

No. 09-1159

IN THE
Supreme Court of the United States

BOARD OF TRUSTEES OF THE LELAND STANFORD
JUNIOR UNIVERSITY,

Petitioner,

v.

ROCHE MOLECULAR SYSTEMS, INC., ET AL.,

Respondents.

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

**BRIEF FOR THE PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA AS *AMICUS
CURIAE* SUPPORTING RESPONDENT**

David E. Korn
Pharmaceutical
Research
and Manufacturers
of America
950 F St., N.W.
Washington, DC 20004
(202) 835-3400

Robert A. Long, Jr.
Counsel of Record
Alan Pemberton
Erika Lietzan
Ranganath Sudarshan
Covington & Burling LLP
1201 Pennsylvania Ave,
NW
Washington, DC 20004
(202)662-5612
rlong@cov.com

February 1, 2011

Counsel for Amicus Curiae

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INTEREST OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies.¹ See PhRMA Member Company List, *available at* http://www.phrma.org/member_company_list. PhRMA members invested an estimated \$45.8 billion in 2009 in discovering and developing new medicines that help patients live longer, healthier and more productive lives. See 2010 Pharmaceutical Industry Profile, *available at* http://www.phrma.org/sites/phrma.org/files/attachments/Profile_2010_FINAL.pdf. This amount reflects roughly 70 percent of total pharmaceutical industry spending on research and development. *Id.*

In the conduct of their research, PhRMA members employ researchers, consultants, service providers and other third parties to assist them in inventing and developing new medicines. In connection with these activities, PhRMA members routinely acquire title to all resulting inventions and patents. Such title is important to ensure that any medicines that

¹ Pursuant to this Court's Rule 37.6, amicus affirms that no counsel for any party authored this brief in whole or in part, that no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief, and that no person other than amicus or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. The parties have consented in writing to the filing of this brief.

are successfully developed will enjoy a sufficient period of market exclusivity to allow them to recoup their research and development expenses, and to provide a return on the developer's investment.

PhRMA members also frequently perform research in collaboration with academic institutions and other entities that receive funding from the federal government. *See id.* These partnerships, and the technology transfer agreements on which they are based, are often an effective way to translate basic research discoveries into commercial medicines while returning significant royalty revenues to academic inventors and their institutions.

Collaborations between academic institutions and PhRMA members almost always involve more than the patent rights of academic inventors. In some cases, inventions by PhRMA members or their collaborators become the subject of later collaborations, and later federal funding. In other cases, PhRMA researchers invent significant improvements that are necessary to convert academic discoveries into commercial products.

The patent ownership issues in this case are important because they have substantial implications for current and future collaborative relationships among PhRMA members, academic institutions, and the government. Intellectual property ownership issues are among the most important, and most carefully negotiated, aspects of technology collaborations. Accordingly, PhRMA's members have a strong interest in the proper interpretation of the Bayh-Dole Act.

SUMMARY OF ARGUMENT

1. The Bayh-Dole Act permits contractors to retain title to their inventions when specified conditions are met, but it does not strip third parties of their ownership or contract rights. By its terms, the Act provides that a contractor may “retain title” to subject inventions. 35 U.S.C. § 202(a). The ordinary meaning of “retain” is to “keep hold of” or “to continue to have.” The Bayh-Dole Act thus defines the circumstances in which contractors may continue to hold title to inventions; it does not extinguish the legal rights of third parties or transfer title from third parties to the contractor. The limited scope of the Bayh-Dole Act is confirmed by the statutory definition of a “subject invention” as an “invention of the contractor.” 35 U.S.C. § 201(e). Congress knows how to vest title when it wishes to do so; it did not use “vesting” language in the Bayh-Dole Act.

2. This interpretation of the Bayh-Dole Act accords with the expectations of government agencies, universities, and other members of the technology transfer community. The regulations implementing the Bayh-Dole Act provide that the “contractor agrees to require, by written agreement, its employees . . . to . . . execute all papers necessary to . . . establish the government’s rights in the subject inventions.” 37 C.F.R. § 401.14(f)(2). The NIH has explained that, “[b]y law, an inventor has initial ownership of an invention. However, awardee organizations are required by the Bayh-Dole Act to have in place employee agreements requiring an inventor to ‘assign’ or give ownership of an invention

to the organization upon acceptance of Federal funds.”

