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 INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS CURIAE

Amicus curiae Intellectual Property Owners Association (IPO) is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in U.S. intellectual property rights. IPO's membership includes more than 200 companies and more than 11,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the Patent and Trademark Office and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual The members of IPO's Board of property law. Directors, which approved the filing of this brief, are listed in the Appendix.²

¹ No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae* or its counsel made a monetary contribution to its preparation of submission. Both parties in this case consented to the filing of *amicus* briefs in support of either party or neither party by letters submitted to this Court on December 3 and December 6, 2010.

² IPO procedures require approval of positions in briefs by a three-fourth majority of directors present and voting. Hoffmann-La Roche, Inc., parent company of Roche Molecular Systems, Inc., is a member of the IPO Board of Directors; however, it did not participate in discussions regarding or vote on the decision to file this brief and did not participate in its preparation.

INTRODUCTION

The Bayh-Dole Act, 35 U.S.C. §§ 200-212 (the "Act"), gives nonprofit institutions and small businesses the option to "retain title" to patents resulting from federally funded research. This case involves an important question of the Act's applicability to an invention that had already been assigned to a third party before any federally funded work had been performed.

The case arises out of a claim by Stanford University against Roche Molecular Systems, Inc. (and associated Respondents) for infringement of a patent covering a method for quantifying the amount of HIV virus in a patient's bloodstream in order to measure the efficacy of antiretroviral drugs. Pet. App. 2a-3a. Roche asserted a defense and counterclaim that it was a co-owner of the patent by virtue of its acquisition of Cetus, a private laboratory where one of the named inventors, Dr. Mark Holodniy, conceived of the technique that ultimately became the basis for the patent. Pet. App. 4a-6a.

As litigated below, the case primarily involved the question of which assignment agreement executed by Dr. Holodniy took priority: (a) an agreement with Stanford, the university that employed him, "to assign or confirm in writing to Stanford and/or sponsors that right, title and interest in . . . such inventions as required by Contracts or Grants," or (b) a later agreement Dr. Holodniy made with Cetus — the private laboratory where he developed the basic technology that led to the invention — in which Dr. Holodniy agreed that he "will assign and do[es] hereby assign to CETUS, my right, title and interest in each of the ideas, inventions and improvements" that Dr. Holodniy

may devise "as a consequence of" his work at Cetus. Pet. App. 12a-15a (internal quotation marks omitted). The Federal Circuit held that the agreement with Cetus, of which "Stanford had at least constructive or inquiry notice," Pet. App. 16a, effected an immediate assignment of any invention arising out of Dr. Holodniy's work at Cetus and thus took precedence over his prior agreement with Stanford, and that, since Roche is the co-owner of the patent, Stanford lacks standing to sue. Pet. App. 14a, 28a.

As one of its secondary arguments below, Stanford also claimed that, even if Dr. Holodniy's assignment to Cetus were otherwise valid, Stanford's receipt of federal funding for the clinical testing that confirmed the utility of the methodology developed by Dr. Holodniy at Cetus entitled Stanford to elect to become the owner of the invention and the resulting patents, under section 202(a) of the Bayh-Dole Act. That provision grants to nonprofit organizations and small business firms the right to "retain title" to "subject inventions," except in certain specified circumstances where such rights would transferred to the federal government. 35 U.S.C. § 202(a); see also Pet. App. 18a. In making this argument, Stanford maintained that the statute gives it full and exclusive title to the invention even if Cetus acquired the rights of Dr. Holodniy's contribution to the invention prior to Stanford's receipt of funding under the Bayh-Dole Act. Pet. App. 18a-19a.³

³ There is no dispute that Stanford is at least a co-owner of the patent by virtue of its government funded clinical research activities by other named inventors who were not subject to any agreement with Cetus. Pet. App. 3a-4a.

