

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 Writ Of Certiorari To The United States  
Court Of Appeals For The Federal Circuit**

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**REPLY BRIEF FOR PETITIONER**

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## **CORPORATE DISCLOSURE STATEMENT**

The corporate disclosure statement included in the Petitioner's opening brief, pursuant to Supreme Court Rule 26.1, remains accurate.

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## REPLY

This case requires the Court to decide whether a university receiving federal research funding secures clear title to resulting inventions of its employees when it fully complies with the requirements of the Bayh-Dole Act, 35 U.S.C. §§ 200-212. The court below held otherwise, ruling that one of Stanford's employee-inventors, whose work was always funded by NIH grants, could nonetheless assign away his rights and thereby require Stanford to share title with his assignee. That decision is wrong because the statute's language and context show that it comprehensively defines the ownership interests of contractors, inventors, and the Government, and gave Stanford a conditional right to title that its employee could not assign away to a third party.

Roche answers this showing on two levels. First, contrary to the Act's title and express language, it argues that the Bayh-Dole Act does not actually govern the disposition of title in federally funded inventions at all, but rather only "regulate[s] the relationship between the government and its contractors, not third-party rights." Resp. Br. ("RB") 16; *see id.* at 15, 18, 19, 21, 40, 45. Roche asserts that the employee-inventor of a contractor remains the first owner of any funded invention, with the power to assign away ownership even before the invention exists. He is thus able to frustrate the statute's express objectives of giving the contractor title and protecting the Government's interests.

Second, to buttress its implausible argument, Roche tries to reframe the facts of the case. Based on the undisputed fact that Dr. Holodniy was allowed lab access and consultation with Cetus employees on

a part-time basis during a portion of 1989, Roche insinuates that the inventions embodied in the patents-in-suit were really the work of Cetus that Stanford has somehow spirited away. RB 5-11. But the facts as Roche spins them are very far from reality.

It is entirely clear that Dr. Holodniy, admittedly with assistance, is the one who developed the assay, Pet. App. 56a, and that the assay itself, while a useful tool, had no promise as a patentable invention. Thus, Cetus reviewers gave it their lowest rating on a five-point scale for patentability, Pet. App. 38a, and approved its full disclosure by publication. On that basis, the work at Cetus was summarized in two abstracts and in a 1991 article published in the *Journal of Infectious Diseases* that “culminated” the work. JA 135; RB 8. After one year, these publications triggered the statutory bar to any conceivable claim of a patentable invention, 35 U.S.C. § 102(b), and any later patent necessarily depended on inventive work apart from what Dr. Holodniy did at Cetus. In fact, the later work at Stanford that gave rise to the patents used clinical testing of human patients taking antiretroviral drugs to “determine[] that HIV RNA, ... was a suitable ‘marker’ of drug efficacy,” Pet. App. 5a, and also to define the actual critical levels indicative of drug efficacy.

The only co-inventors on any of the patents are Stanford employees, which Roche did not dispute for fifteen years prior to the filing of this case,<sup>1</sup> and

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<sup>1</sup> Neither Cetus nor Roche asserted a claim of co-inventorship during the patent prosecution, in 2000 when Stanford



Roche cannot argue co-inventorship now. For this and other reasons, neither Roche's claim nor the decision below, Pet. App 15a, turn at all on whether the inventions were conceived during or after Dr. Holodniy's time visiting at Cetus.

Instead, Roche's claim rests wholly on Dr. Holodniy's purported assignment to Cetus in 1989, Pet. App. 4a, 14a-18a, and it is quite significant that federal funding was already in place at the time the assignment was made. Here, Roche again argues the facts, asserting repeatedly that Dr. Holodniy's work at Cetus was not aided by any Bayh-Dole grant. *See* RB 6-7 & n.1, 8, 12, 16, 21 n.8, 36, 44-45. But these unsupported assertions are plainly wrong, as is obvious from the JID article that Roche discusses at length. *Id.* at 8. Its opening footnote lists as grant support for that work the same NIH grants referenced on the patents, JA 135; Supp. JA 27, 50, 75, and the fact that these grants were in place by 1988 is readily confirmable from official governmental records. *See infra* at 22.<sup>2</sup>

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(continued...)

approached Roche to negotiate a patent license, or any time prior to Stanford's suit in 2005—more than fifteen years after the Cetus work ended. *See* Opening Br. ("OB") 33; RB 11 n.4.