Research universities typically require employees to execute patent disclosure and assignment agreements, and frequently advise their employees not to enter into agreements that may conflict with their assignment agreements with the university. These policies reflect an established framework under which universities take active steps to obtain assignments of rights to inventions, and do not rely on the Bayh-Dole Act to strip inventors and other third parties of ownership rights.

Private parties entering into technology transfer agreements with universities do not assume that the university possesses clear title to any federally-funded invention. Instead, leading treatises advise that licensees should obtain a warranty from the university that it is the sole and exclusive owner of the patent rights being licensed. In addition to seeking contractual assurances, parties to technology transfer agreements with universities engage in due diligence to ensure that assignments of rights have been executed by all inventors, employees, and other individuals or business entities.

3. The Bayh-Dole Act seeks to promote collaboration between universities and the private sector, which is vital to innovation and economic growth. Petitioner’s proposed interpretation of the Act could jeopardize the continued success of this important and successful collaboration. Private firms may become reluctant to host visitors from academia if in doing so they risk losing title to valuable inventions. Private firms might become less willing to fund university-industry research

centers (UIRC)s, which account for roughly half of all industrial funding of academic research in the United States, and could have an incentive to develop research partnerships with foreign universities that are not subject to a “vesting title” regime. The adverse effects of Petitioner’s interpretation are likely to be magnified because the Act applies to inventions that are conceived *or* actually reduced to practice in the performance of work under a federal funding agreement, and because even minimal amounts of federal funding may usurp third party ownership rights.

The interests of members of the technology transfer community, and the public interest, are best served by a legal regime that respects contract rights and established principles governing the ownership of inventions. Petitioner’s approach would make it difficult or impossible for private parties to negotiate flexible and creative contractual arrangements that create optimum incentives to innovate and bring new technologies to market.

ARGUMENT

I. The Bayh-Dole Act Allocates Title To Inventions As Between The Federal Government And Its Contractors, But Does Not Divest Third Parties Of Title

By its terms, the Bayh-Dole Act applies to inventions of government contractors, and allows contractors to retain their rights to government-funded inventions when specified conditions are met. Petitioner contends that the Act affirmatively *vests* title to inventions in the contractor, even if title would otherwise vest in a third party under patent or contract law. The statutory text does not support Petitioner's interpretation.

The statute provides that a “nonprofit organization or small business may . . . elect to *retain title* to any subject invention.” 35 U.S.C. § 202(a) (emphasis added). “Retaining title” is not the same as acquiring title; a contractor cannot “retain” title to an invention it does not already own. *See Oxford English Dictionary* (3d ed. 2010) (“retain” means “[t]o keep in one’s own hands or under one’s own control; to keep back; to keep hold or possession of; *to continue to have.*”) (emphasis added); *Alaska v. United States*, 545 U.S. 75, 104 (2005) (interpreting statute providing that “the United States shall retain title to all property . . .” to mean that “[t]he United States . . . retained title to *its property* located within Alaska’s borders”) (emphasis added).

If Congress had intended the Bayh-Dole Act to vest title in contractors, it would have used different language to achieve that result. Indeed, the Bayh-Dole Act supplanted several federal “vesting

statutes” that demonstrated Congress’s ability to use “vesting” language when it wished to do so. *See, e.g.*, 42 U.S.C. § 2182 (1976) (Department of Energy) (“Any invention or discovery, useful in the production or utilization of special nuclear material or atomic energy, made or conceived in the course of or under any contract, subcontract, or arrangement entered into with or for the benefit of the Commission . . . shall be vested in, and be the property of, the Commission.”); 42 U.S.C. § 2457(a) (1976) (NASA) (“Whenever any invention is made in the performance of any work under any contract of the Administration . . . such invention shall be the exclusive property of the United States, and if such invention is patentable a patent therefor shall be issued to the United States upon application made by the Administrator . . .”); 42 U.S.C. § 5908(a) (1976) (Department of Energy) (“Whenever any invention is made or conceived in the course of or under any contract of the Department . . . title to such invention shall vest in the United States . . .”) (emphases added). Congress was fully aware of these “vesting” statutes when it enacted the Bayh-Dole Act, and it explicitly recognized that they disposed of rights in subject inventions “in a manner that is inconsistent with this chapter,” and stated that Bayh-Dole “shall take precedence over [them].” 35 U.S.C. § 210(a)(6), (7), and (11).