The U.S. Court of Appeals for the Federal Circuit summarily rejected Stanford's argument, holding that "Stanford identifies no authorities or reasons why its election of title under Bayh-Dole had the power to void any prior, otherwise valid assignments of patent rights." Pet. App. 19a. Nevertheless, Stanford's merits brief in this Court, and a supporting amicus curiae brief filed by the United States, take the position that, whatever rights Cetus may have acquired by virtue of its agreement with Dr. Holodniy, those rights were lost when Stanford used government funding for the clinical testing that ultimately resulted in the issuance of the patent. Pet. Br. 26, 32; U.S. Br. 17-19.

For purposes of this *amicus* brief, IPO takes no position on the merits of the Federal Circuit's holding that Cetus had acquired ownership of the patent rights prior to the commencement of the federally funded research, but assumes, *arguendo*, that the Federal Circuit's resolution of that question, and all of the remaining issues involved in this case other than the potential impact of Bayh-Dole, were correct.⁴ Rather, this brief focuses on the issue of

⁴ In its merits brief before this Court, Stanford argues for the first time that Dr. Holodniy's work at Cetus (and consequent conception of the patented invention at issue) was supported by federal research funding that was in place prior to Dr. Holodniy's work at Cetus. See Pet. Br. 17, 32-33 & n.12. However, it is unclear whether there was an agreement with Bayh-Dole provisions executed in connection with such funding and, in any event, the Federal Circuit's decision was premised on the assumption (apparently unchallenged during that appeal) that the work at Cetus was performed prior to the receipt of federal funding. The District Court found that (1) "the invention was clearly conceived at the latest when Holodniy had developed the PCR assay"; (2) "[t]he specific method of using the assay to monitor HIV treatment was . . . clear in the minds of Holodniy and the other Stanford scientists when the assay was completed at Cetus"; and (3) "the invention was

IPO's primary concern — the proper construction of the Bayh-Dole Act and the impact of the Act on the rights of third parties acquired from the inventor before any federally funded work was performed.

SUMMARY OF ARGUMENT

The express language and the legislative purpose of the Bayh-Dole Act require that, in order for an invention to qualify as a "subject invention" under its provisions, see 35 U.S.C. § 201(e), the rights to the invention must not only be conceived or actually reduced to practice in the course of work performed under a funding agreement, but must also be owned by the contracting party at the time that governmentally funded work is performed. Thus, section 202(a) of the Bayh-Dole Act does not permit a contractor receiving federal funding to acquire rights to an invention which, as the Federal Circuit found in this case, had previously been assigned to another party.

Allowing Stanford, by virtue of obtaining federal funding, to eliminate rights acquired by a third party for fair consideration, and to subsequently sue that party for infringement, would be contrary to the intent of the Bayh-Dole Act to encourage private development of governmentally-funded research and to promote cooperation between nonprofit and private research institutions. Instead, Stanford's

conceived during Holodniy's consultancy at Cetus . . . ," Pet. App. 56a-58a, and those findings were not challenged in the Federal Circuit. In addition to its holding on the relative effectiveness of the two assignment agreements, the Federal Circuit reversed the district court's finding that Roche's defense based on co-ownership of the patent was barred by the statute of limitations. Pet. App. 22a-27a.

proposed construction of the Bayh-Dole Act would discourage collaboration between academic institutions and private companies by creating a potential cloud on a private entity's lawfully acquired patent rights.

Indeed, any construction of the Bayh-Dole Act that would transfer the rights of the owner of a patented invention to another party without obtaining the consent of or paying compensation to the owner of those rights should be avoided as potentially raising a serious constitutional issue under the Takings Clause of the Fifth Amendment to the United States Constitution.

ARGUMENT

A. The Express Language of the Bayh-Dole Act Limits Its Applicability to Patent Rights Owned or Controlled by the Federal Contractor.

