No. 09-1159

IN THE
Supreme Court of the United States

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

v.

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

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

**BRIEF OF *AMICUS CURIAE*
BIOTECHNOLOGY INDUSTRY ORGANIZATION
IN SUPPORT OF RESPONDENT**

THOMAS DILENGE
HANS SAUER, PH.D.
BIOTECHNOLOGY
INDUSTRY ORGANIZATION
1201 Maryland Ave., S.W.
Suite 900
Washington, DC 20024
(202) 962-6695

CARTER G. PHILLIPS*
JEFFREY P. KUSHAN
RACHEL H. TOWNSEND
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
(202) 736-8000
cphillips@sidley.com

*Counsel for Amicus Curiae
Biotechnology Industry Organization*

February 1, 2011

*Counsel of Record

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES Page

CONSTITUTION, STATUTES AND REGULATIONS

TABLE OF AUTHORITIES – continued

TABLE OF AUTHORITIES – continued

BRIEF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF RESPONDENTS

The Biotechnology Industry Organization ("BIO") submits this brief as *amicus curiae* in support of respondents in this case.[1]

INTEREST OF *AMICUS CURIAE*

BIO is the country's largest biotechnology trade association, representing the biotechnology industry. It has over 1100 members, including academic institutions, startup businesses, large Fortune 500 corporations, and even university spin-offs and biotechnology centers. The biotechnology industry invests more than 20 billion dollars annually in research and development, and provides employment to hundreds of thousands of highly educated and highly skilled individuals. BIO members are involved in the process of discovering and bringing to market products in the healthcare, agricultural, environmental and industrial biotechnology fields.

The biotechnology industry exists today because of its close relationship to universities. In fact, many BIO members can trace their lineage to small startup companies formed by the partnership of a university researcher, who made a basic science discovery and saw its potential for a commercial application, with industry and other funding sources. These

---

[1] Letters from Petitioner and Respondents indicating their consent to the filing of *amicus* briefs have been filed with the Clerk of this Court. Pursuant to Rule 37.6, *amicus curiae* states that no counsel for a party authored this brief in whole or in part, and no person or entity other than *amicus curiae* or its counsel made a monetary contribution to the preparation or submission of this brief.

partnerships between industry and academia are mutually beneficial to both institutions. They have proven not only essential to the delivery of tangible products and services to patients and the public generally, but also critical to the academic understanding of biotechnology as a coordinated set of scientific disciplines.

Patent rights are particularly important for biotechnology, where product development times are lengthy, and development costs are large. Developing a single biotechnology therapy requires an average investment of $1.2 billion, and the clinical testing period alone consumes more than 8 years on average. Joseph A. Di Masi & Henry G. Grabowski, *The Cost of Biopharmaceutical R & D: Is Biotech Different?*, 28 Managerial & Decision Econ. 469, 475 & tbl.3 (2007). Such investment is risky. For every successful biopharmaceutical product, thousands of candidates are designed, screened, and rejected after large investments have been made. Only a small minority even advance to human clinical trials, and most of those fail to obtain FDA approval. The chances that a biopharmaceutical medicine will advance from the laboratory bench to the hospital bedside are approximately one in 5,000. Tommy G. Thompson, Sec'y of Health & Human Servs., *Remarks at the Milken Institute's Global Conference* (Apr. 26, 2004), *available at* http://www.hhs.gov/news/speech/2004/040426.html.

The ability of biotechnology companies to obtain and control the transfer of ownership interests in patents has been a critical precondition to commercializing biotechnology inventions. BIO members work within a highly collaborative business environment, and rely on a web of relationships with different industry participants to shepherd the

development of a fundamental scientific discovery into tangible products and services. Moreover, based on the experience of BIO members, inventions do not come into being because of funding alone. Instead, inventions result from a serendipitous process, where inventors draw upon prior knowledge and intangible contributions of many partners working to a common end. Certainly, funding is essential to procure materials and services needed to carry out the research that results in inventions, but funding by itself is not the source of a conception or an actual reduction to practice of an invention.

The security of ownership interests in patents is of paramount concern to BIO's members. It is one of many necessary conditions that must be met before biotechnology businesses and their investors are willing to engage in such high-cost, high-risk product development and, thus, directly affects their ability to bring new products to the public. BIO members, accordingly, have a substantial interest in the law governing ownership of inventions made with federal funding and ensuring that the Bayh-Dole Act will continue to provide an effective incentive for the biotechnology industries to continue their extensive symbiotic relationship with universities.

BIO submits this brief to explain the potential negative and unforeseen consequences of Petitioner's proposed construction of the Bayh-Dole Act, which seeks to alter the well-accepted legal principle that the original ownership of an invention vests with the inventor.

SUMMARY OF THE ARGUMENT

The Bayh-Dole Act, since its enactment, has delivered innumerable benefits to the American public. These include not only new products and

services arising out of collaborative research that address unmet medical needs, or solve longstanding industrial and agricultural problems, but the advancements in basic scientific knowledge that result from the close collaborations encouraged by the Act between the private and public research communities. The Act also has greatly facilitated the rapid dissemination of basic research into commercially important technology, and with that, has helped fuel the growth of industries including obviously the biotechnology industry. By any measure, the Act has functioned precisely as its sponsors envisioned.