<sup>2</sup> Roche says that Stanford's opening brief asserts "for first time" that the work done by Dr. Holodniy at Cetus was federally funded. RB 6. That is because Roche has not before, in its BIO or otherwise, disputed that the inventions at issue were in fact federally funded, the oft-repeated claim and premise of this case. *E.g.*, Dkt. 111, at 8; Pet. 5. In any event, any claim that Dr. Holodniy's Cetus work was unfunded would be frivolous, given the record.

**I. DR. HOLODNIY'S ASSIGNMENT TO CETUS WAS INEFFECTIVE BECAUSE BAYH-DOLE GIVES THE CONTRACTOR A CONDITIONAL RIGHT TO TAKE TITLE TO FEDERALLY FUNDED INVENTIONS THAT THE INVENTOR CANNOT TAKE AWAY**

The text and structure of the Bayh-Dole Act, considered in light of its regulations and historical context, show that the statute comprehensively defines ownership rights in federally funded inventions. OB 30-38. Enacted against a backdrop of the Government taking title to most funded inventions, and a muddle of varying procedures, Bayh-Dole created a uniform hierarchy of rights and procedures. OB 9-12, 30-31, 35. Its first section states an intention to regulate “inventions made by nonprofit organizations,” § 200, and its title and section headings evince an intent to govern the entire “[d]isposition of” “Patent Rights in Inventions Made with Federal Assistance.” 35 U.S.C. ch. 18; § 202; OB 12.

The text of § 202(a) gives contractors a statutory right “to elect to retain title.” OB 33-34. That legal right is subject to a governmental license and numerous procedural and substantive safeguards to protect the Government’s interests. For example, if a contractor fails to timely disclose, elect to retain, or file a patent application on a subject invention, the Government may itself “receive title.” 35 U.S.C. § 202(c)(1)-(3). And even if the contractor timely performs all of those requirements, the Government can still “march in” and force the contractor “to grant a ... license” to secure the public’s interest. *Id.* § 203; OB 13-14.

Nothing in the statute references any need for the contractor to obtain an assignment from the inventor in order to trigger the Act. OB 34. Instead, Bayh-Dole takes a different path to recognizing “the equity of inventors” and defines their rights by entitling them to royalties and a subordinate possibility of receiving title. S. Rep. No. 96-480, at 33 (1979); 35 U.S.C. §§ 202(c)(7)(B), (d); OB 36-38. By defining the rights of contractors, the Government, and inventors, Bayh-Dole thus governs all rights in federally funded inventions.

**A. Roche’s Textual Argument Misreads The Words “Invention of the Contractor” and “Retain”**

Roche’s primary textual argument, that the statute applies only where the contractor already has received the inventor’s interest by assignment, focuses myopically on a gross misreading of five words of the statute—the phrase “invention of the contractor” in the definition of “subject invention,” § 201(e), and the word “retain” in § 202(a). RB 18-23.

1. Roche contends that there can be no “invention of the contractor,” and thus no “subject invention” triggering the Act, unless the contractor already owns the invention by assignment from the inventor. RB 18-21. But this is not the natural understanding of the phrase, viewed in context, and the drafters could easily have said “any invention owned by the contractor” had they meant that.

More commonly, the word “of” is used to indicate origin. *See* Random House Dictionary of the English Language 999 (Deluxe Ed. 1985) (second definition in order of frequency: “to indicate derivation, origin, or source”); *accord* American Heritage Dictionary 862

(2d coll. ed. 1985) (most frequent definition).<sup>3</sup> Thus, a person describing the telephone as an “invention of Alexander Graham Bell” means that Bell invented the telephone, not that he owned the rights to it. The same meaning naturally follows when a noun is derived from the action that produced it—*e.g.*, “the writings of Emerson,” or “the decision of the Court.”