The "starting point in every case involving construction of a statute is the language itself." Landreth Timber Co. v. Landreth, 471 U.S. 681, 685 (1985) (internal quotation marks and citations omitted). In this case, the language of the Bayh-Dole Act, as reflected in the definitional provisions of section 201 and the operative provisions of section 202, mandates the conclusion that an invention does not become subject to the provisions of the Bayh-Dole Act unless it is owned by the party that contracts for the government funding at the time that the invention is either conceived or actually reduced to practice.

In order to fall within the scope of the Bayh-Dole Act, a patented invention must constitute a "subject

invention." Section 201 of the Act defines that term as follows:

The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement....

35 U.S.C. § 201(e) (emphasis added).

By its plain terms, this provision sets forth a twoprong test for an invention to qualify as a "subject invention" under the Act: first, the invention must be "an invention of the contractor"; and, second, the invention must have either been "conceived or first actually reduced to practice in the performance under a funding agreement" with the federal government.

Without citing any authority or providing any reasoning, Stanford deals with this language by simply assuming that, since only natural persons can be inventors, the term "invention of the contractor" must mean "all inventions made by the contractor's employees with the aid of federal funding." Pet. Br. 32 (quoting 35 U.S.C. § 201(e)) (emphasis added); see also id. at 33 ("[The invention claimed by the patents-in-suit] was an 'invention of the contractor' because the named inventors on the patents-in-suit. . . were researchers employed by Stanford."). However, nothing in the Act or its legislative history remotely suggests (as even Stanford tacitly concedes, see Pet. Br. at 32 n.10) that Congress intended the determination of whether an invention is an "invention of the contractor" to turn solely on the employment status of the individual inventors.⁵

⁵ The United States' brief deals with the definition of "subject

Since, in fact, the contractor can never actually be the inventor, and the statute clearly differentiates between inventors and contractors (see. e.g., 35 U.S.C. § 202(d), (e)), a more reasonable construction of the term "invention of the contractor" is that the invention must belong to the contractor; i.e., that the contractor must have acquired the rights from the inventor. This construction, unlike Stanford's, is not only consistent with the plain language of the Bayh-Dole Act, but also with this Court's precedents interpreting similar language in other statutory provisions. See, e.g., Ellis v. United States, 206 U.S. 246, 259 (1907) (construing the phrase "the public works of the United States" as meaning works "belonging to the United States") (internal quotation marks omitted) (emphasis added); see also Flores-Figueroa v. United States, 129 S. Ct. 1886, 1888-89 (2009) (treating "knowingly" possessing "a means of identification of another person" as meaning that defendant knew that the 'means identification' . . . belonged to 'another person'") (internal quotation marks omitted) (emphasis altered).

invention" by simply ignoring the portion of the definition that limits its applicability to an "invention of the contractor." See U.S. Br. 5, 17. By ignoring the words "of the contractor," the United States violates "a cardinal principle of statutory construction," rendering those words entirely "superfluous, void, or insignificant." TRW Inc. v. Andrews, 534 U.S. 19, 31 (2001) (internal quotation marks and citations omitted). In order to "give effect . . . to every clause and word of a statute," United States v. Menasche, 348 U.S. 528, 538-539 (1955) (internal quotation marks and citation omitted), this Court should recognize that 201(e)'s definition of a "subject invention" as "an invention of the contractor" imposes an additional requirement that must be met in order for an invention to be deemed a "subject invention" under the Bayh-Dole Act.

The language of section 202(c) of the Bayh Dole Act provides further confirmation that the Act was not intended to confer greater rights on the federal contractor than the contractor already owned. That section provides, in several instances, that the only right that the contracting nonprofit institutions and small businesses are granted under the statute and a funding agreement made pursuant thereto is the right to "retain title" — that is, to keep title to the extent that the contractor already had such title. See Webster's Third New International Dictionary 1938 defn. 2a (1976) (defining "retain" as "to hold or continue to hold in possession or use"); Black's Law Dictionary 1183 (5th ed. 1979) (defining "retain" as "[t]o continue to hold, have, use, recognize, etc., and to keep").