In the 30-plus years of experience under the Bayh-Dole Act, the legal status of the inventor as the original owner of an invention has never been called into question, much less presented an impediment to successful administration of the Act. Within this period, thousands of contracting agencies and private entities have routinely secured effective assignments of the rights of their inventors to inventions developed through their sponsorship These institutions likewise have administered those rights using straightforward contract law principles. Indeed, universities and biotechnology companies have been able to arrange myriad forms of research collaborations, all of which have effectively defined the interests of the parties in the inventions arising from these collaborations, while satisfying their obligations under the Bayh-Dole Act. In short, both private and public institutions have faced no challenges in using written contracts to transfer and manage the ownership of inventions that are subject to the Bayh-Dole Act in the same way they have used these contracts to manage ownership interests in non-federally-sponsored inventions. And, based on these

practices, the collaborative research and movement of federally-funded inventions from the laboratory to the market pursuant to that Act has flourished.

These longstanding practices are grounded on the principle that U.S. law defines the original owner of an invention to be the inventor. This principle has a Constitutional footing; in Article I, section 8, clause 8, the Constitution empowers the Congress to provide exclusive rights to "Inventors." And in every Patent Act passed by the Congress since then, this principle has remained undisturbed.[2] Construing the Bayh-Dole Act, which is part of the Patent Act, as having *sub silentio* changed this fundamental principle would completely distort the American concept of inventorship without a clear basis in the statute and while doing clear violence to the underlying purpose of the Bayh-Dole Act.

Certainly, a university or other federal grantee may, by contract, require an inventor to transfer her rights in an invention, and it may then further dispose of these acquired rights in accordance with the provisions of funding agreements required under the Act. Interpreting the Bayh-Dole Act to vest those rights originally in the contractor – effectively holding that an inventor never holds the initial rights in the invention he has made if the creation of that invention has been supported in any manner by federal funding – is neither necessary nor consistent with the Bayh-Dole Act or its purpose. For decades

---

[2] Even in pending legislation, which now proposes to give the beneficial owner of an invention an enhanced right to file a patent application, Congress continues to leave this principle undisturbed. *See* The Patent Reform Act of 2011, S. 23, 112th Cong. § 3 (2011) (addressing revision to 35 U.S.C. §§ 115 (Inventor's Oath or Declaration) and 118 (Filing by other than inventor).

contractors, federal laboratories and private institutions have transferred ownership interests of the inventor through assignment contracts, successfully preserving the government's interests in inventions governed by the Bayh-Dole Act.

Indeed, the rule proposed by Petitioner would be inimical to the very nature of inventive conduct and technology development in the life sciences. Research collaborations that result in inventions are not predictable, simple or formulaic enterprises. Instead, as illustrated by this case, inventions frequently result from an inventor following a serendipitous path, where that inventor draws upon intangible contributions and know-how made available to gain critical insights that result in conception of the invention, and its reduction to tangible form. Scientists conceive of inventions quite independently of who funded their work, and the exchange of know-how, and use of insights provided through discussions with other scientists, usually plays a much more significant role in helping the inventor achieve the invention than financial support.

A rule that by operation of law awards original ownership of the invention to the contractor on the sole basis of federal funding will erect harmful barriers between scientists who perform work under federal funding agreements and others who do not. This is because such a rule will inherently undervalue any contributions made by non-federally-funded parties to achieve the invention. Such a rule would inhibit (rather than promote) the types of interactions between publically- and privately-funded researchers that the Bayh-Dole Act envisioned, because it will disproportionately empower contractors under the Act relative to third parties. A private party, required to operate under free market

economic principles, will choose to avoid both federal funding and interactions with institutions receiving that funding, because that private party will not have sufficient leverage to negotiate a shared ownership or control of the patented invention that reflects the value that party brings to the invention. And this fact alone will drive the private sector away from these types of arrangements.

Nothing in the Bayh-Dole Act can be read to suggest that Congress intended to empower universities in this way. Indeed, skewing the equation of shared interests in patented technology in this manner would fundamentally undermine the objectives of the Bayh-Dole Act, and will disrupt the collaborative environment that has served the public interest so well for the last 30 years.

Nor would the proposed rule contribute to the certainty of ownership of inventions that arose out of, or in collaboration with, federally-funded research institutions. To the contrary, it could

- call into question established agreements that have been entered into on the basis of the well-accepted legal principles governing original ownership of an invention;
- cloud ownership interests held by employers of private third party co-inventors where proper assignments have been executed;
- raise questions about the ownership of patents where the first actual reduction to practice was federally-sponsored after a patent on the conceived invention was granted to a private third party; and
- create uncertainties about the ownership of inventions where multiple federal grants, and

multiple federal grantees were involved in the invention's conception or first actual reduction to practice.

There is no need to sever the fundamental link between inventorship and original ownership of an invention just to address isolated instances where federally-funded inventors might assign rights in violation of institutional policies. Equitable and contract remedies have long been available to give nonprofit research institutions the rights to which they are entitled and which they need to safeguard the funding agencies' interests.

Accordingly, BIO urges the Court to affirm that the Bayh-Dole Act did not alter the principle that the ownership of an invention originates in the inventor, and that obligations defined in the Act regarding ownership of inventions that have been supported by government money attach after this event has occurred.

