

No. 09-1159

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

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

v.

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

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

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**BRIEF OF *AMICUS CURIAE*  
MASSACHUSETTS INSTITUTE OF  
TECHNOLOGY IN SUPPORT OF PETITIONER**

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**STATEMENT OF INTEREST<sup>1</sup>**

The Massachusetts Institute of Technology has a direct and immediate interest in how the Bayh-Dole Act, 35 U.S.C. §§ 200-211, affects the clarity of title to federally funded inventions. MIT received \$718.2 million in research funding in its 2009 fiscal year. The United States government provided almost 73% of that total (\$522.6 million). In addition, the federal government provided \$746 million to MIT Lincoln Laboratory, a research and development center that applies advanced technology and rapid prototyping to problems of national security. Since the Bayh-Dole Act became law in 1980, MIT has received an aggregate of \$19.9 billion in research funding from the federal government. This enduring flow of research funding to the Institute has produced extraordinary public benefits. A 2009 report concluded that living MIT graduates, faculty, and staff have founded 25,800 active companies, which employ at least 3.3 million people and generate \$2 trillion in annual revenue worldwide. If those MIT-

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<sup>1</sup> Pursuant to this Court's Rule 37.2, counsel of record for all parties received notice, at least 10 days prior to the due date, of *amicus's* intention to file this brief. All parties have consented to the filing of this brief, and their letters of consent have been filed with the Clerk of the Court. Pursuant to this Court's Rule 37.6, *amicus* states that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus* or its counsel made a monetary contribution to the preparation or submission of this brief.

related companies formed a nation, they would comprise the 11th largest economy in the world.<sup>2</sup>

An efficient patent and technology licensing process is a crucial piece of this remarkable innovation system. In fiscal year 2009, MIT was issued 153 new U.S. patents, received 501 new-invention disclosures from its faculty and researchers, filed 131 new U.S. patent applications, and granted 85 patent licenses and options. Twenty-one new companies were formed in 2009 on the basis of MIT licenses. Since 1980, 3,673 U.S. patents have been issued to MIT under the Bayh-Dole Act system. In short, several times every day MIT needs to know, with clarity, who owns this vast array of intellectual property flowing from federal funding.

### SUMMARY OF ARGUMENT

The Federal Circuit's decision disregards the language, structure, and underpinnings of the Bayh-Dole Act. The decision threatens a major disruption to the Act's effectiveness. Congress passed the Act in 1980 to promote the commercialization of federally funded inventions and to ensure rights to inventions for the federal government. The Act has served Congress's goals well for three decades.

Before Bayh-Dole, title to federally funded inventions vested in the federal government. Because each funding agency had its own idiosyncratic rules governing invention ownership,

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<sup>2</sup> Edward B. Roberts & Charles Eesley, *Entrepreneurial Impact: The Role of MIT* 8 (Feb. 2009), available at [http://entrepreneurship.mit.edu/Downloads/Entrepreneurial\\_Impact\\_The\\_Role\\_of\\_MIT.pdf](http://entrepreneurship.mit.edu/Downloads/Entrepreneurial_Impact_The_Role_of_MIT.pdf).

most inventions were not commercialized or used to their full potential. Bayh-Dole replaced this incentive-frustrating system with a comprehensive system that allows title to federally funded inventions to rest in universities, whose laboratories put billions of federal research dollars to work.

Under the Federal Circuit's decision, title to federally funded inventions is burdened with even greater uncertainty than existed under the pre-Bayh-Dole system. The Federal Circuit decision allows a single researcher, even through sheer inadvertence, to transfer title to a private concern and imperil her or his university's title to the invention, as well as the government's statutorily prescribed right to a license as a return on the federal investment. The private concern can enjoy the benefit of taxpayers' investment in research by using "hereby assign" in its form contract rather than the commonplace "agree to assign" in Stanford's form and those of many other universities. These results turn the statutory scheme on its head. The Federal Circuit erred in failing to consider how Bayh-Dole informs the interpretation of patent assignment language under Federal Circuit law. Had the court properly considered Bayh-Dole, it would have held that the chain of title in this case led to Stanford.

Questions of Bayh-Dole's proper interpretation will arise in cases under the federal patent laws, of which Bayh-Dole is a part. Hence, the Federal Circuit almost certainly will be the only Circuit to decide the question presented. MIT respectfully submits that this Court should grant Stanford's petition now.