Specifically, section 202(a) reads as follows:

Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention

35 U.S.C. § 202(a) (emphasis added).

Similarly, section 202(c) mandates:

Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

* * *

(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency)

whether the contractor will *retain title* to a subject invention

35 U.S.C. § 202(c) (emphasis added).

Notably, when the statute speaks of transferring title to the government, it uses different language. Thus, section 202(c) provides that "the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within [statutorily prescribed] times." 35 U.S.C. § 202(c)(2) (emphasis added). "[W]hen the legislature uses certain language in one part of the statute and different language in another, the court assumes different meanings were intended." Sosa v. Alvarez-Machain, 542 U.S. 692, 711 n.9 (2004) (quoting 2A Norman J. Singer, Statutes and Statutory Construction § 46:06, at 194 (6th rev. ed. 2000)).6

This statutory construction is further supported by the structure of section 202(c), which requires that the terms under which the contractor may "retain" and the government may "receive" title to inventions under the Act be embodied in a contract between the contractor and the government. 35 U.S.C. § 202(c) ("Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following [requirements of the statute]"); see also 37 C.F.R. §§ 401.3(a), 401.14(a) (requiring the

⁶ It is also worth noting that the original House version of the bill that ultimately became the Bayh-Dole Act stated that the contractor could "acquire title" under certain circumstances. See H.R. 6933, 96th Cong. § 383(a) (as passed by House, Nov. 17, 1980). The Senate replaced that language with the words "retain title" that appear in the statute as it was ultimately enacted. See H.R. 6933, 96th Cong. § 202(a) (as passed by Senate, Nov. 20, 1980).

inclusion of a standard patent rights clause in all federal funding agreements). The fact that Congress required the Act's provisions to be embodied in a contract further evidences its intent to limit its provisions to parties who expressly consent to the provisions of the Act, and not to eliminate or alter the lawfully acquired rights of third parties who have not consented to its provisions or entered into an agreement with the United States.⁷

B. The Statutory Construction of the Bayh-Dole Act Advanced by Stanford and Its Amici Would Frustrate the Objectives of the Act and Discourage Academic-Industry Collaboration.

The proposed construction of the Bayh-Dole Act advanced by Stanford and its *amici* would lead to results that are contrary to the Bayh-Dole Act's stated objectives of "promot[ing] the utilization of inventions arising from federally supported research and development" and "promot[ing] collaboration between commercial concerns and nonprofit

⁷ Stanford and the United States, as *amicus curiae*, seek support in the Bayh-Dole Act's use of the terms "acquire[]" and "receive[]" in other provisions of the Act when describing the contractor's rights under the statute. *See* Pet. Br. 36 (quoting 35 U.S.C. §§ 203(a), 204); U.S. Br. 21 (same). Sections 203(a) and 204, however, address entirely different aspects of the statutory regime from the question of what patent rights are granted to contractors under the Bayh-Dole Act. Thus, section 203 concerns the government's march-in rights, 35 U.S.C. § 203, and section 204 sets forth a preference for domestic U.S. manufacturing, 35 U.S.C. § 204. The provisions that actually determine the rights acquired by the United States and contracting parties are set forth in section 202 of the Act and the mandatory language of the funding agreement made pursuant to that section.

organizations, including universities." 35 U.S.C. § 200. Permitting a university, by obtaining government funding, to deprive a private research organization of patent rights that it had previously contracted for in good faith and for good and valuable consideration would discourage private companies from working with university personnel out of fear of loss of their rights and, indeed, possible liability for patent infringement based on inventions developed using their facilities and proprietary information.

The Bayh-Dole Act was drafted and enacted between 1979 and 1980, during a period of relative economic and industrial decline in the United States and corresponding rise of foreign industrial powers. The enactment of the Bayh-Dole Act was largely driven by the desire to lift the country out of this slump by spurring the licensing to industry of patented inventions arising from federally-funded research projects. See, e.g., 126 Cong. Rec. 30364 (1980) (statement of Sen. Bayh); id. at 30366 (statement of Sen. Dole).