Because contractors are typically organizations and only individuals can be inventors, the phrase “invention of the contractor” is most reasonably construed to mean an invention made by the contractor through its employees. *See* OB 32. Roche argues that this cannot be, RB 20, but other language in the statute and regulations confirms that Congress intended precisely this meaning. The statute’s preamble states that its policies and objectives apply to “*inventions made by nonprofit organizations and small business firms.*” 35 U.S.C. § 200 (emphasis added). And the title of Bayh-Dole’s implementing regulations defines their scope as addressing “RIGHTS TO INVENTIONS MADE BY NONPROFIT ORGANIZATIONS AND SMALL BUSINESS FIRMS UNDER GOVERNMENT GRANTS.” 37 C.F.R. pt. 401 (Heading); *see also* 37 C.F.R. § 401.1(e) (“made by”).

Since Bayh-Dole’s statement of objectives and governing regulations expressly encompass inventions “made by” funded contractors, it would be

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<sup>3</sup> While the word “of” can sometimes indicate “a possessive relationship,” that is a much less common usage. *See* Random House Dictionary of the English Language 999 (Deluxe Ed. 1985) (seventh definition). Roche’s three cases that follow this usage, RB 18, therefore do not support its argument here.

odd if § 201(e)'s definition of "subject invention," establishing the Act's scope, did not also use the words "invention of the contractor" to reference one "made by the contractor" through its employees.

Finally, this interpretation of "invention of the contractor" is critical to protect third-party rights. Indeed, the insistence of Roche and its *amici*, BIO Br. 20-27; Intel Br. 18-22; PhRMA Br. 24-26, on their misconstruction of these words, while protesting the Act's supposed threat to third-party rights, is a bit like a child seeking mercy as an orphan after murdering his parents. By predicating a contractor's claim of Bayh-Dole title on the inventive contribution of its employees, this language leaves undisturbed the ownership rights derived from independent co-inventorship of unfunded third parties and their assignees. Certainly, also, it does not appropriate to a contractor inventions wholly conceived, and thus invented, by individuals unconnected to the funded university. *See infra* at 16-18.

Thus, far from rendering the phrase "invention of the contractor" superfluous, *see* BIO Br. 10-11; PhRMA Br. 7-8, Stanford's reading of the Act relies directly on that language as integral to a coherent and fair reading of the Act.

2. Consistent with its erroneous reading of "invention of the contractor," Roche contends that a contractor may "elect to retain" title only where the contractor already "owns" the invention by assignment. RB 22. While the word "retain" may sometimes carry that inference, its common definition, as "to *hold* or continue to hold *in possession*," Webster's Third New International Dictionary 1938 (1976) (emphases added); *see* RB 22

(definitions), does not require it. Given the prior history in which the Government had taken title to 80% of funded inventions, 126 Cong. Rec. 1993 (1980), describing the Act's conditional grant of title as allowing the contractor to "retain" it—rather than have the Government take it away—is quite understandable. OB 35. And that meaning of the word is compelled, because the Act viewed as a whole is plainly a comprehensive undertaking to define, as its title states, "Patent Rights In Inventions Made With Federal Assistance," 35 U.S.C. ch. 18, and not simply the bilateral rights of the contractor and the Government. OB 37, 39, 41.

A critical proof of this fact is that Roche's meaning of "retain" in § 202(a) cannot even be squared with its own usage of the term where it appears elsewhere in the Act. Under § 202(d), where "a contractor does not elect to retain title to a subject invention," the Government "may consider ... requests for retention of rights by the inventor." To explain away this provision's express addressing of inventor rights, Roche contends that § 202(d) applies only to "inventions [that] have already been assigned by the inventor to the contractor," RB 38-39, as it claims is necessary even to have a "subject invention." Thus, Respondent claims that the contractor can only "retain title" to an invention that it already owns, while an inventor may be considered for "retention" of title only when he has assigned title away.

Since "identical words and phrases within the same statute should normally be given the same meaning," Roche's construction of the word "retain" must be rejected as irreconcilable with itself. *Powerex Corp. v. Reliant Energy Services, Inc.*, 551

U.S. 224, 232 (2007); *IBP, Inc. v. Alvarez*, 546 U.S. 21, 34 (2005).

Also, the Act's usage in other provisions of "acquire[] title" and "receive[] title," 35 U.S.C. §§ 203(a); 204, indicates that the statutory process by which the contractor "elect[s] to retain title," and fulfills the numerous other statutory requirements, does indeed result in it "acquir[ing] title." *See* OB 36. This conclusion is unmistakably confirmed by the legislative history. OB 38-42.

