-

minat[e]" the nonprofit's "right to retain title" (1) when, in "exceptional circumstances," Bayh-Dole's policies would be better promoted by greater government rights, (2) when the invention implicates the security of "foreign intelligence or counter-intelligence activities," (3) when the invention concerns "nuclear propulsion or weapons related programs," or (4) when the nonprofit is "subject to the control of a foreign government." 35 U.S.C. 202(a), (b). If, as Roche contends, Bayh-Dole "does not regulate" an inventor's "freedom to assign" federally funded inventions, the funding agency's determination to assert direct ownership under Section 202(b) can be defeated by the inventor assigning the invention to a third party. Nothing in Bayh-Dole would support a conclusion that the federal government's assertion of rights in such sensitive areas as foreign intelligence and nuclear weapons could be unilaterally circumvented by the inventor.

2. Even when the funding agency does not invoke the Section 202(a) exceptions, Bayh-Dole reserves important rights to the federal government that would be frustrated if individual inventors were "free to assign" their inventions outside the Bayh-Dole framework. Bayh-Dole provides that "the Federal Government may receive title to any subject invention" if it is not timely disclosed or if the contractor does not timely elect to retain rights or does not timely file a patent application. 35 U.S.C. 202(c)(1)-(3). The Act also grants the federal agency "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced" the invention for governmental purposes. 35 U.S.C. 202(c)(4). Moreover, if the contractor fails to take "effective steps to achieve practical application," to adequately "alleviate health or safety needs," or to

require exclusive licensees to manufacture substantially in the United States, the federal government has "the right" to require the contractor or its licensee to grant a license to another responsible applicant. 35 U.S.C. 203(a). These governmental "rights" apply to inventions in which a "small business firm or nonprofit organization has acquired title under this chapter." *Ibid.* If an inventor were "free to assign" the invention to a third party outside the Bayh-Dole framework, none of these governmental rights in furtherance of the public interest would apply vis-à-vis the third party, which would not have "acquired title under" Bayh-Dole. *Ibid.*

3. Roche's argument that inventors are "free to assign" federally funded inventions is also contrary to the Bayh-Dole provision that expressly addresses inventor rights. Section 202(d) specifies 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. 35 U.S.C. 202(d); see *Fenn* v. *Yale Univ.*, 184 Fed. Appx. 21, 22 (2d Cir. 2006) (summary order). 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). These regulations "impose" requirements upon the inventor that are similar to those imposed upon contractors that take title. 37 C.F.R. 401.9, 401.14(a) (standard clause ¶¶ (d)(1), (d)(3), (i), (j)). It is impossible for the federal government to "impose" these restrictions on an inventor's patent rights if, as Roche contends, "the Act does not regulate" the inventor, but only "relationships of … nonprofit grantees with the Government." Roche Supp. Pet. Br. 11-12 & n.6.

4. The relationship between Bayh-Dole and the agency-specific vesting statutes discussed above further supports the conclusion that Bayh-Dole allocates ownership of federally funded inventions by operation of law. Congress was clearly aware of its authority to dispose of rights in federally funded inventions by operation of law because Bayh-Dole expressly "take[s] precedence over any other Act which would require a disposition of rights in subject inventions" different from Bayh-Dole, and specifically takes precedence over identified vesting statutes that otherwise dictate the disposition of title to government funded inventions. 35 U.S.C. 210(a) (listing 7 U.S.C. 178j; 42 U.S.C. 2182, 2457, 5585(b), 5908, 6981(c), 7879 as among the statutes displaced). Significantly, however, Bayh-Dole does not displace the vesting statutes with respect to large, for-profit contractors. 35 U.S.C. 210(b). Therefore, if Roche's reading of Bayh-Dole were correct, only the employees of non-profit and small-business contractors would be free to assign away the government's statutory rights, whereas employees of large, for-profit contractors could not. See *Hydranautics*, 982 F.2d at 1548, 1553-1554.[2] Nothing in Bayh-Dole suggests that Congress intended to create such a discrepancy.

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[2] Agencies apply Bayh-Dole's policy favoring contractor ownership to large, for-profits in exercising their waiver authority under the agencies' individual vesting statutes. See E.O. No. 12591, 52 Fed. Reg. 13,414 (Apr. 10, 1987); Memorandum on Government Patent Policy, Pub. Papers 248 (Feb. 18, 1983). Such disposition of rights pursuant to statutory authority under the vesting statutes could not be frustrated by an inventor's contrary assignment. Cf. *Hydranautics*, 982 F.2d at 1548, 1553-1554.