The limited scope of the Bayh-Dole Act is confirmed by the language of § 201(e), which defines a “subject invention” as “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement” (emphasis added). If Petitioner

were correct that “the Act confers title to inventions directly upon funded research institutions,” Pet. Br. at 30, there would have been no reason for Congress to require that the invention be an invention “of the contractor.” *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979) (“In construing a statute we are obliged to give effect, if possible, to every word Congress used.”).

Petitioner and its amici advance two primary textual arguments in support of their contention that the Bayh-Dole Act’s conferral of rights is not contingent on a transfer of ownership rights from the inventor to the contractor. *First*, they argue that Section 202(d), which specifies a protocol for the inventor to receive title “[i]f a contractor does not elect to retain title to a subject invention,” is the only way in which an inventor can take title to a federally funded invention. *See, e.g.*, U.S. Br. at 7. But Section 202(d) applies only if the Bayh-Dole Act’s threshold requirement has been met – *i.e.*, if the invention is an invention “of the contractor,” and therefore the contractor has a title that can be “retained.” If the contractor has secured the prerequisite title, Section 202(d) specifies the manner in which the inventor may keep the title previously assigned to the contractor. But if the contractor has not obtained an assignment from the inventor, Section 202(d) does not extinguish the inventor’s rights.

Second, petitioner and its amici argue that the statement in Section 210(a) that the Bayh-Dole Act gives “precedence” to the Act’s “[d]isposition of rights” requires that title automatically vests in the contractor, regardless of the Patent Act’s provision that ownership initially vests in the inventor. *See*

U.S. Br. at 8. This argument rests on the false premise that the disposition of inventor's rights contemplated by Bayh-Dole is at variance with other statutes. As discussed above, the Bayh-Dole Act assumes that federally funded contractors have obtained an assignment of ownership rights from the inventor. The Act is thus consistent with long-settled principles of patent law, which recognize that ownership of an invention initially vests in the inventor. *See Gayler v. Wilder*, 51 U.S. 477, 493 (1851) (“[T]he discoverer of a new and useful improvement is vested by law with an inchoate right to its exclusive use, which he may perfect and make absolute by proceeding in the manner which the law requires.”); 1 William C. Robinson, *Treatise On The Law Of Patents For Useful Inventions* § 403 at 574 (1890) (“The right of an inventor to a patent vests in him at the moment his invention is completed . . .”).²

² The legislative history of the Bayh-Dole Act indicates that Congress was concerned with allocating ownership rights to inventions of the contractor, not with stripping third parties of ownership rights under patent or contract law. *See* 126 Cong. Rec. 1796 (Feb. 5, 1980) (Statement of Sen. Bayh) (“The bill that we are considering today strikes a careful balance, it seems to me, between the rights of the *Federal Government* . . . and the equally important rights of the *inventor and the public*”); *The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the Sen. Comm. on the Judiciary, 96th Cong., 1st Sess.* 97 (1979) (Statement of Patrick Iannotta, President, Ecolotrol Inc.) (“Frankly, it was a very frustrating experience trying to deal with the Government. (continued...)”)

II. The Court of Appeals' Decision Accords With The Settled Expectations Of Government Agencies, Universities, And Third Parties

Petitioner contends that the court of appeals' decision disrupts a settled framework guaranteeing a research contractor clear title to a federally funded invention, regardless of competing ownership claims. Pet. Br. 45-48. As discussed below, there is no such settled framework. To the contrary, government agencies, universities, and other members of the technology transfer community all recognize that the inventor's title to an invention must be properly assigned to the contractor in order for a contractor to retain rights under the Bayh-Dole Act.

A. Federal Agencies Recognize That Contractors Cannot Retain Title Under The Bayh-Dole Act Without Assignments From Inventors

Under 35 U.S.C. § 206, the Secretary of Commerce is authorized to implement the Bayh-Dole Act, and to promulgate standard contract clauses for funding agreements. The Secretary's regulations and contract clauses are codified at 37 C.F.R. § 401. Section 401.14, which provides "standard patent rights clauses" to be used by agencies in their funding agreements, obligates the funding recipient

After all, *all we were trying to do was to protect what we already owned.*") (emphases added).

to execute written assignments from inventors of funded inventions:

The contractor agrees to require, by written agreement, its employees . . . to . . . execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions.