ARGUMENT

I. THE BAYH-DOLE ACT BUILT UPON AND DID NOT CHANGE ACCEPTED PRINCIPLES OF INITIAL OWNERSHIP OF INVENTIONS

1. The sponsors of the Bayh-Dole legislation, aware of the scant number of federally-funded inventions that had been commercialized under existing funding policies, understood that federal grant recipients needed to be able to take control of their inventions without interference from the government bureaucracy. Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va. L. Rev. 1663, 1664 (1996) (the sponsors recognized

that "[i]f the results of federally-sponsored research were to be rescued from oblivion and successfully developed into commercial products, they would have to be patented and offered up for private appropriation.") The Bayh-Dole Act that passed had that basic goal in mind. It removed the red tape associated with the process of effecting transfers of previously existing interests in patents, both for the government and for the contractors operating with federal funding. It did not purport to grant either the contractor or the government an extraordinary power to strip independently existing rights of third parties.

2. Nor did the Bayh-Dole Act effect a profound revision of the Patent Act. In particular, it did not alter the law that provides that inventors, not their employers (including federal contractors), are the original owners of their inventions. And it most certainly did not, as the United States urges, subordinate the inventor's original right in his or her invention to the government or to the entities receiving government funding. U.S. Br. 13.

This is because the Act did not statutorily assign original title in inventions made with federal funding directly to contractors, instead of inventors. Instead, the Act's provisions presuppose that a contractor could come into possession of title to an invention (without specifying how), and explicitly provide the rules and obligations under which contractors can thereafter "retain" that title if the invention was supported with federal funds. 35 U.S.C. § 202(a). Because the Bayh-Dole Act does not specify any mechanism by which the contractor would first come into possession of the title that the Act allows it to "retain," the contractor's title would logically flow, under normal patent law principles, from an event

that occurred after the original title vested in the inventors when the invention was made.

As Respondent correctly notes, Resp. Br. 15, 22, the use of the word "retain" indicates that Congress recognized the necessity of a prior transfer from the inventor of his rights in the invention. The natural meaning of "retain" compels the conclusion that this provision refers to rights in inventions that have been previously transferred.

The Act uses similar language to explain that the government, pursuant to a funding agreement, "may receive title" to a subject invention where the contracting institution does not affirmatively act. 35 U.S.C. § 202(c)(1)-(3). Neither party, however, is given the right by the Act to "take" title from the inventor, nor does the Act speak of "vesting" title in inventions that have been made by the contractor's inventors or other individuals who are not a party to the funding agreement.

3. Respondent rightly focuses attention on the phrase "invention of the contractor" in § 201(e) to show that Congress assumed that the contractor had independently acquired the actual inventor's rights. A "subject invention" is an invention that was (a) conceived or first actually reduced to practice[3] with federal funds, and that is (b) "an invention *of the*

---

[3] Conception of an invention is complete "when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Burroughs Wellcome Co.* v. *Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). An actual reduction to practice of an invention "requires that the claimed invention work for its intended purpose." *Hybritech Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986). It is "[c]onception [that] is the touchstone of inventorship." *Burroughs Wellcome*, 40 F.3d at 1227.

contractor."[4] *Id.* § 201(e) (emphasis added). Under Petitioner's theory, federal funding is by itself the trigger that makes ownership of an invention vest in the contractor. That theory renders the phrase "invention of the contractor" mere surplusage in defining "subject invention," for if spending federal money alone were enough to make an invention the contractor's, then there would be no reason to require that it also be "an invention of the contractor." But the phrase "an invention of the contractor" can be given effect separate from federal funding by simply giving consequence to the well-established principle that the inventor is the original owner of her invention. In other words, the phrase "invention of the contractor" necessarily assumes an act which transfers ownership of the federally-funded conception or first actual reduction to practice from the inventors who make inventions to the contractor. A construction that fails to give effect to every clause and word where such is possible should be avoided. *Duncan* v. *Walker*, 533 U.S. 167, 174 (2001) ("'It is our duty "to give effect, if possible, to every clause and word of a statute."'").

4. Interpreting the Bayh-Dole Act to provide for an automatic vesting of title to an invention made with federal funding in the government or its contractor would also read out of the statute at least one critical section, contrary to the cardinal maxim that a statute is read, where possible, to give effect to all its parts. *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Specifically, 35 U.S.C. § 202(d) states that the government can grant requests for

---

[4] Because the contractor is a nonprofit organization or small business, and because only natural persons can be inventors, the phrase "of the contractor" must mean "owned by the contractor," not "invented by the contractor."