## II. BAYH-DOLE DOES NOT "CONFISCATE" PRIVATE INVENTIONS, AND ROCHE'S CLAIM THAT THESE PATENTS WERE INVENTED BY CETUS IS CONTRARY TO THE FEDERAL CIRCUIT'S PREMISE

This case comes to the Court on the premise that Stanford has a validly patented invention conceived and reduced to practice by Stanford inventors with federal funding *after* Holodniy left Cetus. Pet. App. 5a-6a, 15a. Amici express no opinion whether Stanford will be able to sustain that contention on remand. The premise is important, however, because it demonstrates that the issue before the Court concerns not the outer limits of the Bayh-Dole framework, but its core. Contrary to Roche's suggestion, the Federal Circuit did not award Roche an equitable "*share*[]" of the patents in recognition of Cetus's "major contributions" to the invention. Roche Supp. Pet. Br. 11. Rather, the Federal Circuit adopted a categorical rule that would allow a university inventor to assign the *entirety* of *any* federally funded invention to *any* third party, even one with no connection to the invention.

Contrary to Roche's contentions, giving effect to Bayh-Dole's disposition of rights when a university researcher makes an invention in the course of a federally funded project does not confiscate the inventions of private companies. Bayh-Dole only reaches inventions made by government contractors pursuant to federal research funding. It is Roche's argument, not Stanford's, that threatens to chill future collaboration between universities and industry by raising the prospect that the product of their cooperation will be assigned to a third party.

### A. The Federal Circuit's Decision Does Not Rely On Cetus's Purported Contribution To The Patents But On A Broad Legal Holding That University Inventors Are Free To Assign Inventions Conceived And Reduced To Practice Using Federal Funds

#### *1. Cetus's contribution to the discovery was published in 1991 and could not form the basis for Stanford's patented inventions*

Roche contends that construing Bayh-Dole to preclude inventors from assigning federally funded inventions to third parties would result in "confiscat[ing] intellectual property rights from non-funded entities whose private resources and expertise lead to the conception of inventions." Roche Supp. Pet. Br. 2. In its petition-stage briefs, Roche attempted to rewrite the Federal Circuit's opinion, characterizing it as holding that "[t]he invention was conceived and the assay completed at Cetus *before* Stanford performed any work using federal funds." Roche Supp. Pet. Br. 3 (citing Pet. App. 14a). That assertion mischaracterizes the court of appeals' decision. To the contrary, the Federal Circuit declined to decide precisely how long before Stanford's May 1992 patent application the inventions were "conceived." Pet. App. 14a. Instead, the court of appeals held that Cetus owned Holodniy's patent rights "*[e]ven if* Holodniy conceived and reduced to practice [the inventions] *after departing Cetus*." *Id.* at 15a (emphasis added). Likewise, the Federal Circuit assumed that the inventions were federally funded under a grant from NIH. Pet. App. 5a-6a, 18a-21a.

Stanford's appeal from the district court's finding of obviousness rests on the premise that the patented

inventions were conceived and reduced to practice *after* publication of an April 1991 article in the *Journal of Infectious Diseases* (JID) that reported the results of Holodniy's collaboration with Cetus researchers. See Pet. App. 38a-39a. Holodniy and his Cetus collaborators published the JID article without filing a patent application on the results of their work. *Ibid.* The district court held that the inventions claimed by Stanford were obvious in light of what was already publicly known through the 1991 JID article. 563 F. Supp. 2d 1016, 1016, 1023-24, 1027-28, 1043 (N.D. Cal. 2008). Stanford's appeal of that holding contends that the patented inventions reflected novel and non-obvious work performed at Stanford by Stanford researchers after publication of the JID article. See Stanford C.A. Br. 6-26. The Federal Circuit did not reach the merits of the obviousness issue. Instead, the court of appeals held that Stanford lacked standing to enforce the patents because Holodniy had, by signing the Visitor Confidentiality Agreement (VCA), assigned his future inventions to Cetus, including inventions made at Stanford with federal funding. See Pet. App. 12a-15a, 28a.

Thus, as the case comes to this Court, it presents the question whether Holodniy's purported assignment of his future inventions could be effective as to a future invention both conceived and reduced to practice at Stanford while Holodniy was working under federal funding, notwithstanding Stanford's assertion of its right under Bayh-Dole to retain title. In other words, this case lies at the very heart of federally funded research to which Bayh-Dole is addressed.