37 C.F.R. § 401.14(f)(2). If the Bayh-Dole Act automatically vested title in the contractor, it would not be necessary for contractors to obtain “written agreement” from their inventor employees to “establish the government’s rights.”

Petitioner argues that the statement in § 401.14(a)(1) that “[t]he Contractor may retain the entire right, title, and interest throughout the world to each subject invention,” “cannot be squared with a view that Bayh-Dole determines only the disposition of rights between the Government and the institution.” Pet. Br. at 43. But Petitioner omits key language from the regulation, which specifies that the contractor’s rights are “subject to the provisions of this clause.” 37 C.F.R. § 401.14(b). Those provisions include the requirement that the contractor obtain the “written agreement” of employee inventors to “execute all papers necessary . . . to establish the government’s rights.”

Bayh-Dole compliance guidelines published by the National Institutes of Health (NIH) confirm this understanding. In a section entitled “20 INVENTION REPORTING TERMS WITH WHICH

EVERY NIH AWARDEE SHOULD BE FAMILIAR,”
the very first paragraph informs contractors:

1. ASSIGNMENT.

Transfer of title or ownership in patent rights in the form of a written assignment document. *By law, an inventor has initial ownership of an invention. However, awardee organizations are required by the Bayh-Dole Act to have in place employee agreements requiring an inventor to “assign” or give ownership of an invention to the organization upon acceptance of Federal funds.*

NIH Policies, Procedures, and Forms, *A ‘20-20’ View of Invention Reporting to the National Institutes of Health*, available at https://s-edison.info.nih.gov/iEdison/twenty_questions_updated.jsp (Adapted and updated from: 24 NIH GUIDE 33, Sept. 22, 1995) (emphasis added). Given its annual budget of over \$30 billion,³ and its position as the nation’s “largest funding agency for biomedical research,⁴ NIH’s views merit careful consideration.

In sum, the regulations and the NIH guidelines both reflect the understanding that the contractor’s duty to secure ownership rights from the inventor is

³ *NIH Budget*, available at <http://www.nih.gov/about/budget.htm>.

⁴ Benn Steil, et al., *Technological Innovation and Economic Performance*, 362 (2002).

a prerequisite to enjoying the benefits of the Bayh-Dole Act.

B. Research Universities Do Not Assume That The Bayh-Dole Act Automatically Confers Title On Contractors

Petitioner and its university amici contend that the court of appeals' decision will require them to begin performing "wide-ranging inquir[ies] on subject inventions" to search for "unknown prior assignment[s] by a named inventor," and that such diligence will "significantly increase [their] administrative costs." Pet. Br. at 46-47; *see also* Brief of The Association Of American Universities, et al. ("AAU Br.") at 31-32 (decision "undermines the certainty of university title that is central to Bayh-Dole's success," and "re-injects uncertainty into the commercialization of federally funded inventions."). These contentions are belied by assignment policies and procedures that are already in place at a broad spectrum of research universities.

Most universities have written intellectual property policies in their faculty/staff handbooks that claim ownership of inventions derived using university resources. *See* G. Kenneth Smith, *Faculty And Graduate-Student Generated Inventions: Is University Ownership a Legal Certainty?*, 1 Va. J. L. & Tech. 4 (1997). Pursuant to these policies, universities generally require new hires to sign patent disclosure and assignment agreements as a condition of employment. *See id.*

Academic institutions take affirmative measures to require their employee inventors to execute

written assignments. See, e.g., Yale University *Patent Policy* (February, 1998), available at <http://www.yale.edu/ocr/pfg/policies/patents.html> (“Inventors shall execute assignments or other documents assigning to the University all their rights in the invention and any patent applications or resulting patents on the invention. Yale will retain title to all such patent applications and resulting patents.”); Duke University *Policy on Inventions, Patents, and Technology Transfer* (1998), available at http://olv.duke.edu/Inventors/PoliciesAndProcedures/policy_on_inventions.pdf (“Inventions resulting from research or other work conducted by university employees in whole or in part on university time or with significant use of university funds or facilities shall be considered the property of the university. Employees shall upon request assign to the university all rights and title to such inventions and shall make known and available to the university all supportive technology related to the same.”); Cornell University *Inventions and Related Rights Policy Statement 1.5* (July, 1995), available at <http://www.dfa.cornell.edu/dfa/treasurer/policyoffice/policies/volumes/academic/inventions.cfm> (“All inventions made by an individual with (i) a university appointment in furtherance of his/her university responsibilities, and/or (ii) with the use of university resources, including those provided through an externally funded grant, contract, or other type of award or gift to the university, belong to the university. . . . If [Cornell] determines that Cornell has an ownership interest, the inventor must assign all rights and titles of the invention to the university or its designee . . .”).