"retention of rights by the inventor" where the contractor does not elect to retain title. 35 U.S.C. § 202(d). If the inventor never had title to his invention, as Petitioner posits, because title automatically vested in the contractor, then the language used in this portion of the statute would not make sense. Instead, the natural meaning of the words used in this clause reveal that the inventor must have necessarily had possession of title to his invention at a time prior to the point in time when title will be transferred to the government or the contractor. In other words, this clause is also perfectly consistent with the well-established principle that the inventor is the original owner of her invention.[5]

5. Contrary to the United States' position, U.S. Br. 21, 35 U.S.C. § 210 is not a provision of the Act that changed the provisions of the Patent Act that govern original ownership in inventions, including those made with some degree of federal funding. As § 210 provides by its express terms, the Bayh-Dole

---

[5] Interpreting the Bayh-Dole Act to provide for an automatic vesting of title to an invention made with federal funding would also conflict with 35 U.S.C. § 202(e) that implicitly recognizes the ownership right of inventors. Under that provision, "when a Federal employee is a coinventor of any invention made with a nonprofit organization … the Federal agency employing such coinventor may, for the purpose of consolidating rights in the invention … license or assign whatever rights it *may acquire* in the subject invention to the nonprofit organization." 35 U.S.C. § 202(e)(1) (emphasis added). If the Bayh-Dole Act was a title vesting statute, as Petitioner urges, then there would be no need to "consolidate rights." Moreover, this provision explicitly recognizes cases in which inventorship rights dictate that rights under the Bayh-Dole Act are not exclusive to the contractor – as in this case. In the normal course of business, the federal agency would acquire its rights to the invention by an employment agreement and assignment.

provisions, which form Chapter 18 of the Patent Act, are to have precedence over "any other Act" (*i.e.*, acts other than title 35, United States Code) that govern the disposition of rights in inventions made with federal funding. The phrase "any other" in § 210 plainly is referring to portions of the United States Code other than the Patent Act that regulated the government ownership interests in inventions. And given that one purpose of § 210 was to make uniform a heterogeneous collection of such laws, it is logical that § 210 enumerates these other Acts that provide for government interests in inventions (i.e., provisions in 7 U.S.C., 30 U.S.C., 42 U.S.C., 50 U.S.C., 22 U.S.C., and 15 U.S.C.). Without this clarification, these other Acts of Congress could have frustrated the objective of the Bayh-Dole Act to establish a uniform federal policy governing disposition of the ownership interests of the government in inventions supported by federal funding.

The Bayh-Dole Act accordingly sought only to set up a simplified and unified contract-based system for transferring rights existing in inventions between the government and its funded contractors.[6]

6. Section 202, which speaks to "Disposition of rights" in a "subject invention," does not speak to rights in a patent[7], much less "vesting" of title in a

---

[6] And as Respondents note, Congress specifically referred to vesting title when the procedure was different than that provided by Title 35 of the U.S. Code. Resp. Br. 23. Moreover, when it did so, Congress thought it important to particularly enumerate the procedures to follow. *Id.* at 23-24. That the Bayh-Dole Act does neither, even though displacing those acts, is equally consistent with an inference of no vesting and vesting. Pet. Br. 35.

[7] A "subject invention" is not a patent or even necessarily "a patentable invention" (though it might be), but rather simply

patent with contractors, whether "presumptively" or by "automatic[]" transfer of title from an inventor. Pet. Br. 26; U.S. Br. 18, 21, 26. It did not because the Patent Act, of which the Bayh-Dole Act is a part, already addresses vesting and transfer of patent title in explicit detail.

In particular, 35 U.S.C. § 101 provides that "whoever invents" an invention eligible for patent protection is entitled to receive a patent. The inventors – that is to say, the natural person or persons who made the invention – are the individuals specified in the statute who must then file a patent application to secure the patent.[8] *See id.* § 111. Once the patent is granted, title to that property right initially vests in the inventor or inventors, *i.e.*, the patentee(s). *Id.* §§ 151, 261. 35 U.S.C. § 261 then provides that the property interest may be disposed of through assignments from the "applicant" or the "patentee." Thus title can pass from the inventor to a successor-in-interest by a written conveyance, and

---

"any invention … conceived or first actually reduced to practice in the performance of work under a funding agreement." 35 U.S.C. § 201(e). There are of course many more requirements for an "invention" to be patentable. *See id.* §§ 101, 112, 102, 103.

[8] This of course derives from the fact that the U.S. Constitution provides the government with the power "[t]o promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. Thus people, not corporations are granted patents. Section 118 of the Patent Act allows a few exceptions to the general rule that applications must be filed by inventors. If an inventor cannot be located, or refuses to perform his contractual obligation to assign an invention to his employer, then the employer may file in place of the inventor, but even then the patent issues listing the name of the person(s) who are the inventor(s).

can do so immediately after it is established.[9] *Waterman* v. *Mackenzie*, 138 U.S. 252, 255 (1891); see also 35 U.S.C. § 100(d) ("'patentee' includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.").

Of course, if a formal assignment has not been made, this Court has recognized that contract law can nevertheless require that result. *Solomons* v. *United States*, 137 U.S. 342, 346-48 (1890). Thus, where a contractor is entitled to, but fails to secure an assignment from an inventor before the inventor subsequently conveys rights in the patent covering a "subject invention" to a third party, specific performance can compel a transfer of the ownership of the patent property right. See *Fenn* v. *Yale Univ.*, 2005 WL 327138, at *6 (D. Conn. Feb. 8, 2005) (unpublished decision ordering inventor to assign patent obtained by breach of employment contract requiring assignment to university); see also *Fenn* v. *Yale Univ.*, 283 F. Supp. 2d 615, 625-28, 631, 640 (D. Conn. 2003) (detailing employment contract with assignment requirements and inventors breach).