*2. The Federal Circuit did not give Cetus a "share" of the inventions to reward Cetus's "contribution," but rather adopted a broad ruling that university inventors can freely assign federally funded inventions*

Roche contended throughout its petition-stage briefs that the Federal Circuit's holding merely recognized Roche's right to "*share*[]" title in light of "major contributions" that Cetus made to the invention. Roche Supp. Pet. Br. 11. See also *id.* at 13; Br. in Opp. 12-13, 19-20. To the contrary, the Federal Circuit adopted a categorical rule that researchers are free to assign their federally funded inventions to third parties—without consideration of equities. Under the Federal Circuit's rule, if Holodniy had been the sole inventor, he would have been free to assign his invention to any third party of his choosing, including one with no connection to the invention.

That Roche receives only a "share" of the patents is due only to the fortuity that Holodniy was one of multiple Stanford inventors, and the other researchers did not assign their rights to Cetus or another third party. The rule advocated by Roche does not apply only to Holodniy or only to assignment by one of multiple co-inventors. Rather, on Roche's view, each inventor had the "statutory right to assign his interest in [the] patents" as he saw fit. Br. in Opp. 18. If each of the co-inventors had assigned his rights to a third party, or if Holodniy had been the sole inventor, Stanford (and consequently the federal government) would have been left with no interest whatsoever in the federally funded invention. The fact that "Stanford remains a co-owner of the patents-in-suit" based on assignment from Holodniy's co-inventors, Br. in Opp. 11, is mere happens-

tance that is entirely irrelevant to the legal question presented in the case.

Roche's repeated references to the fact that the inventions built upon work that Holodniy had done at Cetus, Br. in Opp. 3-6, 20, 24, is also a red herring. The fact that the inventions built on Holodniy's work at Cetus was relevant to the assignment issue only because the VCA purported to assign all future inventions made "as a consequence of [Holodniy's] access to CETUS' facilities or information." Pet. App. 123a. But the Federal Circuit's holding, as Roche elsewhere acknowledges, does not require that the inventor's assignee have a connection to the invention. Rather, under the Federal Circuit's broad ruling that an inventor has a "statutory right to assign his interest," Br. in Opp. 18, Holodniy could have assigned his rights in these federally funded inventions in satisfaction of a personal debt or for any other reason.

Roche's arguments sound in *quantum meruit*—that Roche should be rewarded for the value of Cetus's contributions. But that is not the rule under review by this Court.

### B. Bayh-Dole Does Not Interfere With Rights Of Industry Collaborators

Despite Roche's hyperbolic contentions, the position advocated by Stanford and the United States would not "confiscate" the intellectual property of industry collaborators. To the contrary, Bayh-Dole respects the rights of industry collaborators who are not federally funded. For 30 years, research institutions and private enterprises have entered into mutually agreeable contractual arrangements regarding their cooperative research endeavors. It is Roche's argu-

ment, not Stanford's, that threatens to hamper continued research collaboration.

1. Bayh-Dole applies only to "subject inventions." 35 U.S.C. 201(e). In order to qualify as a "subject invention," the invention must first be an "invention of the contractor" and, further, it must be "conceived or first actually reduced to practice in the performance of work under a funding agreement." *Ibid.* To qualify as an "invention of the contractor," it must be an "invention or discovery [of the contractor] which is or may be patentable" under the Patent Act. 35 U.S.C. 201(d). Thus, Bayh-Dole does not apply to Cetus's inventions. This case, however, is premised on the assumption that the inventions were the discoveries of Stanford researchers acting under an NIH grant—the very core of activity that Bayh-Dole addresses.

Similarly, if, as Roche implies, Br. in Opp. 5-6, Cetus employees were co-inventors, Bayh-Dole would not govern disposition of the Cetus co-inventors' interest in the invention. In Section 202(e), Bayh-Dole addresses the circumstance when university employees and government employees are co-inventors and recognizes that Bayh-Dole would not govern the disposition of rights arising from the federal employees' co-inventorship. 35 U.S.C. 202(e) (noting that federal agency could assign rights that it acquires pursuant to E.O. 10096 to the nonprofit "for the purpose of consolidating rights in the invention"). Although the statute does not specifically address the situation when the co-inventor is employed by a private entity using private funding, subsection (e) strongly suggests that only the rights of those co-inventors conducting research under a federal funding agreement are governed by Bayh-Dole. Again, no question of private co-inventors is pre-

sented here because all the co-inventors were Stanford researchers acting under federal funding. See Pet. App. 15a, 18a-21a.

2. The fact that Bayh-Dole governs disposition of inventions made by nonprofits with federal funding has not, contrary to Roche's assertions, "discourage[d] scientific cooperation" between universities and commercial concerns. Roche Supp. Br. 13-14. Rather, it is Roche's theory of university researchers as free agents, able to assign federally funded inventions to third parties, that threatens this cooperation.