Indeed, Petitioner's own patent policy takes this approach. See Stanford University *Research Policy Handbook: Inventions, Patents, and Licensing (RPH 5.1)* (July 15, 1999), available at <http://rph.stanford.edu/5-1.html> ("All potentially patentable inventions conceived or first reduced to practice in whole or in part by members of the faculty or staff (including student employees) of the University in the course of their University responsibilities or with more than incidental use of University resources, shall be disclosed on a timely basis to the University. Title to such inventions shall be assigned to the University, regardless of the source of funding, if any.").

Several universities explicitly acknowledge a nexus between their Bayh-Dole duties and the need for inventors to execute written assignments. For example, Yale University's patent policy states:

Current governmental regulations permit educational institutions to retain rights and title to patentable inventions which results from federally funded experimental, developmental and research work. *Retention of rights by University is contingent upon the fulfilling of a number of obligations on the part of the University and of the Inventor(s)* and these obligations must be discharged in order to protect the interests of all parties. . . . *Incumbent upon members of the University community who apply for and receive federal funding to support research or who use federal monies in the conduct of*

their research is the requirement for written agreement that they will promptly disclose patentable inventions to the University and will execute all instruments necessary to protect the rights of the government and/or the University.

Yale University Patent Policy at ¶ 9. Similarly, the University of California system advises faculty at its affiliated universities that the university is “obligated to have written agreements with its faculty and technical staff requiring the disclosure and assignment of inventions.” University of California, Technology Transfer, *The Bayh-Dole Act: A Guide To The Law And Implementing Regulations* (1999), available at <http://www.ucop.edu/ott/faculty/bayh.html#FN4a>.

Universities also routinely allow their faculty to consult with private enterprise, commonly advise their employees not to enter into agreements that would conflict with the employees’ assignment agreements with the university, and employ procedures to clear any potential conflicts that may arise. The policy of the Massachusetts Institute of Technology (“MIT”) is typical:

It is the responsibility of individual members of the MIT community to ensure that the terms of their consulting agreements with third parties do not conflict with their commitments to the Institute Each individual should make the nature of his or her obligations to the Institute clear to any third party for whom he or

she expects to consult. Specifically, the scope of the consulting services should be distinguished from the scope of research commitments at the Institute.

MIT *Policies & Procedures*, § 13.1.5, available at <http://web.mit.edu/policies/13/13.1.html>. Similarly, the Johns Hopkins University requires faculty members to obtain clearance from the university before entering into consulting agreements, in recognition that such agreements can clash with “[u]niversity policies” and “government regulations”:

In cases where faculty enjoy rights to Intellectual Property under this policy, they have an obligation to report fully any outside activities and interests related to their teaching, research, or service to their Department Chair, Dean or other designated University official and obtain their prior approval before the activity begins. The report must be in writing and must include the names of companies for whom he/she consults, the number of days committed to each consulting agreement and a copy of any proposed consulting agreements associated with Intellectual Property. Consulting agreements must be reviewed for compliance with University policies and government regulations and approved by the appropriate Divisional office before the *consultation can begin*.

The Johns Hopkins University *Intellectual Property Policy*, § VI E 2, (April 2, 2001) available at

http://jhuresearch.jhu.edu/JHU_Intellectual_Property_Policy.pdf (emphasis added).

These policies reflect an established framework under which universities take active steps to minimize the risk that employee inventors might jeopardize Bayh-Dole title rights. The court of appeals' decision thus accords with existing expectations in the technology transfer community, by holding that title under the Bayh-Dole Act is not automatically vested, but instead is "retained." See Homer A. Neal et al., *Beyond Sputnik: U.S. Science Policy In The Twenty-First Century* 107 (2008) ("Bayh-Dole requires universities to obtain written agreements from faculty and research staff committing that they will assign IP ownership to the institution."); Stephen Fishman, *What Every Inventor Needs To Know About Business & Taxes* 23 (2d ed. 2005) ("The Bayh-Dole Act works like this: . . . The university must have written agreements with its faculty and technical staff requiring disclosure and assignment of inventions.").