The possibility of finding a basis in contract to compel the transfer of title, however, does not suggest that the Bayh-Dole Act itself changed the predicate event of vesting initial ownership of a patented invention in the inventors. Nor is such an

---

[9] 35 U.S.C. § 152 provides that a patent can be granted in an assignee of the inventor, but only upon application made and sworn to by the inventor. In other words, a conveyance by the inventor is required whenever transfer of ownership is involved. *See also* George T. Curtis, *A Treatise on the Law of Patents* § 170 (4th ed. 1873) ("[T]he legal title to an invention can pass to another only by a conveyance which operates upon the thing invented after it has become capable of being made the subject of an application for a patent.")

interpretation of the Act necessary since contract law is more than capable of providing a remedy if an inventor acts outside the boundaries of commitments that individual has previously accepted by assigning his interests in the invention to another.

7. To be sure, the Bayh-Dole Act does provide blanket permission for recipients of federally-funded research, who elect to retain rights in the "subject invention," to procure patents on those inventions, thereby protecting the government's interest as well as the recipient's. 35 U.S.C. § 202(c)(3). However, that authority did not obviate the need to follow the statutory mandate that the individuals who are the "inventors" of the subject invention file the patent application in their name. Nor did it *sub silentio* remove the requirement of obtaining an assignment of title from the inventors in that application to effect the transfer in ownership of the patent application (and any patent that may issue on that application) for the invention that arose from the federal funding the employer received.

Indeed, the implementing regulations of the Bayh-Dole Act make clear that the federal funding agency expects the university to use written agreements that bind its employees to ensure the government interests in the patent applications are properly protected under existing statutory requirements. In particular, 37 C.F.R. § 401.14(f) specifies that:

> *Contractor* Action to Protect the Government's Interest.
>
> ….
>
> (2) The *contractor* agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as

> responsible for the administration of patent matters and in a format suggested by the *contractor* each subject invention made under *contract* in order that the *contractor* can comply with the disclosure provisions of paragraph (c), above, and to execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions.[10]

Rule 401.14(f) thus establishes a contractual obligation under which the contractor agrees to safeguard the government's interest through written agreements with its inventors. And, consistent with provisions of the Patent Act, apart from the Bayh-Dole Act, these written agreements first require the inventors to file the patent application in their own names, to include the required oath or declaration as to their inventorship of the invention, and to assign their ownership rights to their employer either during the patenting process[11] or thereafter.

This is precisely what many agencies informed the public was the process for perfecting the government's interest in patents on inventions made with federal funding. For example, the National Institutes of Health in a public notice stated:

---

[10] That the implementing regulations touched on the inventor's responsibilities rather than the Act is not unusual since the Act was not directed to title and given that this was how prior agencies made express provisions for the disposition of title to patents. *See, e.g.*, 45 C.F.R. § 650.4(b) (1977) (providing that the National Science Foundation would "determine the disposition of the invention [made under the grant] and title to and rights under any patent application.")

[11] As this Court long-ago recognized, "[i]nventions may be assigned before they are patented." *Cammeyer* v. *Newton*, 94 U.S. 225, 226 (1876).

> The Bayh-Dole Act requires that there be employee agreements in place at the awardee organizations that obligate inventors to assign title to Federally-supported inventions to the organization.

24 NIH Guide, No. 33, *A "20-20" View Of Invention Reporting To The National Institutes Of Health* (Sept. 22, 1995), *available at* http://grants.nih.gov/grants/guide/notice-files/not95-003.html (answer to question 17 "What happens to an invention when the inventor/principal investigator transfers to a new institution?")[12]

8. It also is abundantly clear, based on past practices, that universities have historically recognized and accepted that they must first obtain title to subject inventions from their inventors, and that they do not receive that title automatically simply by operation of the Bayh-Dole Act. Universities consistently require their inventors to execute assignments as to "subject inventions" made by those inventors, no later than by the time the inventors file their patent applications, as part of the invention disclosure process and/or as part of their conditions of employment. See, *e.g.*, Resp. Br. 34 (citing university policies concerning assignment); *id.* at 34-35 (citing Stanford assignment of the patents at issue); *Fenn*, 283 F. Supp. 2d at 621-22, 628 (pre- and post-Bayh-Dole inventor assignment policy of Yale for patents covering inventions obtained with the aid of federal funds); *Regents of Univ. of N.M.* v. *Knight*, 321 F.3d

---

[12] This agency further noted that, where the inventor leaves the contracting organization, then either the inventor or the organization, with agency permission, may transfer rights to the new organization to which the inventor moves. 24 NIH Guide, *supra*.

1111, 1114-15, 1118-19 (Fed. Cir. 2003) (post-Bayh-Dole UNM faculty assignment of patents to UNM covering inventions made at a funded laboratory); *Univ. of Pittsburgh* v. *Townsend*, 542 F.3d 513, 517-18 (6th Cir. 2008) (post-Bayh-Dole inventor assignment policy of University of Pittsburgh for patents covering inventions obtained from government-sponsored research grants). And for the past 30 years, without reading the Act as automatically vesting title in inventions arising from federally-funded research, research has thrived and inventions made with federal funding have successfully been brought to market.

Indeed, the argument now advanced by Petitioner and the United States is as new to the universities as it is to BIO. It affects everyone's settled expectations, with no clear benefits to anyone, except Stanford University in this particular case. In fact, as explained below, Petitioner's interpretation will have severe detrimental effects. Thus, Petitioner's attempt to have this Court rewrite history and the statute, effectively relieving it and other contractors from their obligations to secure clear title to federally-funded inventions and control the conduct of their employees, should be rejected.