Roche's counterarguments are hypertechnical and unpersuasive. While the Act references other conceivable ways by which a contractor may get title—*e.g.*, assignments from the Government derived from a federal-employee co-inventors, § 202(e)(2)—those situations are rare. The drafters plainly conceived of the detailed statutory process, including election to retain and compliance with numerous explicit statutory requirements, as the principal avenue by which the contractor would "acquire[] title under this subchapter," § 203(a). Indeed, if Roche were correct that a contractor's title must always flow from the inventor, the contractor would almost never "acquire title *under this subchapter*." This strange result also strongly suggests that Roche's reading is wrong.

#### **B. The Purported "Absence of Vesting Language" Does Not Support Roche's Interpretation**

In addition to misreading five words of the statute, Respondent's textual argument focuses on the supposed omission of appropriate vesting language. RB 23-26; *see* BIO Br. 14-15; Intel Br. 11-12; IPO Br. 15; PhRMA Br. 6-7.

First, this argument depends upon Respondent's misreadings of the words "invention of the contractor" and "retain." When those words are properly understood, the statute extends to federally funded inventions made by the contractor's employees, and creates a conditional right in the contractor to "hold" title to those inventions by complying with the statute's many requirements. *See supra* at 5-9.

Second, this argument simply ignores the statute's comprehensive character in defining the rights of all parties, and setting numerous conditions upon the contractor's continued right to title, on whose failure "title" may revert to the Government or, at times, to the inventor. OB 12-16, 30-38. The statute defines these requirements and consequences with great care, and its language leaves no doubt that what is at stake is "title" to the invention. *E.g.*, §§ 202(c)(1)-(3),(d).

It is quite implausible that the statute, while setting forth this comprehensive scheme in painstaking detail, omitted to mention anywhere what Roche argues is the key triggering event—an assignment from the inventor. This is especially true given the federal interest at issue. *See infra* Section I.D. Notwithstanding the United States' substantial stake in advancing its statutory interests, resting on billions of dollars in research funding, Roche would render the Act inapplicable and the federal interest largely unprotected whenever the contractor fails to get an assignment with priority over even the broadest imaginable assignment to a third-party—like the one Cetus extracted here.

In a similar vein, Roche notes that the legislative history does not contain statements affirmatively



denying that the contractor would be required to secure an assignment from its employee-inventor. RB 41. No such statements should be expected where the new statute supplanted many agency vesting statutes by which the Government had simply taken title without regard to any other assignments. Indeed, Roche's argument is an unsupported reversal of the principle of *expressio unius est exclusio alterius*. OB 34. The failure to discuss any need for an assignment when so many other requirements were being specifically imposed strongly indicates that no such requirement exists.

**C. Roche's Reading Of 37 C.F.R. § 401.14(a), ¶ (f)(2) As Requiring Employee Agreements To Assign Inventions To The Contractor Is Plainly Wrong**

Roche also purports to find a requirement that contractors secure assignments of title from their inventors in vague language from the standard patent rights clause, 37 C.F.R. § 401.14(a). RB 42. That language is found in ¶ (f)(2), which requires the contractor to demand a written agreement from its technical employees:

to disclose promptly in writing ... each subject invention made under the contract in order that the contractor can comply with the disclosure provisions of [37 C.F.R. § 401.14(a), ¶ (c)], and to execute all papers necessary to file patent applications on subject inventions and *to establish the government's rights in the subject inventions.*

37 C.F.R. § 401.14(a), ¶ (f)(2) (emphasis added).

Roche suggests, and its *amici* directly assert, an analogy between the last clause of this provision, requiring that employees agree to “execute all papers necessary ... to establish the Government’s rights in subject inventions,” and the form agreement under the pre-Bayh-Dole IPA clauses, through which contractor employees were required “promptly [to] report and assign all subject inventions.” RB 42; *see* AAUP Br. 10-11; BIO Br. 16-17; Intel Br. 6-7, 16-17; IPO Br. 17 n.10; PhRMA Br. 10-11.

This is wrong for several reasons. First, by its terms, ¶ (f)(2) only applies where a “subject invention” already exists. Thus it cannot possibly be the source of a duty on inventors to make assignments to contractors, without which Roche says there is no “subject invention” triggering the Act.