C. Universities Entering Into Technology Transfer Agreements Frequently Provide Warranties That They Have Secured Assignments From Inventors

According to some of Petitioner's amici, research agreements between universities and private industry prior to the Federal Circuit's decision have assumed that clear title to federally funded inventions belonged to universities. See, e.g., AAU Br. at 24-25 (sponsored research agreements "start with the premise that the university will have the

right under Bayh-Dole to . . . license the inventions”); Brief of National Venture Capital Association at 6-7 (“a startup company holding an exclusive license from a university, for example, could easily prove that the ownership of its license was valid simply by pointing to its agreements with the university. No further inquiry or investigation was required.”).

Contrary to these contentions, an assumption that universities own clear title to federally funded inventions is contrary to widely-followed best practices applied to technology transfer agreements. One of the primary assurances sought by participants in technology licensing transactions is a warranty that the university has clear title to the transacted invention. A leading treatise on technology transfer agreements, in a “Model Exclusive License Agreement Conforming to Stevenson-Wydler and Bayh-Dole Act Licensing Restrictions” lists the following as the *very first* warranty and disclaimer to be sought from a university:

A. The UNIVERSITY warrants that it is the lawful owner of the PATENT RIGHTS identified in paragraph 1.B above.

Michael J. Lennon, *Technology Transfer Guide* (Lennon) § 6.03[G] at 6-96 (Supp. 2001); *see also* Lennon § 9.02 at 9-7-8 (2000) (“REPRESENTATIONS, WARRANTIES, AND COVENANTS OF THE OWNER-LICENSOR IN TECHNOLOGY TRANSFER TRANSACTIONS . . . The licensor should warrant that the inventorship in the licensed patents resides solely and exclusively in the named inventors.”). Such a warranty would be

unnecessary if the Bayh-Dole Act automatically vested title in federal contractors.

Industrial participants in transactions with universities also seek assurances that licenses to funded inventions are sufficient, standing alone, to allow commercialization:

Warranties and Representations for
Agreements with Academic Institutions

The UNIVERSITY represents and warrants to the LICENSEE that, as of the Effective Date of this Agreement:

a) The LICENSEE does not need any license or right which is owned by the UNIVERSITY not already granted under the terms of this Agreement that is necessary or useful for the LICENSEE and its affiliates to manufacture and use the Licensed Intellectual Property Rights.

Id. § 5.10 at 5-16-17.⁵ Another leading treatise advises industrial collaborators to exercise similar caution:

⁵ The Lennon treatise further advises:

The representations and warranties of the parties to a technology transfer transaction guarantee the underlying assumptions of the agreement, for example, that the licensor has unencumbered title to the technology and has the right to grant the licenses conveyed to the licensee to commercialize it.

(continued...)

REPRESENTATION BY INSTITUTION REGARDING PROPRIETARY POSITION

Institution represents that Institution is not party to any agreement which in any way restricts Institution's power to convey by assignment or license agreement rights to Inventions and Know-How in the Field which may be conceived under this Research Agreement . . .

Michael Epstein & Frank L. Politano, *Drafting License Agreements* 26-159 (4th ed. 2004) (in appendix entitled "Model Provisions For Licenses And Sponsored Research Contracts Involving Academic Institutions"). These negotiated provisions would be unnecessary if industrial participants could rely upon the vesting of title under the Bayh-Dole Act.

In addition to seeking contractual assurances from universities, parties to technology transfer agreements engage in due diligence efforts to ensure that transacted patents carry clear title. According

The basic clauses normally state that the licensor is the exclusive owner of the technology, has the right to grant the licenses conveyed, and is not aware of any conflicts with the rights of third parties that would be created by the conveyance of these licenses from the licensor to the licensee.