## ARGUMENT

### A. The Bayh-Dole Act Fuels the Innovation Segment of Our National Economy

Over the past 50 years, colleges and universities have become the primary performers of basic research in science and engineering in the United States.<sup>3</sup> In 2007, universities performed 54% of the nation's basic research and 14% of all national R&D.<sup>4</sup> The federal government funds more than half of that university research. Recognizing basic research as a national interest, the federal government invested \$32.7 billion in university research in 2008, or 63% of total university research expenditures.<sup>5</sup>

The nation's investment in its research universities has yielded significant economic returns. "Most economic historians agree that the rise of American technological and economic leadership in the [post-World War II] era was based in large part

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<sup>3</sup> David Roessner, et al., *The Economic Impact of Licensed Commercial Inventions originating in University Research, 1996-2007, Final Report to the Biotechnology Industry Organization* 12 (Sept. 3, 2009), available at [http://www.bio.org/ip/techtransfer/BIO\\_final\\_report\\_9\\_3\\_09\\_rev\\_2.pdf](http://www.bio.org/ip/techtransfer/BIO_final_report_9_3_09_rev_2.pdf).

<sup>4</sup> Association of American Universities, *University Research: The Role of Government Funding* 1 (May 2006), available at [www.aau.edu/WorkArea/DownloadAsset.aspx?id=1122](http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=1122).

<sup>5</sup> Association of University Technology Managers, *AUTM U.S. Licensing Activity Survey: FY 2008* 8 (2008) ("2008 AUTM Survey").

on the strength of the American university system.”<sup>6</sup> Today, research-intensive American universities dominate the rankings of global higher education,<sup>7</sup> and university research is critical to American industrial competitiveness.<sup>8</sup>

The Bayh-Dole Act plays a central role in this system of innovation. Enacted in 1980 as an amendment to the Patent Act, Bayh-Dole expanded and accelerated the transformation of ideas in the lab into the products, jobs, and revenues of commercial enterprise.

Prior to Bayh-Dole, the federal government’s many funding agencies shared no uniform policy for technology transfer. Each agency had its own patent policies, some of which were hostile to universities’ holding title to patents. Procedures for allowing universities to manage federal patents were inconsistent and required time-consuming

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<sup>6</sup> Bhaven N. Sampat, *Recent Changes in Patent Policy and the “Privatization” of Knowledge: Causes, Consequences, and Implications for Developing Countries*, in *1 Knowledge Flows and Knowledge Collectives: Understanding the Role of Science and Technology Policies in Development* 39, 56, available at <http://unpan1.un.org/intradoc/groups/public/documents/apcity/unpan017425.pdf>.

<sup>7</sup> Academic Ranking of World Universities—2009, available at <http://www.arwu.org/ARWU2009.jsp>; Top 200 World Universities, available at <http://www.timeshighereducation.co.uk/hybrid.asp?typeCode=438>.

<sup>8</sup> National Academy of Engineering, *The Impact of Academic Research on Industrial Performance* vii (2003).

negotiation.<sup>9</sup> Relatively few universities operated technology transfer offices,<sup>10</sup> and American universities in total obtained only 250-300 U.S. patents a year.<sup>11</sup> The federal government licensed for commercialization fewer than 5% of the approximately 28,000 patents it held.<sup>12</sup>

Congress recognized that the federal government was investing billions of dollars in cutting-edge research and leaving the vast majority of resulting ideas on the shelf. Congress enacted Bayh-Dole with the express objectives, among others, “to use the patent system to promote the utilization of inventions arising from federally supported research or development[,]” “to promote collaboration between commercial concerns and nonprofit organizations, including universities[,]” and “to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions[.]” 35 U.S.C. § 200.

Bayh-Dole aimed to achieve its stated ends with a simple but profound reversal of assumptions. Rather than the federal government holding patents under numerous conflicting policies, universities now hold

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<sup>9</sup> BayhDole25, Inc., *The Bayh-Dole Act at 25* 2 (Apr. 2006), available at [http://www.bayhdole25.org/sites/bayhdole25.org/files/BayhDole25\\_WhitePaper\\_20060417.pdf](http://www.bayhdole25.org/sites/bayhdole25.org/files/BayhDole25_WhitePaper_20060417.pdf).