Prior to the Bayh-Dole Act, patents for inventions that were invented within universities under at least partial federal funding were frequently claimed by the federal government and licensed nonexclusively See S. Rep. No. 96-480, at 2 (1979). to all comers. Most private companies had no interest commercially developing such inventions without an exclusive license since they would otherwise gain no competitive advantage from their investment. See. e.g., The University and Small Business Patent Procedures Act, Part 1: Hearings Before the S. Comm. on the Judiciary, 96th Cong. 2 (1979) (statement of Sen. Bayh, Member, S. Comm. on the Judiciary) ("[T]he agencies have had very little success in attracting private industry to develop and market these inventions because when the agencies

retain the patent rights there is little incentive for any company to undertake the risk and expense of trying to develop a new product."); S. Rep. No. 96-480, at 2 (noting that "of the more than 28,000 patents in the Government patent portfolio, less than 4 percent are successfully licensed").

The Bayh-Dole Act sought to remedy this by uniform path toward the exclusive creating a licensing of federally-funded inventions to private industry. For inventions already owned by the federal government, the Bayh-Dole Act enabled federal agencies to grant exclusive licenses and partially exclusive licenses to private industry. See 35 U.S.C. §§ 207(a)(2), 209. For inventions developed with federal funds by nonprofit organizations (e.g., universities) or small businesses, the Bayh-Dole Act generally granted these contractors an option to retain title to the patents so that they could then exclusively to private industry commercialization. See, e.g., S. Rep. No. 96-480, at 2 (noting that while only 4 percent of the federal patent portfolio had been licensed, "[u]niversities . . . which can offer exclusive or partially exclusive licenses on their patents if necessary, have been able to successfully license 33 percent of their patent portfolios"); see also 126 Cong. Rec. 1798 (1980) (statement of Sen. Thurmond).

The sponsors of the Bayh-Dole Act were particularly concerned that patented inventions in the biomedical field were left unlicensed and undeveloped, when they could be saving lives in the hands of a financially-incentivized company. See 126 Cong. Rec. 30366 (1980) (statement of Sen. Dole) ("In the field of medical innovation, the obstruction of patent rights by Federal agencies is an extremely serious problem. Indeed, when medical inventions offering potential cures for diseases are withheld, it

is the very lives of Americans which are affected."); id. at 8740 (statement of Sen. Bayh) (providing a list of "over 30 promising medical discoveries" that were not developed due to government delays in deciding ownership of patent rights); S. Rep. No. 96-480, at 21 (attributing the failure to develop drugs from federally-funded research to the "lack of incentives to the private sector to commit the time and money needed to commercialize these discoveries").

The construction of the Bayh Dole Act urged by Stanford and the United States, however, would turn this purpose on its head. Instead of encouraging universities to grant exclusive rights to private industry, it would permit a university, simply by obtaining a federal grant, to acquire exclusive rights that had previously been granted to a private company for valuable consideration under a valid agreement. Further, the university could then turn around and sue the very company that had provided the facilities and information that led to the invention, simply because the university subsequently conducted further research under a federal grant which the private company neither sought nor consented to.

Stanford's reading of the Bayh-Dole Act would deprive private companies of certainty in their patent rights, thereby chilling academic-industry collaboration. Consider the example of a university employee (not funded by any federal grants covered by the Bayh-Dole Act) who, with the university's consent, accepts a compensated research position at a private company alongside his university post. The researcher benefits from the company's facilities and resources, and the company may expend considerable funds on his work. To protect its investment, the private company ordinarily would require the researcher to assign to it any inventions that arise

from his work at the company. Stanford's construction of the Bayh-Dole Act, however, would permit the university to subsequently reduce to practice any invention resulting from the researcher's work at the company (which did not benefit from any federal grants) using Bayh-Dole funds and divest the private company of its patent rights entirely.