Id. § 4.01[P] at 4-34.

to one leading authority, the first due diligence task for a company seeking to license a university patent is to seek an answer to the following question: “Have assignments of the rights to be transferred been executed by all inventors, employees, and any other individuals or business entities so that ownership, and the licensee’s right to use the licensed technology, will not be disputed?” Lennon § 9.01[A] at 9-3. Parties to technology transfer agreements are well aware that “[w]ithout clear title vested in the licensor or assignor, the licensee or assignee may not receive the rights bargained for.” *Id.* Again, these efforts would be unnecessary if the parties understood that the Bayh-Dole Act automatically vested title in the university.

III. The Public Interest Is Served By Affirming The Court Of Appeals’ Decision

A. An Expansive Interpretation of Bayh-Dole May Jeopardize Collaboration Between Universities And Third Parties

Collaboration between universities and the private sector is vital to innovation and economic growth in the United States. Between 1980, when Congress enacted the Bayh-Dole Act, and 2000, funding from private industry for science and engineering research at universities doubled, from four percent to almost eight percent of total university research dollars. Amy Zusman, *Challenges Facing Higher Education In The Twenty-First Century*, in *American Higher Education In The Twenty-First Century: Social, Political, and Economic Challenges* 124 (Philip G. Altbach et al.

eds., 2005). Most life scientists agree that “research support from industry ‘provides resources for research that could not be obtained elsewhere’ and ‘involves less red tape than federal funding.’” Karen Seashore Louis & Melissa S. Anderson, *The Changing Context of Science*, in *Capitalizing Knowledge: New Intersections of Industry and Academia* 79 (Henry Etzkowitz et al. eds. 1998).

Pharmaceutical companies view collaborative arrangements with universities as a “source of discoveries leading to new products.” Panel on the Gov. Role in Civilian Tech., Comm. on Sci., Eng’g, & Pub. Policy, Nat’l Acad. of Scis., et al., *The Government Role in Civilian Technology: Building A New Alliance*, 165 (1992). The relationship between industry and academia enables basic science research to be converted into applied technology that is useful to society. See, e.g., Stuart O. Schweitzer, *Pharmaceutical Economics And Policy* 31-32 (2007) (“Often academic researchers who receive government research grants and contracts have direct connections to the private sector. . . . These relationships can be viewed as useful linkages between the ‘theoretical’ world of academia and the ‘practical’ world of industry.”). As one commentator has observed, “Bayh-Dole is widely viewed as having created incentives for socially useful collaboration between academia and industry. The resulting commercialization of research harnesses the collective intellectual and creative talents of university faculty, speeds the development of new and improved therapies, stimulates regional economic growth, and contributes to the economic viability of research institutions.” Shaili Jain,

Understanding Physician-Pharmaceutical Industry Interactions: A Concise Guide 94 (2007).

The continued success of partnerships between academia and private industry may be placed at risk if, as Petitioner contends, title to inventions automatically vests in federally funded universities, irrespective of prior contractual agreements. For example, private firms may be reluctant to host visitors from academia like Dr. Holodniy if, regardless of their efforts to secure rights over inventions arising from such collaboration, universities are later able to play a Bayh-Dole “trump card” that grants them title. More generally, if private firms cannot rely on written agreements to guarantee their rights in inventions resulting from collaborative arrangements with academia, the incentives to pursue such collaborations will be diminished.

The adverse effects of Petitioner’s interpretation of the Bayh-Dole Act would be magnified because the Act applies to inventions that are conceived *or* first actually reduced to practice in the performance of work under a funding agreement. 35 U.S.C. § 201(e). Thus, even if an invention is first conceived by an inventor working in the private sector without any government funding and is *constructively* reduced to practice through the filing of a patent application, the university could still acquire ownership of the invention under Petitioner’s interpretation if it was first *actually* reduced to practice at the university in the performance of work under a funding agreement. This outcome contravenes the settled framework of 35 U.S.C. § 102(g). *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986)

(“constructive reduction to practice occurs when a patent application on the claimed invention is filed”); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996) (“the person who first reduces an invention to practice is ‘prima facie the first and true inventor.’”) (quoting *Christie v. Seybold*, 55 F. 69, 76 (6th Cir. 1893) (Taft, J.)). Moreover, Petitioner and its amici do not suggest that any minimum threshold of federal funding is necessary to trigger ownership rights under Bayh-Dole. In the absence of such a threshold, even a minimal amount of federal money risks “contaminating” privately-sponsored research, an interpretation that raises Fifth Amendment implications.