<sup>10</sup> *2008 AUTM Survey*, *supra* note 5, at 13.

<sup>11</sup> David C. Mowery, et al., *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act* 133 (2004).

<sup>12</sup> Homer A. Neal, et al., *Beyond Sputnik: U.S. Science Policy in the 21st Century* 106 (2008).

patents under a single, comprehensive legislative system.<sup>13</sup> *Id.* § 202(a).

The resulting change in technology transfer has been dramatic. The number of university technology licensing offices has grown into the hundreds.<sup>14</sup> As summarized in the following figure, the number of U.S. patents issued to universities has grown dramatically since the passage of Bayh-Dole, to reach into the thousands each year:

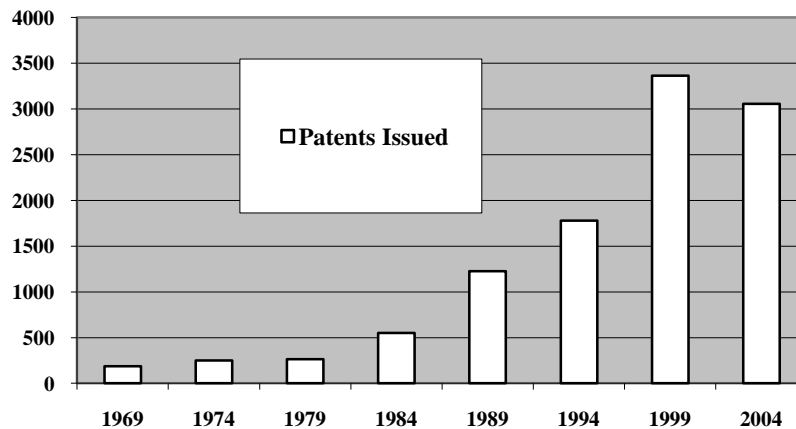


Figure 1: Number of U.S. Patents issued to U.S. Universities, 1969-2004.<sup>15</sup>

<sup>13</sup> Jonathan R. Cole, *The Great American University: Its Rise to Preeminence, Its Indispensable National Role, Why It Must Be Protected* 163 (2009).

<sup>14</sup> *2008 AUTM Survey*, *supra* note 5, at 13.

<sup>15</sup> David C. Mowery, et al., “The growth of patenting and licensing by U.S. universities: an assessment of the effects of the Bayh-Dole act of 1980,” 30 *Research Policy* 99, 104 (2001); United States Patent & Trademark Office, *U.S. Colleges and Universities-Utility Patent Grants 1969-2005*, [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/asgn/table\\_1\\_2005.htm](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/asgn/table_1_2005.htm).

In every year since 1995, universities have obtained 10 times more patents than they did in a typical year before 1980. Universities received approximately 1.5% of all U.S. patents issued in 1981 and over 5% in 2008, when universities received 3,280 patents.<sup>16</sup>

This increase in patenting and exploitation of federally funded inventions is not the result of happenstance. It is a direct consequence of the tradeoff between title and use that Bayh-Dole mandates. In return for allowing universities to retain title to inventions conceived or implemented with federal dollars, Congress requires universities to comply with substantive requirements that further Congress's stated objectives. The Act requires, *inter alia*, disclosure and diligent patenting of inventions; the licensing and exploitation of the rights to those inventions; the payment of royalties to inventors and reinvestment in further research; and the government receiving a paid-up license to practice the invention. *See* 35 U.S.C. § 202(c).

The results under Bayh-Dole speak to the statute's effectiveness at achieving its aims. In 1991, universities executed 1,229 new patent licenses and patent-license options—a sharp increase over the typical number before 1980.<sup>17</sup> That number has more than quadrupled again since 1991 to 5,132 in 2008.<sup>18</sup>

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<sup>16</sup> Cole, *supra* note 13, at 166; *2008 AUTM Survey*, *supra* note 5, at 9.

<sup>17</sup> *The Bayh-Dole Act at 25*, *supra* note 9, at 23.

<sup>18</sup> *2008 AUTM Survey*, *supra* note 5, at 9.