For 30 years, universities have routinely entered into sponsored research agreements with private industry with the understanding that, if federal funding is also involved, the inventions of university researchers will be governed by the terms of Bayh-Dole. Some agreements may specify the terms of a license that the industry collaborator will receive regarding any inventions; some simply indicate that industry sponsors will have the first right to negotiate a license. All of these agreements, however, start with the premise that the university will have the right under Bayh-Dole to retain title to federally funded inventions and will be in a position to license the inventions back to the private entity that helped sponsor the research. Roche's argument threatens the foundation of that collaboration by raising the prospect that individual university researchers could assign resulting inventions to yet another third party, thereby depriving both the university *and* the private sponsor of the benefit of their collaboration.

The Engineering Research Centers (ERCs) organized at numerous universities under the auspices of

NSF to support targeted research are examples of how such industry and university collaboration can be organized. See, *e.g.*, Engineering Research Centers: Linking Discovery to Innovation, http://www.erc-assoc.org/factsheets/ERC%20Overview%20Fact%20Sheet_09-final.pdf (last visited Dec. 23, 2010). In many instances, sponsoring companies become members of an ERC, and members are entitled to preferential access to discoveries and to negotiate licensing terms. Although these collaborations have proceeded smoothly, on the assumption that the university can retain title to the inventions of university researchers, Roche's arguments raise the prospect that university researchers would be free to assign ERC inventions to members' competitors who had not participated in sponsoring the ERC's work. Faced with such a risk, corporations might well choose not to participate as members in future ERCs.

The facts of this case provide examples both of how collaborative research *should* and *should not* be conducted. In February 1989, Cetus negotiated with Stanford a Materials Transfer Agreement (MTA) that set forth the terms of their collaboration. Pet. App. 33a-34a. Under the terms of the MTA, Cetus agreed to "provide Stanford with 'certain research substances and know-how' in exchange for certain concessions on the part of Stanford," including "the first option to an exclusive license, at a reasonable royalty to be negotiated in good faith …, or at CETUS' option, a nonexclusive license." *Ibid.* (quoting MTA). Roche asserted a license under the MTA, but the district court rejected that defense because Stanford had not consented to assignment of the license from Cetus to Roche. *Id.* at 70a-72a. As the MTA reflects, Cetus was in a position

to negotiate the rights it would obtain in return for its contribution to Stanford's invention, but Cetus failed to negotiate a license that could be assigned to Roche. Roche's complaint thus lies with Cetus's negotiators, not Bayh-Dole.

Instead of relying on the MTA—which Cetus negotiated openly *with Stanford*, but which did not convey rights that Cetus could assign to Roche—Roche relies on a VCA, signed by Holodniy without actual notice to Stanford. See Pet. App. 16a (holding only that Stanford had "inquiry notice of the VCA"). In the VCA, Holodniy purportedly assigned away all future inventions he might conceive as a "consequence" of what he learned at Cetus. *Id.* at 4a. In other words, Cetus specifically set out to obtain for itself exclusive ownership of any inventions that Holodniy made at Stanford after he left Cetus, as long as Holodniy's experience at Cetus contributed to his ability to make the invention.

If agreements like the VCA were sufficient to defeat universities' Bayh-Dole rights, universities could not afford to permit their researchers to visit other research facilities and would naturally be reluctant to hire researchers who had worked for employers who used such forms. Cf. *Guth* v. *Minnesota Mining & Mfg. Co.*, 72 F.2d 385, 388-389 (7th Cir. 1934), cert. denied, 294 U.S. 711 (1935) (patent assignment contract unlimited in time and subject matter was unenforceable because it would prevent moving to new employment). Thus, it is Roche's argument that, if accepted, would discourage continued collaboration between universities and private industry.

## III. THE FEDERAL CIRCUIT'S DECISION UNDERMINES THE CERTAINTY OF TITLE THAT IS FUNDAMENTAL TO BAYH-DOLE'S COMMERCIALIZATION OBJECTIVES

Congress enacted Bayh-Dole to encourage collaboration between universities and private enterprise in commercializing inventions arising from federally funded research. Bayh-Dole has spurred the commercialization of thousands of inventions and contributed hundreds of billions of dollars to the economy. The court of appeals' decision raises questions whether inventions believed to be owned by the university may, in fact, be owned by another party. The inevitable result of this uncertainty is that some university inventions will not be licensed, and some beneficial products will never be developed.