By exposing private organizations to the possibility of forfeiture of their rights — and even to legal liability — the construction of the statute urged by Stanford and the United States would defeat the express goals of the statute. In so doing, it would also sub silentio create a broad exception to the longstanding and well established principle of patent law that an individual inventor, and no one else, owns the rights to his inventions in the first instance and has the initial right to assign those rights, including the patent rights arising therefrom. See 35 U.S.C. § 261; 8 Donald S. Chisum, Chisum on Patents § 22.01, at 22-2 (1993); United States v. Dubilier Condenser Corp., 289 U.S. 178, 187 (1933).8

Indeed, the United States as *amicus curiae* expressly advances the argument that the Bayh-Dole Act "take[s] precedence" over the fundamental statutory and common law principle that "the right

⁸ It has long been settled that title to a patented invention vests in the first instance to the inventors. See, e.g., Crown Die & Tool Co. v. Nye Tool & Mach. Works, 261 U.S. 24, 35-36 (1923); Manual of Patent Examining Procedure § 301 (8th ed. 2010) ("The ownership of the patent . . . initially vests in the named inventors of the invention of the patent.") (citing Beech Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248 (Fed. Cir. 1993)). The inventor's ownership right in a patent is treated as an interest in personal property, and it follows that the inventor may assign that interest to another person or entity. See 35 U.S.C. § 261; Crown Die & Tool Co., 261 U.S. at 36-37.

to obtain a patent on an invention . . . belongs to the inventor, who may assign that right." See U.S. Br. at 21 & n.2 (citing 35 U.S.C. §§ 101, 115, 116, 152) (internal quotation marks omitted). As this Court has explained, as a general matter, in the field of patent law "congressional action should not be overread for negative implications." Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 28 (1997); see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 739 (2002) (stating that "[t]he responsibility for changing [settled patent law] rests with Congress" and that "[f]undamental alterations in these rules risk destroying the legitimate expectations of inventors in their property"). Yet, there is absolutely nothing in the language of the Bayh-Dole Act, its legislative history, or any of the contemporaneous discussion of the proposed legislation or its intended effect that even hints at any intent to overturn the wellestablished rule that an employer must obtain an assignment agreement from its employees if it wishes to obtain ownership of their inventions.9

Stanford and *amici* argue extensively that if universities were required to obtain proper assignments from their employees in order to retain

⁹ The United States' reliance on 35 U.S.C. § 210(a), see U.S. Br. at 21, is misplaced. That provision was only intended to assure that the Act takes precedence over prior laws that were "inconsistent" with the Act, citing twenty-one statutes that governed the disposition of federally-funded inventions prior to its enactment. It implies nothing whatsoever about the question before this Court — whether the Act was intended to change the fundamental rules governing the ownership of inventions by employees of nonprofit institutions. Section 210(a) merely serves to assure that rules established by the Bayh-Dole Act are applied uniformly and supersede any prior inconsistent rules, but the terms of those rules themselves are set forth in section 202.

title under the Bayh-Dole Act, subsequent licensing activities would "wreak havoc" by requiring an impracticable level of due diligence to discover assignments of which the university may have no See, e.g., Pet. Br. 50-51; U.S. Br. 30-31; NVCA Br. 13-14. However, in the commercial world, private companies that engage in research routinely obtain assignment agreements from their employees. and prospective licensees routinely take measures to ensure that the licensor has clean title to the invention. See, e.g., Mark S. Holmes, Patent Strategy, Negotiations, Licensing: and Forms § 11:3.5, at 11.6 (Practicing L. Inst. 2010) ("Licensees should not be shy about seeking assurances that the licensor holds all rights necessary to license the covered patents and technology.").¹⁰ As noted above, Bayh-Dole was intended to extend these types of normal commercial licensing practices to government funded research projects, not create a radically different set of rules.