Critically important economic activity flows from these university licenses. As illustrated below, a 2008 study estimates that the sale of products based on university-licensed patents contributed, in aggregate, between \$47.4 *billion* and \$186.6 *billion* to the U.S. gross domestic product between 1996 and 2007 (the variance within this range depends upon assumptions about royalty rates).<sup>19</sup>

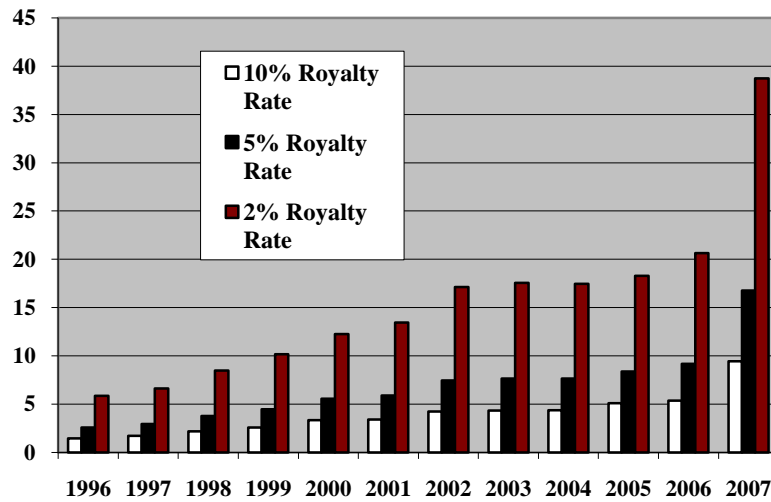


Figure 2: Annual Change in U.S. G.D.P. due to University-Licensed Products, Selected Royalty Rates, 1996-2007 (in billions of dollars).<sup>20</sup>

In addition to generating sales revenue, patent licenses also lead to necessary investments in pre-product technology development. An MIT study in 1995 estimated that its 205 then-active, exclusive

<sup>19</sup> Roessner, *supra* note 3, at 32-33.

<sup>20</sup> *Id.* at 33. (The large increase in 2007 was due primarily to one university's sale of a patent interest.)

licenses had induced \$922 million in investments in pre-production development. Extrapolating those results to all research universities' then-active, exclusive licenses, the study estimated that university licenses resulted in pre-production investments between \$2.5 billion and \$5 billion in 1993, with the creation of between 20,000 and 40,000 jobs.<sup>21</sup>

Many university licensees are newly created start-up companies. From 1980 through 2006, 5,724 new companies have been created as a result of universities licensing federally funded inventions.<sup>22</sup> Start ups and other small businesses are a primary engine for new job creation. One study estimated that over the 12-year period 1996 through 2007, university-licensed inventions and products have created more than 279,000 jobs.<sup>23</sup>

In enacting Bayh-Dole, Congress intended to achieve exactly this alignment of incentives as well as the resulting positive economic effects. As one of the Act's sponsoring Senators recently explained:

Bayh-Dole recognizes that the idea alone has no value. [The Act] is designed to create the incentive for

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<sup>21</sup> Lori Pressman, et al., "Pre-Production Investment and Jobs Induced by MIT Exclusive Patent Licenses: A Preliminary Model to Measure the Economic Impact of University Licensing", VII *Journal of the Association of University Technology Managers* 28, 37, 44-45 (1995).

<sup>22</sup> Association of University Technology Managers, *AUTM U.S. Licensing Survey: FY 2006* 5 (2006).

<sup>23</sup> Roessner, *supra* note 3, at 34-35.

entrepreneurs to invest in the idea and provide the development capital necessary to create a valuable product out of the idea. The marriage of intellectual property and its developmental partner is the basis of Bayh-Dole's success.<sup>24</sup>

A 2001 report by the National Institutes of Health to Congress likewise described the substantial benefits that the Bayh-Dole system has created: "Current practices in technology transfer have yielded a dramatic return to the taxpayer through the discovery of new technologies that extend life and improve the quality of life and through the development of products that, without the successful public-private relationship, might not be available."<sup>25</sup>

Finally, and perhaps most significant of all, federally funded university research, patented and licensed through the Bayh-Dole patent system, and amplified by nonfederal, venture capital investment, continuously re-invents yesterday into a surprising, exciting, and enriched tomorrow. Needless to say, inventions were conceived in university laboratories long before Bayh-Dole. But the Act exerts powerful leverage in the technology transfer system, and that system fuels innovation that is essential to the nation's competitive edge in science and technology and its economic well-being.