### A. Prior To Bayh-Dole, Lack Of Certainty Regarding Universities' Ability To Own And License Federally Funded Inventions Impeded Their Successful Commercialization

Before Bayh-Dole, government contractors' rights to inventions resulting from federally funded research were governed by a convoluted and often contradictory assortment of 26 different federal agency policies. U.S. Gov't Accountability Office, GAO-09-742, *Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions* 4 (2009) ("GAO Report"); H.R. Rep. No. 96-1307, pt. 1, at 3 (1980) ("House Report"); Senate Report 2-3. This "potpourri" of policies "confus[ed] and discourage[d]" contractors, Bradley Graham, *Patent Bill Seeks Shift to Bolster Innovation*, Wash. Post, Apr. 8, 1979, at M1 - especially universities and small businesses, which lacked large

legal staffs to negotiate this "policy maze," Senate Report 2-3.

Agency policies generally provided that the government would take title to patents arising from federally funded research unless the agency waived its rights. Senate Report 2. Government agencies proved ineffective at bringing the inventions they owned to market. Government agencies owned between 25,000 and 30,000 patents, but less than approximately 4% to 5% of them were developed commercially. Graham, *supra*, M2; GAO Report 2. In order for a university to obtain ownership of a federally funded invention, it generally had to wait until the invention was identified and then petition the funding agency for a waiver. Senate Report 2, 21, 30. Waiver proceedings were lengthy, often a year or more, and extremely burdensome on both agencies and contractors. *Ibid.* Because universities and other government contractors had no certainty that they would obtain title to inventions resulting from federally funded research, they were unable to attract private companies as licensees willing to provide essential funding and assistance in bringing new discoveries to market. See *id.* at 21, 30; H.R. Con. Res. 328, 11th Cong. 2-3 (2010) ("2010 House Resolution").

In the late 1960s and early 1970s, HEW and NSF sought to spur innovation by implementing IPA programs under which universities were given a first option to own and manage inventions resulting from agency-funded research. Senate Report 21; Howard Bremer, Joseph Allen, & Norman J. Latker, *The Bayh-Dole Act and Revisionism Redux*, 78 Pat., Trademark & Copyright J. 483, 485 (Aug. 14, 2009). While these programs achieved some commercialization, see Senate Report 21, they ultimately failed to give universities

the certainty necessary to fully realize the potential of federally funded research. Contractors were still forced to navigate a convoluted web of confusing and often conflicting agency policies. House Report 3. And the Carter administration's termination of HEW's IPA program in 1978 demonstrated that any given IPA program could be "changed at the whim of a political appointee." Bremer, *supra* at 487.

### B. By Providing Universities Clear Title, Bayh-Dole Has Been Enormously Successful In Encouraging Commercialization Of Federally Funded Inventions

In what has been described as one of the most inspired legislative acts in American history, *Innovation's Golden Goose*, The Economist, Dec. 14, 2002, at 3, Congress enacted Bayh-Dole in 1980 to "end this uncertainty" surrounding ownership of federally funded patents "and prevent these promising inventions from being suffocated under reams of unnecessary bureaucratic redtape." Senate Report 21. Recognizing that universities and nonprofit organizations had shown themselves to be "much more efficient in delivering these important discoveries to the marketplace than are [government] agencies," *id.* at 29, Congress amended the Patent Act to "automatically grant" nonprofit government contractors "title to inventions arising from Government-supported research," *id.* at 36 (reprinting Congressional Budget Office letter).

Bayh-Dole has been incredibly successful in stimulating innovation by giving universities certainty regarding their ownership of federally funded inventions. Whereas approximately 250 patents were issued to universities in 1980, with only a small percentage of

them resulting in commercial products, universities received over 3,000 patents and executed over 5,000 licenses and options in 2008. BayhDole25, Inc., *The Bayh-Dole Act at 25* 23 (2006); Press Release, Ass'n of Univ. Tech. Managers, *New Survey Reveals Universities' Impact on the U.S. Economy* (Feb. 2010). 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 U.)
- TRUSOPT® opthalmic drops used for glaucoma (U. of Florida).[3]

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[3] 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, *The Bayh-Dole Act: A Guide to the Law and Implementing Regulations* 8 (1999); Press Release, Ass'n of Univ. Tech. Managers, *supra*; Arundeep S. Pradhan, Op-Ed, *Defending the University Tech Transfer System*, Business Week, Feb. 19, 2010; Jo Thomas, *Satisfaction in Job Well Done Is Only Reward for E-Mail Software Inventor*, N.Y. Times,

Bayh-Dole has also made an extraordinary contribution to the national economy. Just last month, Congress recognized that the "economic activity spurred on by the Bayh-Dole Act include[s] the formation of more than 6,500 new companies from the inventions created under the Act, an estimated contribution of $450,000,000,000 to United States gross industrial output, and the creation of 280,000 new high technology jobs between 1999 and 2007." 2010 House Resolution 4; see also 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/techtransfer/BIO_final_report_9_3_09_rev_2.pdf. Bayh-Dole has also led to "the creation and dominance of the United States biotechnology and information technology industries." 2010 House Resolution 3.