Certainly, nothing in the facts of this case justifies the imposition of fundamentally different principles of patent ownership for employees of nonprofits who obtain government funding. On the contrary, it is clear from the Federal Circuit opinion that, if Stanford had used slightly different language in its agreement with Dr. Holodniy, or if it did not have at least constructive notice of Dr. Holodniy's subsequent assignment agreement with Cetus, it could easily have acquired, and been able to retain,

¹⁰ Indeed, the federal government itself requires such assurances. The agency-wide implementing regulations for the Bayh-Dole Act provide that "[t]he 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." $37 \text{ C.F.R.} \S 401.14(f)(2)$.

sole title to the invention at issue in this case without requiring any drastic change in the established principles of patent ownership.

In sum, the construction of the Bayh-Dole Act advanced by Stanford and its *amici* would discourage private investment in patentable inventions by allowing nonprofits to retroactively invalidate an otherwise valid agreement by an inventor to convey patent rights to a private party. Such a result would discourage collaboration between commercial developers and persons affiliated with academic research institutions — exactly the opposite of the effect that Congress intended the Bayh-Dole Act to achieve.

C. The Construction of the Bayh-Dole Act Proposed by Stanford and the United States Should Be Rejected Because It May Raise Serious Constitutional Issues Under the Takings Clause of the Fifth Amendment.

As this Court has repeatedly stated, "where a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, [the Court's] duty is to adopt the latter." Jones v. United States, 526 U.S. 227, 239 (1999) (quoting United States ex rel. Att'y Gen. v. Del. & Hudson Co., 213 U.S. 366, 408 (1909)). "The avoidance canon rests upon [the courts'] 'respect for Congress, which [the courts] assume legislates in the light of constitutional limitations." Harris v. United States, 536 U.S. 545, 556 (2002) (quoting Rust v. Sullivan, 500 U.S. 173, 191 (1991)).

Here, the construction of the Bayh-Dole Act urged by Stanford and the United States would raise a serious constitutional question as to whether a statute mandating the uncompensated, compulsory transfer of title in a patentable invention from a private company to a university or to the government amounts to a violation of the Takings Clause.

This Court's decisions establish that patent rights are a form of property protected by the Takings Clause. See, e.g., 35 U.S.C. § 261 (2006) ("[P]atents shall have the attributes of personal property."); Festo, 535 U.S. at 730; Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank, 527 U.S. 627, 642 (1999); United States v. Burns, 79 U.S. (12 Wall.) 246, 252 (1870) ("[T]he government cannot, after the patent is issued, make use of the improvement any more than a private individual, without license of the inventor or making compensation to him."); Cammeyer v. Newton, 94 U.S. 225, 234 (1876) (declaring, in a case of patent infringement by federal officials, that "private property, the Constitution provides, shall not be taken for public use without just compensation."); see also McKeever's Case, 14 Ct. Cl. 396, 421 (1878) (holding that patents are constitutional private property under the Takings Clause). A patent "confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser." James v. Campbell, 104 U.S. 356, 358 (1881). Indeed, this Court has expressly held, in an analogous context, that the investment-backed expectations in trade secrets are protected by the Takings Clause of the

Fifth Amendment. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1001-04 (1984).¹¹

The Takings Clause may be implicated not only when the government takes property for its own use, but also when it mandates its transfer to a private entity. See Kelo v. City of New London, 545 U.S. 469, 475-77 (2005). Thus, if the Bayh-Dole Act were construed as transferring to a private nonprofit institution, without compensation, the rights to an invention that had previously been assigned to another, such a construction could raise "grave and doubtful constitutional questions," and should be avoided. Jones, 526 U.S. at 239 (internal quotation marks and citation omitted).