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<sup>24</sup> Senator Birch Bayh, "Bayh-Dole: Don't Turn Back the Clock," 41 *les Nouvelles* 215, 217 (Dec. 2006).

<sup>25</sup> Association of University Technology Managers, *AUTM Licensing Survey: FY 2000* 2d Introductory Page (2000).



**B. The Bayh-Dole Act System Rests Upon Clarity of Title to Federally Funded Inventions—A Clarity that the Federal Circuit Opinion Undermines**

The Federal Circuit’s decision threatens to undermine the landmark and proven achievements of Bayh-Dole, and to replace them with a chaotic patchwork of uncertainty as to who owns federally funded inventions. In particular, the Federal Circuit failed to consider Bayh-Dole’s relevance to the chain of title to the underlying inventions. Had the court considered the import of the Bayh-Dole Act to the federal question of patent assignments, the court would have found that the chain of title led to Stanford and stopped there.

As demonstrated, Bayh-Dole by design replaced an uncertain system of ownership of inventions conceived or first reduced to practice under a federal funding agreement—what the Act calls “subject inventions”—with a clear sequence of ownership rights. In particular, the Act provides that universities and other defined parties who contract with the federal government to conduct research may “*elect to retain title* to any subject invention[.]” provided they comply with the Act’s substantive requirements for disclosure, licensing, and the payment of royalties to inventors. 35 U.S.C. § 202(a)-(c) (emphasis added). Significantly, the Act provides that, if the university does *not* elect to retain title, then the determination whether the underlying inventor may retain rights to the underlying invention rests with the relevant federal agency, in consultation with the university or other contractor:

*If a contractor does not elect to retain title to a subject invention* in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

*Id.* § 202(d) (emphasis added).

Section 202(d), and indeed the entire Act, are premised on universities and other contractors obtaining title to subject inventions from researchers and others who perform the underlying research. Otherwise Bayh-Dole makes no sense in giving a university the right to “elect to retain title to any subject invention[.]” *id.* § 202(a), or, conversely, the right “not [to] elect to retain title to a subject invention in cases subject to” the Act. *Id.* § 202(d).

The Act further assumes that the university will hold title by requiring that any funding agreement between the university and the government contain “a prohibition upon the assignment of rights to a subject invention in the United States without the approval of a Federal agency[.]” *Id.* § 202(c)(7)(A). That prohibition necessarily assumes that the university in the ordinary course obtains and retains title. Likewise, section 203, which sets forth the federal government’s “march-in rights” concerning subject inventions, speaks of “any subject invention in which a small business firm or nonprofit organization *has acquired title under this chapter*[.]” *Id.* § 203(a) (emphasis added). And the final clause of section 202(d), quoted above, makes clear that

even if the federal agency, in consultation with the university, decides that an inventor will retain rights to the underlying invention, the inventor's exercise of those rights is "subject to the provisions of this Act and regulations promulgated hereunder." *Id.* § 202(d). If the Act assumed that the inventor had title to subject inventions, then the restriction on the inventor's exercise of retained rights would be a non sequitur; an inventor who had title in the first instance would be able to exercise those rights free and clear of any obligation to comply with Bayh-Dole or implementing regulations. But that is not what the Act provides.

The Federal Circuit's decision in this case disregarded all of Bayh-Dole's structural underpinnings. In particular, the Federal Circuit erroneously concluded that Bayh-Dole was relevant only at the time Stanford, in 1995, made its election to retain title to the underlying subject invention. The Federal Circuit framed the Bayh-Dole inquiry as whether the Act in 1995 "automatically void[ed] the patent rights that Cetus received from Holodniy [one of the inventors]" in 1989; the court concluded that the Act did not void that purported receipt of title by Cetus. Pet. App. 21a.