### C. The Federal Circuit's Decision Undermines The Certainty Of University Title That Is Central To Bayh-Dole's Success

By making ownership of federally funded inventions turn not on Bayh-Dole, but on contracts that individual researchers might have signed decades ago without noticing or understanding the potential impact and perhaps without even retaining a copy, the court of appeals re-injects uncertainty into the commercializa-

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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., http://www.northwestern.edu/newscenter/stories/2007/12/lyrica.html (last visited Dec. 23, 2010).

tion of federally funded inventions, with an attendant waste of federal research dollars.

*1. The court of appeals' decision casts doubt on university title*

Under the rule adopted by the Federal Circuit, university ownership of federally funded inventions turns on judicial construction of dueling assignments executed years before the invention. The court concluded that Stanford's "agree to assign" language creates only a promise to assign rights in the future whereas the VCA's "hereby assign" language immediately granted Cetus a right in Holodniy's future inventions. Pet. App. 13a-14a. The court held that Bayh-Dole was inapposite to the question to whom Holodniy had assigned his invention. *Id.* at 19a, 21a.

As discussed above, that analysis was flawed. The Federal Circuit should have first analyzed what right Holodniy had to the invention under Bayh-Dole. Holodniy's right under Bayh-Dole to own the invention was doubly contingent, and depended both on Stanford declining to exercise its right to retain title and on NIH, as the federal funding agency, approving an application by Holodniy to leave title with him, subject to the reservation of federal rights. 35 U.S.C. 202(d). Because Stanford *did* elect to retain title to the invention and because NIH *did not* approve an application by Holodniy to retain title himself, Holodniy had no rights that he could convey to Cetus through the VCA. See *Hydranautics*, 982 F.2d at 1553 (under pre-Bayh-Dole statute, purported assignee of inventor employed by federal contractor lacked standing to sue on the patent because the inventor "had no right to assign it"); *Heinemann*, 796 F.2d at 456 (under E.O. 10096, in-

vention of federal employee was "not the property of" the inventor, but rather was "the property of the Government," despite absence of valid assignment).

By making a university's ownership of federally funded inventions turn on the language of prior assignments by the inventor, of which the university might have no actual knowledge, the court of appeals' decision makes it virtually impossible for a university and a prospective industry licensee to be certain that the university owns the invention in question. They must prove a negative—that no co-inventor ever prospectively assigned his or her rights to a third party. To prevent the loss of patent rights (or identify that the rights are lost and truncate the investment in that technology), 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 virtually unbounded searches would constitute a far worse waste of patent lawyer resources than existed under the regime that Bayh-Dole was intended to correct. *See* Senate Report 30 (condemning the "onerous burden" of "trying to determine the ownership of patents arising from the agencies' research and development grants and contracts"). Moreover, the Federal Circuit's decision actually creates an incentive for companies to utilize VCAs or similar devices to entice university researchers to make private, secret assignments that might reduce (or eliminate) future royalty payments to the university or, alternatively, cloud the title of patents licensed to their competitors. No matter how much effort is expended, it will be impossible for a university and its licensee ever to

know with certainty that no such third-party assignment exists.

Given the large sums of money that must frequently be invested to develop a basic scientific invention into a marketable product, the uncertainties created by the court of appeals' decision will substantially impede commercialization. Bringing a new drug to market, for example, can cost hundreds of millions of dollars in testing and clinical trials that can last a decade. GAO Report 6-7, 10. A university and its licensee-collaborator, believing that title rested in the university, could therefore invest in a technology for over a decade only to face a title challenge at the time of commercialization. See *ibid.* The additional risk that the newly developed drug, even if safe and effective, would belong to some third-party assignee of the university researcher would inevitably lead some companies to forgo licensing universities' Bayh-Dole inventions, especially when those inventions are only at the very preliminary stages of product development.

While it is impossible to predict the precise number of commercialization arrangements that will not materialize, there can be no question that Bayh-Dole's objective of encouraging development of federally funded inventions will be undermined by the introduction of this additional uncertainty in licensing university patents.