Second, whereas the IPA agreements expressly mandated non-clerical workers to “assign all subject inventions,” *see* RB 42, ¶ (f)(2) omits that language, and instead refers to executing papers necessary to “establish the government’s rights in the subject inventions.” The decision to omit previous agreement language that expressly required an assignment is hardly an indication the drafters intended to maintain that requirement. *Brewster v. Gage*, 280 U.S. 327, 337 (1930).

Third, Roche’s divined meaning is especially odd given that, elsewhere, when 37 C.F.R. § 401.14 requires conveyance of title, it is unmistakably clear—as one would expect. *See, e.g.*, 37 C.F.R. § 401.14(a), ¶ (d) (“The contractor will convey ... title to any subject inventions”); ¶ (f)(1)(ii). Likewise, it refers to the “inventor” when the inventor is at issue. *See, e.g., id.* § 401.14(a) ¶¶ (c)(1); (k)(2); (k)(3);

(I)(2)(B). Vague language buried in a regulation would be a strange way to require an assignment of title, unmentioned in the statute and without which the Act is supposedly rendered wholly inapplicable.

Finally, ¶ (f)(2) should be read in context with the statutory provisions it is designed to implement, not by reference to prior regulations that the Act superseded. So viewed, ¶ (f)(2)'s requirements plainly refer to rights and duties actually set out in § 202(c). Paragraph (f)(2)'s first clause, requiring that employees agree in writing to “disclose promptly” the making of any subject invention, plainly supports the contractor's own disclosure duty in § 202(c)(1). Likewise, the next clause, demanding that employees agree “to execute all papers necessary to file patent applications,” is in direct service of § 202(c)(3)'s requirement that the contractor do just that.

The clause at issue, demanding a further agreement to “execute papers necessary ... to establish the Government's rights in the subject inventions,” similarly finds direct antecedent in the very next provisions of the statute, §§ 202(c)(4), (6). Those sections assure the Government a fully paid up license and related rights, and require that the patent specification include a statement of the Government's support and rights. The final phrase of ¶ (f)(2) references documents necessary to secure these rights, and perhaps other incidental documents. *See* United States Patent and Trademark Office, Forms, <http://www.uspto.gov/forms/index.jsps>.

In short, ¶ (f)(2), whose application is only triggered by the existence of a subject invention, certainly is not the source of any legal requirement that contractors secure assignments of title, as Roche

says is necessary before there can be a subject invention in the first place.

**D. Roche's Construction Directly Undermines  
The Statute's Express Objective To Protect  
The Interests Of The Government**

Roche and its *amici* have no answer to the fact that their reading critically undermines Bayh-Dole's major objective of "ensur[ing] 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; *see* OB 48-51; U.S. Br. 31-33; CVSG Br. 18.

The statute seeks to protect these interests by allowing the Government to initially take title based on enumerated special circumstances, § 202(a)(i)-(iv); to later "receive title" in other instances, § 202(c)(1)-(3); and also to "march-in" and confer rights upon another, § 203. The Government is thereby enabled to enforce an array of statutory and contractual duties to be carried out by the contractor, including, among others, the use of royalties only for education and research, § 202(c)(7)(C), and honoring the preference for United States manufacture, § 204. If a funded inventor working for a contractor had the power to independently assign an ownership interest in the invention to a third party, these avenues of Government recourse to enforce its interests would be gravely undermined.

Indeed, Roche's only suggested solution where an inventor has transferred title to a third party is "for the Government to sue [the contractor] for breach of contract, including, if appropriate, reclaiming the amount funded." RB 54. But how is there even a

breach of contract if there is no “subject invention”? *See supra* at 12. In any event, this cumbersome, inefficient, and, here, likely time-barred remedy, is certainly not one of the specific Government remedies carefully set out in the Act.

**E. Roche’s Arguments Raising The Specter Of Due Process Violations, Takings From Third Parties, And Diminished Collaboration, Rest On A Strawman Reading Of The Act That No Party Endorses**

Respondent and its *amici* devote significant briefing to unsubstantiated assertions that bad things will happen if the Act is read as its fair meaning in context would indicate. Upon examination, these assertions have no basis under the construction of the Act that Stanford and the United States urge the Court to adopt. Even if they did, these policy arguments are more appropriately addressed to Congress, not this Court.