The Federal Circuit erred in failing to recognize that Bayh-Dole was relevant to answering the critical *antecedent* question of federal law in the case: whether Holodniy had patent rights to convey to Cetus in 1989.<sup>26</sup> Before Holodniy ever visited Cetus,

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<sup>26</sup> The Federal Circuit expressly held that "the question of whether contractual language effects a present assignment of patent rights, or an agreement to assign rights in the future," is a federal question implicating the Patent Act. Pet. App. 12a.

he had executed the Copyright and Patent Agreement in favor of Stanford (the “CPA”). *Id.* 118a. Holodniy expressly recognized in the CPA that Stanford “enters into agreements (‘Contracts or Grants’) with third parties including the United States Federal Government (‘Sponsors’)”; he agreed to disclose “any invention (whether or not it may be considered patentable) under or in the course of a[] Contract or Grant”; and he further “agree[d] to assign or confirm in writing to Stanford and/or Sponsors that right, title and interest in and to ... such inventions as required by Contracts or Grants[.]” *Id.* 118a-119a. The obvious purpose of the CPA was to ensure both the disclosure of, and Stanford’s acquisition of title to, any subject invention created under a federal grant. It is thus clear that the CPA was designed to allow Stanford to comply with the substantive provisions of Bayh-Dole. *See* 35 U.S.C. § 202(a)-(c).

The Federal Circuit, however, failed to consider the effect of Bayh-Dole on the rights that Stanford obtained to any subject invention through the CPA. The court instead resolved that question by relying on cases that did not involve Bayh-Dole and that did not involve competing claims of ownership by assignees with “agree to assign” and “hereby assign” clauses in their assignment agreements. Those cases concerned whether an assignee had legal title so as to be able to sue on assigned patent rights. *Pet. App.* 13a-14a. Stanford’s use of the language, “I agree to assign” in the CPA, *id.* 119a, is commonplace form

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The Bayh-Dole Act, codified at 35 U.S.C. §§ 200-211, of course is now part of the Patent Act.

language that reflects the fact that, at the time an individual begins her or his research work at a university, she or he has no invention to assign.

The Federal Circuit did not consider at all whether its formalistic reliance on the inapposite distinction between “agree to assign” and “hereby assign” does violence to the language, structure, and objectives of Bayh-Dole. The Act presumes that universities obtain title to subject inventions that their researchers invent under federal grants. By disregarding the impact on Bayh-Dole’s structural scheme, the Federal Circuit has created tremendous uncertainty regarding the question of title in the case of any university that has used “agree to assign” language in its invention agreements, as well as any university whose researchers and employees working on federally funded grants have visited private research facilities in the course of their work. This result runs directly counter to the clarity of title, and increased commercial exploitation of inventions, that Congress sought to ensure through Bayh-Dole.

The transfer of ownership, even inadvertently, of federally funded inventions from universities to private entities directly undermines Congress’s substantive goals. Universities, in exchange for the retention of title, must comply with the Act’s substantive requirements, which, as described, are designed to and do further Congress’s objectives in the Act. *See* 35 U.S.C. § 202. Private entities that do not receive federal funding are not subject to those requirements. Bayh-Dole also requires that, where the contractor elects rights, the relevant “[f]ederal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have

practiced for or on behalf of the United States any subject invention throughout the world[.]” 35 U.S.C. § 202(c)(4). Where a single researcher who has “agreed to assign” inventions to a nonprofit university, as Bayh-Dole envisions, instead “hereby assigns” purported rights in those inventions to private commercial laboratories, the Federal Circuit’s decision literally means that this statutorily prescribed return on the federal government’s investment is nullified to the advantage of a private business. These results are contrary to Bayh-Dole’s purpose and undermine the overall statutory scheme.

In sum, the Federal Circuit erred by evaluating the assignment issue in a vacuum, without proper consideration of Bayh-Dole’s relevance to this question of federal law. The court should have concluded, in light of the text, structure, and purpose of Bayh-Dole, that the Federal Circuit law on contractual assignments of patents results in the chain of title leading to Stanford and subject to Bayh-Dole. Because the Federal Circuit erred in its interpretation of this important federal statute in this critical context, the Court should grant certiorari.

Because the question is one of surpassing national importance; because the Federal Circuit significantly erred and in doing so undermined the purpose and effectiveness of Bayh-Dole; and because the question will not benefit from further percolation in the federal courts, *amicus* respectfully submits that the Court should grant certiorari now. At a minimum, *amicus* respectfully suggests that the Court should ask for the views of the United States,

which has a critical interest under Bayh-Dole in the resolution of this question.

**CONCLUSION**

Stanford's petition for a writ of certiorari should be granted.

April 26, 2010

Respectfully submitted,

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