Understandably, universities may prefer to not be burdened with the obligation of regulating the conduct of their researchers in connection with securing title to inventions made by those researchers or in monitoring interactions of those researchers with third parties. That administrative burden, however, is not an unreasonable cost for universities to bear to perfect their interests in, and to thereby derive the economic benefit of, patents on inventions over which the university has a legitimate claim of ownership.

II. INTERPRETING THE STATUTE AS PETITIONER SUGGESTS WOULD DETER COLLABORATION BETWEEN PRIVATE INDUSTRY AND CONTRACTORS

1. Many biotech inventions are the product of collaborative efforts. *See, e.g.*, Eisenberg, *supra*, at 1671 (noting that in biomedical research fields, researchers in government, university and commercial laboratories often work collaboratively on the same problems.) Such joint work allows for shared costs, shared risks, shared facilities, and shared expertise. Given the numerous benefits to society that these collaborations yield – including both advancements in scientific knowledge and understanding as well as tangible products and services that benefit patients – collaborations plainly should be encouraged.

Collaborations require that both parties to the collaboration see individual and mutual benefits from the collaboration. For the biotechnology industry, investment in collaborative research and development is predicated on – and motivated by – an expected return on investment in the form of marketable products that are protected by patents whose ownership is clear and ascertainable. Legal certainty, in the form of clear rules of patent ownership, is one of the many necessary conditions that must be met before biotechnology companies and their investors are willing to engage in the high-cost, high-risk endeavor of developing a biotechnology product from its inception through clinical trials to regulatory approval.

Petitioner's interpretation of the Bayh-Dole Act would establish a regime under which companies that help to make an invention in collaboration with a nonprofit research institution will face far greater

uncertainty as to whether their financial and inventive contribution will result in ownership interests in patents on inventions arising from those collaborations.

When companies can neither predict nor control the results of their investments, they understandably tend to be less likely to engage in related research and development. *See* Wendy H. Schacht, CRS Rep. RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology* CRS-14 (Dec. 8, 2006). Under the arrangements that have existed for decades, private third parties have cooperated with universities to the benefit of both parties and the public. The Court should be quite cautious in construing the Bayh-Dole Act in a way that would undermine the positive collaborations that have developed during the past 30 years.

2. Petitioner asserts that their rule provides the "clarity" necessary to benefit collaboration and encourage technological development. *See* Pet. Br. 45-48, 52-53. But Petitioner's unprecedented proposition that original ownership of an invention can be divorced from inventorship, far from contributing to legal certainty in the life sciences, will call into question prior agreements that relied on longstanding existing ownership law and will discourage industry from collaborating with universities (or other "contractors").

Petitioner's rule will create new uncertainties where conception and actual reduction to practice occur at separate institutions, where there is joint invention, and anytime multiple federal grants are involved. It will also call into question those collaborative agreements where the private-industry participant bargained for an allocation of rights as a

condition of entering into the collaboration, sharing technology and other know-how and providing economic support.

3. Under Petitioner's interpretation, if a conception or a first actual reduction to practice was made under a federal grant, then the grantee, *e.g.*, university, automatically gains title. This rule will create particularly inequitable situations in the biotechnology setting.

Biotechnology companies often are able to conceive of a new therapeutic invention without conducting clinical testing of the agent. For example, the company's researchers may identify a new agent, test it in sophisticated animal and laboratory models, and thereby verify that it is a promising agent for use in human treatment. Even though the company may not have established that the invention will achieve therapeutic results in humans, it would nevertheless be appropriate for the company to file a patent application at this stage of development. See *Burroughs Wellcome Co.* v. *Barr Labs., Inc.*, 40 F.3d 1223, 1228-30 (Fed. Cir. 1994). That filing would constitute, at a minimum, a "constructive" reduction to practice of the invention. *Id.*

Development, of course, does not stop at this point. Instead, companies often partner with university hospitals to conduct proof-of-concept clinical testing in humans of their new agent. These proof-of-concept clinical trials may constitute the first "actual" reduction to practice of the invention in humans, though they require only ordinary skill to carry out. Where such clinical studies merely confirm the operability of the invention that was fully conceived previously, they do not provide any inventive contribution and are neither necessary to obtain a patent nor entitle the clinical investigators to co-

inventorship, *id.* at 1228, 1230, or presumptive co-ownership, *Ethicon, Inc.* v. *U.S. Surgical Corp.*, 135 F.3d 1456, 1465 (Fed. Cir. 1998).

Of course, university laboratories are often selected because of a particular expertise they possess through their ongoing clinical research activities. Invariably, those activities enjoy some degree of federal funding.

Under Petitioner's theory, whereby a contractor's ownership interest vests either at the point of conception or the first actual reduction to practice of the invention, the university laboratories could claim an ownership interest in the invention by performing an act *after* the invention was otherwise "invented" by employees of the private company.

That scenario would create endless conflicts and uncertainty in industry and in a process that is already subject to tremendous risks and challenges. In particular, a business that planned its decade-long development of a new therapeutic product under well-accepted legal principles governing original ownership of an invention, would face unanticipated conflicts and risks of losing control of patent rights in technology it developed. Petitioner's interpretation could call into question many of these established agreements, to the great detriment of the industry.