*2. Universities cannot protect themselves from the court of appeals' decision by changing their researcher contracts*

In its petition-stage briefs, Roche argued that Stanford and other universities could "easily avoid the ruling below" by amending their researcher agreements "to grant immediate assignments" of interest in future inventions. Br. in Opp. 15. That argument is flawed as a matter of policy and inaccurate as a matter of fact.

a. To begin, Roche's argument that universities should respond to the Federal Circuit's decision by adopting "hereby assigns" language demonstrates that Roche's position in this litigation is not one of principle, but of opportunism. In the next case with facts like this one, if Roche's advice is followed, the industry collaborator will *not* obtain any ownership interest because the faculty researcher will already have assigned all his rights in future inventions to the university. Roche's argument, in other words, is "good for one ride only," with Roche the only rider.

b. Relegating ownership of Bayh-Dole inventions to the realm of competing assignment provisions cannot, in any event, provide the kind of certainty of title that is essential to the continued commercialization success of federally funded inventions. While inserting a "hereby assigns" provision in employment agreements might prevent a researcher from thereafter assigning away the university's Bayh-Dole rights, such a provision would be impotent to protect the university against "hereby assigns" contracts that the researcher already signed with a previous employer, when pre-

viously visiting a lab, or when engaging in earlier consulting arrangements.

Moreover, it is impossible to know that "hereby assigns" language will always be upheld as having priority over other formulations that have not yet been considered. Indeed, because issues of patent ownership can arise in the regional circuits, it is not even clear that other cases involving the same competing clauses will be resolved in the same fashion as this case.

c. Finally, changing contractual terms prospectively cannot eliminate the problems created by the Federal Circuit's decision regarding inventions that have already been conceived, or research already performed, under employment contracts that utilize the "agree to assign" language. Many inventions made under such agreements are only now entering the lengthy product development phase, and many more inventions will be conceived over the next decade for which ownership disputes will arise based on patent assignments and confidentiality agreements signed long ago. See GAO Report 6-7, 10. The Federal Circuit's decision casts a shadow on the effective commercialization of inventions deriving from billions of dollars in past, current, and ongoing federal research funding.

Congress enacted Bayh-Dole with the specific purpose of providing universities and other nonprofits with certainty that they would own their federally funded inventions and could enter into collaborative licensing arrangements to commercialize them. Bayh-Dole has been incredibly successful in achieving those goals, but the uncertainties generated by the Federal Circuit's decision now threaten that success. Making ownership of Bayh-Dole inventions turn on dueling assignment

provisions benefits no one other than Roche in this particular case. That is no justification for undermining one of the greatest legislative achievements in the past half century.

## CONCLUSION

The judgment of the court of appeals should be vacated.

Respectfully submitted,

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

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# APPENDIX A

## EX. ORD. NO. 10096. UNIFORM GOVERNMENT PATENT POLICY FOR INVENTIONS BY GOVERNMENT EMPLOYEES

Ex. Ord. No. 10096, Jan. 23, 1950, 15 F.R. 389, as amended by Ex. Ord. No. 10695, Jan. 16, 1957, 22 F.R. 365; Ex. Ord. No. 10930, Mar. 24, 1961, 26 F.R. 2583, provided:

NOW, THEREFORE, by virtue of the authority vested in me by the Constitution and statutes, and as President of the United States and Commander in Chief of the armed forces of the United States, in the interest of the establishment and operation of a uniform patent policy for the Government with respect to inventions made by Government employees, it is hereby ordered as follows:

1. The following basic policy is established for all Government agencies with respect to inventions hereafter made by any Government employee:

(a) The Government shall obtain the entire right, title, and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or (3) which bear a direct relation to or are made in consequence of the official duties of the inventor.

(b) In any case where the contribution of the Government, as measured by any one or more of the criteria set forth in paragraph (a) last above, to the invention, is insufficient equitably to justify a requirement of

assignment to the Government of the entire right, title and interest to such invention, or in any case where the Government has insufficient interest in an invention to obtain entire right, title and interest therein (although the Government could obtain some under paragraph (a), above), the Government agency concerned, subject to the approval of the Chairman of the Government Patents Board (provided for in paragraph 3 of this order and hereinafter referred to as the Chairman), shall leave title to such invention in the employee, subject, however, to the reservation to the Government of a non-exclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes, such reservation, in the terms thereof, to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention.

(c) In applying the provisions of paragraphs (a) and (b), above, to the facts and circumstances relating to the making of any particular invention, it shall be presumed that an invention made by an employee who is employed or assigned (i) to invent or improve or perfect any art, machine, manufacture, or composition of matter, (ii) to conduct or perform research, development work, or both, (iii) to supervise, direct, coordinate, or review Government financed or conducted research, development work, or both, or (iv) to act in a liaison capacity among governmental or nongovernmental agencies or individuals engaged in such work, or made by an employee included within any other category of employees specified by regulations issued pursuant to section 4(b) hereof, falls within the provisions of paragraph (a), above, and it shall be presumed that any invention made by any other employee falls within the provisions of paragraph (b), above. Either presumption may be

rebutted by the facts or circumstances attendant upon the conditions under which any particular invention is made and, notwithstanding the foregoing, shall not preclude a determination that the invention falls within the provisions of paragraph (d) next below.