Concerns about “contamination” apply with added force to university-industry research centers (UIRCs). Such centers, which account for roughly half of all industrial funding of academic research in the United States, allow industry and academia jointly to define research portfolios, facilitate industry access to university basic science research, and promote transfer of technology to the marketplace. See Fraunhofer Institute for Systems and Innovative Research, National Academy of Engineering, *Technology Transfer Systems In The United States and Germany: Lessons and Perspectives* 18 (H. Norman Abramson et al. eds., 1997). A 1994 study of over one thousand UIRCs showed that these centers received funding in excess of \$4.12 billion, and involved 12,000 university faculty and 22,300 doctoral-level researchers. Wesley Cohen et al., *University-Industry Research Centers in the United States* (1994). At most UIRCs, support from private industry is matched by funding from federal

government entities. *Id.* The continued viability of UIRCs could be threatened by an interpretation of the Bayh-Dole Act that allows universities to assert sole title to inventions whenever private funds are combined with federal funds.

Faced with a legal regime in which universities can invoke the Bayh-Dole Act to obtain sweeping ownership rights, private firms may be encouraged to develop research partnerships with foreign universities based in countries that do not allow government contractors to claim title in inventions to which they have no contractual rights. Any such development could have negative consequences, including reducing the competitiveness of American institutions of higher learning and stemming the flow of talented foreign students to the United States.

B. The Public Interest Is Furthered By Respect For Contractual Agreements

The public interest, and the interests of members of the technology transfer community, are best served by respecting contract rights and well-established principles concerning ownership of inventions and transfer of those rights by assignment.

Ownership of an invention inures in the inventor, unless and until assigned. 35 U.S.C. §§ 101, 261 (“[w]hoever invents or discovers a new and useful [invention] may obtain a patent therefore”; patents are “assignable in law by an instrument in writing”). Under Petitioner’s interpretation of the Bayh-Dole Act, universities can divest inventors and their

assignees of title to their inventions merely by invoking federal funding.

For example, assume that a researcher who does not receive any federal funding conceives of an invention while working for a private company. Pursuant to the inventor's contractual agreement with the company, all rights to the invention belong to the company. The company files a patent application on the invention, thereby constructively reducing the invention to practice. Thereafter, the researcher is hired away by a university, where the invention is first actually reduced to practice. It later comes to light that a small amount of federal grant money was used in the actual reduction to practice. On that basis, the university claims ownership of the invention under the Bayh-Dole Act. The university could assert such a claim, in Petitioner's view, even if the researcher had never entered into an assignment agreement with the university (and even if the assignment agreement between the researcher and the university expressly excluded the invention at issue).⁶

These results are inappropriate. Universities, private companies, and employees all benefit by defining their respective rights through explicit agreements. If the right of employee-inventors to

⁶ Similarly, under Petitioner's view, if two research teams are engaged in independent, parallel research efforts, the government-funded team that first actually reduces an invention to practice could claim exclusive ownership rights even if the invention was first conceived and constructively reduced to practice by the private research team.

control disposition of their inventions is curtailed, the incentive for those employees to innovate (and to work for recipients of federal funds) may be weakened.

The Federal Circuit's holding encourages universities and private industry to enter into contracts that determine their respective rights in collaborative arrangements. As discussed above, private parties are well equipped to navigate contractual issues and further their interests through negotiated agreements. Flexible contractual arrangements allow technology transfer participants to establish incentives for the mutual benefit of all parties. Petitioner's approach, in contrast, would make it difficult or impossible for private parties to negotiate flexible and creative arrangements that create optimum incentives to innovate and bring new technologies to market. That result is detrimental to the public interest and contrary to the purpose of the Bayh-Dole Act, which seeks "to promote collaboration between commercial concerns and nonprofit organizations, including universities." 35 U.S.C. § 200.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

David E. Korn
Pharmaceutical Research
and Manufacturers
of America
950 F St., N.W.
Washington, DC 20004
(202) 835-3400

Robert A. Long, Jr.
Counsel of Record
Alan Pemberton
Erika Lietzan
Ranganath Sudarshan
Covington & Burling LLP
1201 Pennsylvania Ave, NW
Washington, DC 20004
(202)662-5612
rlong@cov.com

Counsel for Amicus Curiae