Respondent argues that the statute cannot affect the rights of third parties because it contains no procedural protections of their rights, RB 28-31, and that Stanford’s reading of the statute would work an unconstitutional taking of property from third parties and a denial of due process, RB 43-46. It further argues, largely based on these concerns, that reading the statute as Stanford does will substantially “chill innovative collaboration.” RB 50-52. Roche’s *amici* join the chorus trumpeting this parade of horrors. BIO Br. 26; Intel Br. 18-22.

1. The statute expressly defines the rights of a funded contractor’s employee-inventors, and there can be no serious contention that this prospective definition constitutes a substantive violation of rights.

Given that the inventor's possibility of securing title under the clearly defined statutory scheme is remote and entirely within the Government's discretion, § 202(d), the absence of an explicit statutory legal remedy to secure it is hardly surprising.

2. As to unrelated third parties whose rights Roche and its *amici* insist will be imperiled by Stanford's reading of the Act, the statute provides no procedural protections for those parties because it does not deprive them of any rights.

For example, Roche and its *amici* contend that Stanford's reading would take away vested rights of third parties—*e.g.*, private businesses—who are assignees of independent co-inventors who did not work for the contractor or utilize federal funding. RB 43-46; IPO Br. 18-21; PhRMA Br. 25. But, as Stanford's *amici* AAU noted, if Cetus employees had been co-inventors of the patents-in-suit, the Act would not govern disposition of the Cetus co-inventors' interest in the inventions. AAU Br. 23-24. This issue has no bearing on the outcome here, since there were indisputably no Cetus co-inventors, but Stanford entirely agrees with AAU, whose brief speaks for scores of universities. A funded contractor's ownership interest under Bayh-Dole is limited to the interest arising from the inventive activities of its own funded employees. Thus the Act does not give a federal contractor a title that overrides that of independent, unfunded co-inventors—who may often work for private companies. The plain-meaning interpretation

Stanford advances thus fully protects independent co-inventors.<sup>4</sup>

This conclusion rests on the statute's text. Just as an "invention of the contractor" is one made by the contractor's employees, *supra* at 5-7, an invention co-invented by employees of a private company working without federal funding is also an invention of that inventor and that company. Thus, an invention may be both "of the contractor" and "of" another who is independently responsible for co-inventing it, in which event the contractor's rights derived under the statute must co-exist with the co-inventor's right to an equal and undivided interest in the invention.

This reading of the statute is required by the language of § 202(e), which recognizes that where Government employees are co-inventors with a funded contractor's employees, the federal agency may, "for the purpose of consolidating rights in the invention," assign to the contractor the title it receives from its own employee. By providing for this eventuality, this section shows that the contractor does not otherwise get title under the Act to the interest arising from the federal employees' co-inventorship. No reason appears why co-inventors in private industry should not be treated by the Act in the same way that it expressly deals with Government co-inventors.

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<sup>4</sup> Roche's assertion that this conclusion is "irreconcilable with Stanford's argument" is baffling. RB 36. Stanford was able to perfect its title and to secure complete ownership of the patents-in-suit only because all co-inventors were Stanford employees.

Thus, Respondent’s proposed lodgings, reflecting that Stanford itself “shares ownership with other private entities of numerous patents” to which Bayh-Dole applies, are unsurprising. RB 35 & n.13. That result follows directly where privately funded individuals associated with corporations are co-inventors of the inventions, making the corporation a co-owner with Stanford.

3. Roche’s *amici* raise a similar alarm that Bayh-Dole may be a means of appropriating inventions originally conceived without Government funding by private researchers, and later reduced to practice by a funded contractor. BIO Br. 7, 21-22; Intel Br. 19-20. But as Stanford noted, OB 32 n.11, a contractor’s employees are only co-inventors if they play a part in conception, and a privately conceived invention does not become the property of a university when the university’s employees later reduce the invention to practice with the aid of federal funding. While the disjunctive language of § 201(e)—requiring that the invention be “conceived or first actually reduced to practice” in the course of funded work—may be satisfied, there is no “invention of the contractor” if no employee plays a part in conception.<sup>5</sup>

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<sup>5</sup> In a misdirected tangent, Roche suggests that the district court erred in finding sufficient proof that the inventions were produced “in the performance of work under a funding agreement.” *See* RB 30-31. But the Federal Circuit did not address that issue, and it is not before this Court. Roche presses this issue on the erroneous premise that Stanford’s reading of the Act allows a federal contractor to elect title and “divest third parties of intellectual property rights.” RB 31. Because Roche never had any rights to the inventions, it is not



4. For these reasons, Roche and its *amici* offer no basis for asserting that Stanford's reading of the Act will somehow impair collaboration between universities and non-funded private companies.