(d) In any case wherein the Government nether (1) pursuant to the provisions of paragraph (a) above, obtains entire right, title and interest in and to an invention nor (2) pursuant to the provisions of paragraph (b) above, reserves a non-exclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes, the Government shall leave the entire right, title and interest in and to the invention in the Government employee, subject to law.

(e) Actions taken, and rights acquired, under the foregoing provisions of this section, shall be reported to the Chairman in accordance with procedures established by him.

2. Subject to considerations of national security, or public health, safety, or welfare, the following basic policy is established for the collection, and dissemination to the public, of information concerning inventions resulting from Government research and development activities:

(a) When an invention is made under circumstances defined in paragraph 1(a) of this order giving the United States the right to title thereto, the Government agency concerned shall either prepare and file an application for patent therefor in the United States Patent Office [now Patent and Trademark Office] or make a full disclosure of the invention promptly to the Chairman, who may, if he determines the Government

interest so requires, cause application for patent to be filed or cause the invention to be fully disclosed by publication thereof: *Provided, however*, That, consistent with present practice of the Department of Agriculture, no application for patent shall, without the approval of the Secretary of Agriculture, by filed in respect of any variety of plant invented by any employee of that Department.

(b) [Revoked. Ex. Ord. No. 10695, Jan. 16, 1957, 22 F.R. 365]

3. (a) [Revoked. Ex. Ord. No. 10930, Mar. 24, 1961, 26 F.R. 2583]

(b) The Government Patents Board shall advise and confer with the Chairman concerning the operation of those aspects of the Government's patent policy which are affected by the provisions of this order or of Executive Order No. 9865, and suggest modifications or improvements where necessary.

(c) [Revoked. Ex. Ord. No. 10930, Mar. 24, 1961, 26 F.R. 2583]

(d) The Chairman shall establish such committees and other working groups as may be required to advise or assist him in the performance of any of his functions.

(e) The Chairman of the Government Patents Board and the Chairman of the Interdepartmental Committee on Scientific Research and Development (provided for by Executive Order No. 9912 of December 24, 1947), shall establish and maintain such mutual consultation as will effect the proper coordination of affairs of common concern.

4. With a view to obtaining uniform application of the policies set out in this order and uniform operations thereunder, the Chairman is authorized and directed:

(a) To consult and advise with Government agencies concerning the application and operation of the policies outlined herein;

(b) After consultation with the Government Patents Board, to formulate and submit to the President for approval such proposed rules and regulations as may be necessary or desirable to implement and effectuate the aforesaid policies, together with the recommendations of the Government Patents Board thereon;

(c) To submit annually a report to the President concerning the operation of such policies and from time to time such recommendations for modification thereof as may be deemed desirable;

(d) To determine with finality any controversies or disputes between any Government agency and its employees, to the extent submitted by any party to the dispute, concerning the ownership of inventions made by such employees or rights therein; and

(e) To perform such other or further functions or duties as may from time to time be prescribed by the President or by statute.

5. The functions and duties of the Secretary of Commerce and the Department of Commerce under the provisions of Executive Order No. 9865 of June 14, 1947 [set out above] are hereby transferred to the Chairman and the whole or any part of such functions and duties may be delegated by him to any Government agency or officer: *Provided*, That said Executive Order No. 9865 shall not be deemed to be amended or affected by any

provision of this Executive order other than this paragraph 5.

6. Each Government agency shall take all steps appropriate to effectuate this order, including the promulgation of necessary regulations which shall not be inconsistent with this order or with regulations issued pursuant to paragraph 4(b) hereof.

7. As used in this Executive order, the next stated terms, in singular and plural, are defined as follows for the purposes hereof:

(a) "Government agency" includes any executive department and any independent commission, board, office, agency, authority, or other establishment of the Executive Branch of the Government of the United States (including any such independent regulatory commission or board, any such wholly-owned corporation, and the Smithsonian Institution), but excludes the Atomic Energy Commission.

(b) "Government employee" includes any officer or employee, civilian or military, of any Government agency, except such part-time consultants or employees as may be excluded by regulations promulgated pursuant to paragraph 4(b) hereof.

(c) "Invention" includes any art, machine, manufacture, design, or composition or matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States.