4. The Patent Act provides that two or more persons may apply for a patent jointly. 35 U.S.C. § 116. Co-inventors are co-owners, each having an undivided right to do as she pleases with her interest in the invention without the consent of other co-owners. *Id.* § 262; see *Schering Corp.* v. *Roussel-UCLAF SA*, 104 F.3d 341, 344 (Fed. Cir. 1997). This right enables each co-inventor to be able to assign its ownership interest to its employer, even if it was in

advance of the invention being made. If patented inventions developed from federally-sponsored dollars include co-inventors from different establishments, it should be the case that each of those establishments should be entitled to control the disposition of the patent, provided assignments have been properly executed.

Petitioner's position is that use of federal monies subordinates inventors' rights, regardless of how many inventors there are. By that argument, it does not matter how many different inventive entities there are in a patented invention, the title vests automatically in just the entity that is funded.[13] Petitioner's rule could call into question any prior disposition of patent rights by co-inventors who were not part of the federally-funded institution.

5. An invention may be conceived jointly by researchers at two or three different federally-funded universities. And it may be first actually reduced to practice at yet another federally-funded institution. Not uncommonly, one or more of these institutions will be operating under separate funding agreements. Indeed, this is not an unrealistic scenario given that today's inventions often involve different branches of science, *e.g.*, biomedical advances often rely on electronics as well as the biological sciences.

---

[13] *Amici* Association of American Universities et al. suggest that § 202(e) would prevent the Bayh-Dole Act from vesting ownership rights of co-inventors that were not working at the contractor who was federally-funded. Assoc. of Am. Univ. Br. 23. But the logic of Petitioner's argument does not guarantee that outcome. Petitioner's position is that use of federal monies subordinates inventor's rights and the logical extension of that argument is that it does not matter how many different inventors there are, the title vests in just the funded party automatically.

Petitioner's theory, where original title is divorced from the inventors and depends only on the federal grants under which investigators worked on the conception or first actual reduction to practice, could greatly dilute ownership – "vesting" each of the funded entities with an equal, and conflicting, claim to title to the invention. Thus, the ownership of such inventions would have no clear origin. And, because these ownership rights would not be traceable through written contracts, a potential licensee seeking assurances of clear title, would face an entirely new layer of uncertainty.

6. Private industry and public university collaborations are usually governed under detailed agreements that provide for an allocation of ownership rights in any inventions that may be made during the collaboration. The agreements may allocate rights based on the amount of, or importance of the know-how provided by one of the collaborators. However, under Petitioner's theory, despite these bargained-for rights, the university may end up with a superior ownership right to the inventions arising from the collaboration even if the contribution by the private company was clearly the most important contribution to achieving the invention.

The university may also end up with a superior ownership right in the clinical trial scenario discussed above, despite not having contributed at all to the conception of the invention. Such trials are often governed by collaboration agreements and the private company who is the patent owner, and whose employee(s) were the inventors, usually will not assign title in the invention simply to have the clinical trials carried out in a particular laboratory. However, under Petitioner's theory, notwithstanding the parties agreement, that would be the automatic

result where the university was carrying out proof-of-concept trials.

7. Petitioner's rule, cast as an absolute effect of the statute, would create uncertainty and/or chaos over existing industry ownership rights in inventions touched by federal funding. It would of course be devastating if a biotech company, after investing hundreds of millions of dollars in technology it assisted in developing, and subsequently patented, discovered that it did not have title to the underlying patent(s) despite otherwise valid assignments of the interests of its inventors to the company. Yet that result could ensue under Petitioner's theory where there was co-inventorship with a federally-funded contractor or where the federally-funded contractor sponsored proof-of-concept clinical trials. And such a result would certainly deter any future collaboration where federal monies were provided.

Petitioner's interpretation of the Act would also fundamentally disrupt the process by which the private sector and universities negotiate interests in patents arising from collaborative research. In particular, the rule advanced by the Petitioner would operate to unfairly discount both economic and intangible contributions of the private party in a collaboration, as it would, as a matter of law, cause an automatic vesting of ownership in any invention that enjoys any degree of support from federal funding. Such a rule will have the practical effect of discouraging collaborations that could yield useful inventions, as it removes the arms-length process of negotiating interests in the fruits of a collaboration.

In short, the environment that will result from this rule is the same environment that caused the private sector to avoid investing in development of federally-supported technology prior to the Bayh-Dole Act. The

statute was not adopted to be self-defeating, but that is precisely what Petitioner's and United States' interpretation will accomplish. There is no need to inflict this result in the biotechnology industry to deliver a solution dictated by one set of unique facts. Absent a clear statement from Congress requiring such upheaval, which simply does not exist, the Court should maintain the *status quo*, which has served the interests of all affected parties and the nation's economy well.

8. Petitioner, the United States, and several amici warn that the opinion below would create new uncertainties that would arise from "rogue" inventors who might have executed unknown prior assignments, casting a cloud of uncertainty over university-licensed patents, preventing universities from warranting clear title, and discouraging potential corporate licensees from investing in the licensed technology. Such fears are overstated. The supposed "new" risk of defective title is not new at all.