First, increased certainty of the contractor's title to federally funded inventions will make potential licensees more willing to purchase an exclusive or other license. *See* NVCA Br. 7; BIO Br. 20. Roche's interpretation of the Act creates uncertainty because it permits enforcement (sometimes years later) of an undisclosed assignment of future rights in ongoing federally funded research. Indeed, Roche and some *amici* acknowledge this effect, but dismiss it by noting that "such risks are not unique to federal contractors," RB 47, and that such uncertainty "is not the end of the world," AIPLA Br. 30-31.<sup>6</sup>

Second, greater certainty of the contractor's title will also make it easier, not harder, for universities and industry to enter into reliable collaboration agreements to facilitate inventive research. Certainty of the contractor's title makes it possible for industry collaborators to contract only with the contractor, and not also with all individual

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(continued...)

being "divested" of any rights by Stanford's election of title, whatever level of proof is required.

<sup>6</sup> It is no answer to require warranties. *See* PhRMA Br. 18-22. The greater the uncertainty of title, the less likely universities will be to enter into technology transfer agreements warranting clear title. Also, such warranties may be a poor substitute for certainty in the eyes of a technology company seeking a sound license, not a warranty-enforcing lawsuit.

researchers. Such university-industry arrangements commonly contemplate that the collaborating private company will have a right at some price to an exclusive or other license—as the NIH interpretive guidance envisions, OB 54, and as was actually negotiated in this case. AAU Br. 25. Thus, increased certainty that the university actually will have clear title and the ability to deliver such a license can only make such arrangements more reliable, thus giving a sounder basis for collaboration “between commercial concerns and non-profit organizations.” 35 U.S.C. § 200.

## **II. EVEN ASSUMING CONTRACTORS MUST SECURE AN ASSIGNMENT, STANFORD GOT TWO SUCH ASSIGNMENTS, AND THE ACT MUST AT LEAST BAR FUNDED EMPLOYEE-INVENTORS FROM ASSIGNING AWAY THE UNIVERSITY’S PROSPECTIVE BAYH-DOLE RIGHTS**

For the reasons set forth above, the Bayh-Dole Act creates a conditional right of funded contractors to take title to the inventions made by their employees with the aid of federal funding that does not depend upon the contractor first securing an assignment. This Court’s recognition of that fact is of great importance because the uncertainties caused by a contrary ruling would severely impair achievement of the Act’s objectives.<sup>7</sup>

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<sup>7</sup> In addition to the critical uncertainty about the reliability of the contractor’s title to the funded inventions, requiring an assignment would raise a new layer of interpretive questions. Does the Act create a legal obligation on funded contractors to secure inventor assignments to funded inventions? *E.g.*,

However, even a ruling that contractors must get an assignment of title in order to trigger the Act would not justify affirming the decision below. For Stanford secured an assignment of future rights—*twice*—which Dr. Holodniy executed in 1988 and 1995. Pet. App. 41a, 94a, 112a. With such an assignment in place, the Bayh-Dole Act would mean very little indeed if it did not bar the employee-inventor working under federal funding from making a later effective assignment of the same rights to an independent third party, thus substantially impairing the statutory interests of both the Government and the contractor.

This conclusion is most emphatically clear on the facts of this case, where the two federal grants on which Stanford's Bayh-Dole title depends were in place during 1989, and supported Dr. Holodniy's research at Cetus. The JID article—which Cetus approved for publication, JA 38, and which Roche concedes represented the “culminat[ion]” of Dr. Holodniy's Cetus visits, RB 8—expressly identifies the two grants as support for the published research: AI-27666 for AIDS-related clinical trials,

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(continued...)