This Court need not decide whether such a construction of the Bayh-Dole Act would indeed amount to a violation of the Takings Clause. "[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council, 485 U.S. 568, 575 (1988) (citing NLRB v. Catholic Bishop of Chicago, 440 U.S. 490, 499-501, 504 (1979)). Here, the construction of the Bayh-Dole

¹¹ Indeed, during Congressional consideration of the Bayh-Dole Act, the Society of University Patent Administrators, which supports Stanford here, submitted a statement to the Senate Judiciary Committee that "the fifth amendment provides generic protection for all individual property," and that "there is little doubt that the term 'property' as used in the fifth amendment includes intellectual property." See The University and Small Business Patent Procedures Act, Part 1: Hearings Before the S. Comm. on the Judiciary, 96th Cong. 194 (June 6, 1979) (written testimony of Howard Bremer, President, Society of University Patent Administrators).

Act that more faithfully reflects both the language of the Act and Congressional intent is one that would obviate the need for this Court to address a potential constitutional issue, and IPO urges this Court to adopt that construction and to hold that the grant of federal funding to a nonprofit institution does not alter pre-existing rights granted by the inventor to a third party.

CONCLUSION

For the foregoing reasons, IPO respectfully requests that the Court hold that the Bayh-Dole Act does not operate to transfer to a nonprofit institution rights to an invention that belonged to another party at the time the invention became subject to the Act's provisions.

Respectfully submitted,

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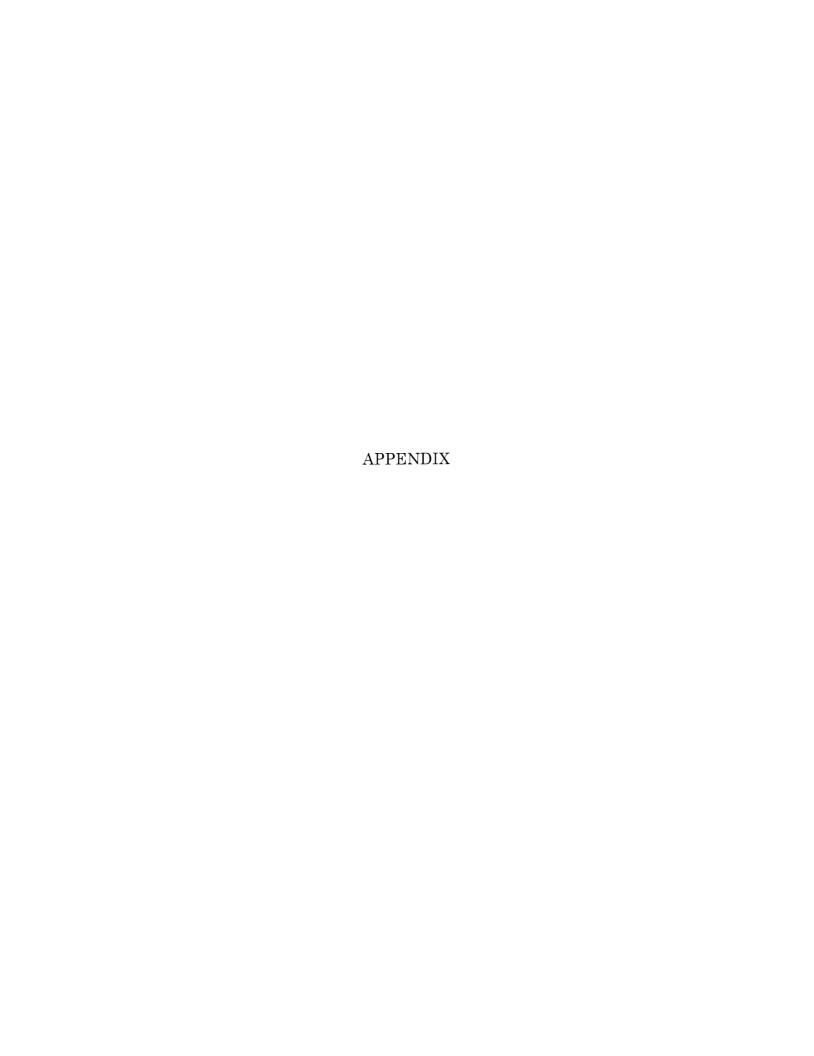
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APPENDIX1

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