This risk, however remote, was always assumed to exist by in-licensing companies regardless of whether the would-be licensor is a private company, a federal contractor, or a university. That is why biotechnology companies routinely conduct extensive due diligence on the patent's chain of title, by seeking warranty of title from and other contractual remedies against the licensor; by relying on the protections of 35 U.S.C. § 261 (an unrecorded assignment is void against a subsequent purchaser for valuable consideration unless recorded in the U.S. Patent and Trademark Office within a specified time limit), and others. Thus, this risk has been managed as a routine business practice.

III. EQUITABLE AND CONTRACT REMEDIES ARE AVAILABLE WHERE INVENTORS ASSIGN RIGHTS TO INVENTIONS IN VIOLATION OF UNIVERSITY POLICIES, OR IN A MANNER INCONSISTENT WITH BAYH-DOLE

The Bayh-Dole Act allocates the rights and obligations between federal funding agencies and their contractors through use of funding agreements that bind both the agency and the contractor and its successors, assigns, and subcontractors. 35 U.S.C. § 202(c)(1)-(8); *Id.* § 201(b) (defining "funding agreement"). Because the inventor is typically neither a party to the funding agreement nor in privity with the funding agency, it is the contractor's responsebility to protect the government's interest by securing rights to the invention from the inventor through separate written instruments. See, *e.g.*, 24 NIH Guide, *supra*.

Universities and other nonprofit research institutions meet this obligation in a number of ways, such as by obtaining express assignments or obligations to assign inventions to them from their faculty; by binding their researchers to pervasive research policies that require them to comply with the conditions of extramural grant awards; or by patent and intellectual property policies that are incorporated in employee handbooks as a condition of employment. See, e.g.*, Georgetown University Policy And Procedures For Inventions, Copyrights, Patents, and Technology Transfer* B.3-4 (1999), *available at* http://facultysenate.georgetown.edu/Archives/Patent IntelProp/intell-prop-policy1999.pdf.; Univ. of Minn., *Intellectual Property Policy* § IV subd. 2. (b), § VII (4) (1999), *available at* http://www1.umn.edu/usenate/policies/intelproperty.html; GAO Report to Cong.

Comms., GAO/RCED-98-126, *Technology Transfer Administration of the Bayh-Dole Act by Research Universities* 14 (May 1998) (noting that inventors at University of Wisconsin-Madison assign rights to its licensing foundation, WARF, under Bayh-Dole). Contractual obligations, whether express or implied, thus operate as the main constraint on the disposition of invention ownership rights by nonprofit federally-funded inventors. Additionally, such inventors may, in highly fact-specific situations, be under equitable obligations to their institutions that affect their ability to dispose of ownership rights in inventions made under federal support. For example, as an intended third-party beneficiary of the funding agreement, an inventor who knowingly accepts the benefits of the funding agreement through and from his institution could be deemed to be under an equitable obligation not to execute bad-faith assignments, or otherwise act in ways that are inconsistent with his institution's obligations to the government under that funding agreement. There is no reason why equitable relief, for example in the form of specific performance of an inventor's obligation to assign, or rescission of a bad-faith assignment to a third party that may have occurred, would not be available to give a nonprofit research institution the rights to which it is entitled and which it needs to safeguard the funding agency's interests.

Indeed, in instances where university-employed inventors have concealed valuable inventions from their institution, or assigned inventions in bad faith to third parties for personal gain, courts have recognized the availability of a number of equitable and contract remedies, including for breach of contract, breach of fiduciary duty, fraud, tortious interference, theft, unjust enrichment, and con-

version of property. See *St. John's Univ.* v. *Bolton,* 2010 WL 5093347, at *6-7 (E.D.N.Y. Dec. 10, 2010); *Fenn*, 283 F. Supp. 2d at 620, 640. Petitioner, their supporting amici, and the United States have provided no explanation why such time-tested remedies are so inadequate that the Bayh-Dole Act must be interpreted, in the absence of a clear statement from Congress, contrary to the Patent Act's fundamental principle that original ownership of inventions vests in inventors – not their employers.

This is not a case where the Federal Circuit's rule will deprive the government of any rights to inventions arising out of federal sponsorship, or deprive the public of technology arising from such funds, or impede collaborative efforts, or even deprive a university of ownership rights in federally-funded inventions. In other words, all of the issues the Bayh-Dole Act sought to correct from the prior government ownership of inventions regime, are left intact with that court's ruling. Written assignment of patent rights has been the norm for federally-sponsored research, for 30 years, even for Petitioner. And there is scant justification, if any at all, to change that paradigm.

CONCLUSION

For all of the foregoing reasons, Amicus respectfully requests this Court affirm the Federal Circuit's decision in this case because the Bayh-Dole Act does not automatically vest title in patents to contractors.

Respectfully submitted,

THOMAS DILENGE
HANS SAUER, PH.D.
BIOTECHNOLOGY
INDUSTRY ORGANIZATION
1201 Maryland Ave., S.W.
Suite 900
Washington, DC 20024
(202) 962-6695

CARTER G. PHILLIPS*
JEFFREY P. KUSHAN
RACHEL H. TOWNSEND
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
(202) 736-8000
cphillips@sidley.com

Counsel for Amicus Curiae
Biotechnology Industry Organization

February 1, 2011

*Counsel of Record