PhRMA Br. 10-11. If so, does it also require such inventors to make such assignments, and what happens if they fail to do so? *See, e.g., Heinemann v. United States*, 796 F.2d 451, 452, 456 (Fed Cir. 1986) (Government still has title despite its own employee's failure to make a required assignment); AAU Br. 7-9. Perhaps most importantly, how can the Government secure sufficient rights to protect and enforce its statutory interests? *See supra* Section I.D; Pet. App. 19a.

and AI-27762 for establishing a Center for Aids Research. JA 135, 98-99.

Ignoring the JID article, Roche now baldly and repeatedly denies that Dr. Holodniy's research while he visited at Cetus was federally funded. RB 6-7, 8, 12, 13, 15 n.7, 16, 21 n.8, 36, 44-45. It does so without citing any evidence, and relying only on out-of-context quotations from Stanford's Federal Circuit briefing. RB 6-7 & n.1. But these quotations are from arguments addressing the point at which the critical inventive work began at Stanford, not the point at which federal funding began, and Roche's attempted inference is simply not credible. Moreover, what is explicit in the JID article is confirmed by the public record. NIH, Project Report, Project Numbers 27666, 27762, <http://bit.ly/Redirect-To-NIH-Website-With-Grant-27666-History>, <http://bit.ly/Redirect-To-NIH-Website-With-Grant-27762-History> (NIH sites showing grants began in 1988); *see also* JA 28, 96, 98. Both courts below held that Dr. Holodniy visited Cetus to advance his research at Stanford, Pet. App. 18a, 63a-64a, so these grants applied to his activities there.

Thus, Dr. Holodniy's research at Cetus was conducted when Stanford had equitable rights in the fruits of his research based on the 1988 agreement to assign, and also had an expectation of receiving future title under the Bayh-Dole Act because the work was already federally funded. Accordingly, even assuming that the Act depends on an assignment from the inventor to trigger its application, the Act must at least mean that its policies may not be directly frustrated by a further assignment of rights to a third party. Such an

assignment is in derogation of both the prior assignment of rights to Stanford and the express policies of the Act.

The conclusion that Dr. Holodniy's purported assignment to Cetus should have no legal effect is buttressed by equity's substantial role in the determination of patent rights, especially regarding rights in inventions that do not presently exist. OB 59-60. As *amicus* Shukh explains, both the Cetus assignment and Dr. Holodniy's earlier agreement to assign Stanford rights in future inventions transferred equitable but not legal title to the yet-to-be-created inventions.<sup>8</sup> In evaluating the equities to determine which ownership claim should be recognized, the Act's express objective to direct title to the funded contractor must be given paramount significance.

Other equities also weigh heavily in favor of Stanford and against giving legal effect to the Cetus assignment. One, of course, is Stanford's first-in-time receipt of an equitable interest. Another is that

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<sup>8</sup> *Amicus* Shukh's brief shows that this Court has never approved of the Federal Circuit's case law holding that equitable title can automatically convert into legal title, Pet. App. 13a; see *Filmtec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991), and that holding is contrary to longstanding authority. See Shukh Br. 18-24. Indeed, the statutory authority for assignment of patent rights permits assignment "in law" of only present interests, *i.e.*, "patents" or "applications." 35 U.S.C. § 261. Any future interest, such as Cetus supposedly received, can be assigned, if at all, only in equity. *Mitchell v. Winslow*, 17 F. Cas. 527, 531 (C.C.D. Me. 1843) (Story, J.) (A present assignment of future rights "may be enforced as such a [present] contract in rem, in equity.").

neither Cetus nor Roche asserted its alleged rights for more than fifteen years, and then only as a defense to litigation after the time to pursue an affirmative ownership claim had lapsed.

Not only has Roche's delay undone certainty and rendered relevant evidence unavailable, *e.g.*, Dkt. 95-4, at 246:16-248:23; *cf.* JA 43, but it also has no justifiable basis. Roche's attempted explanation is a non sequitur. The fact that Roche "commercialized PCR-based testing kits," RB 57, in no way preserved its alleged ownership rights under the assignment or counters the injustice and disruption resulting if Roche could assert title now.

In short, even if the Act required contractors to secure inventor assignments of title, Stanford did that, and Dr. Holodniy's purported assignment to Cetus would still be ineffective to convey title to the patents-in-suit to Roche.

**CONCLUSION**

The decision below should be reversed.

Respectfully submitted,

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