

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.,
ROCHE DIAGNOSTICS CORPORATION, and
ROCHE DIAGNOSTICS OPERATIONS, INC.,
Respondents.

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

**BRIEF OF *AMICI CURIAE* WISCONSIN ALUMNI
RESEARCH FOUNDATION ET AL. IN SUPPORT OF
STANFORD'S PETITION FOR CERTIORARI**

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STATEMENT OF INTEREST*

Amici have no interest in the patents-in-suit or the outcome of this particular lawsuit. *Amici* are, however, gravely concerned that the Federal Circuit's decision will cloud universities' title to thousands of federally funded inventions, contrary to Congress's intent and the public interest.

At stake here is who owns the rights to the inventions generated by the tens of billions of dollars that Congress annually appropriates to support academic research. Those funds enable critical research in many fields, including medicine, biotechnology, applied mathematics, and electrical engineering. The resulting inventions have charted new approaches to critical problems, founded entire industries, and improved millions of lives throughout the world. In the health field, for example, fortifying foods with vitamin D helped eradicate rickets, the blood thinner Coumadin® has enabled patients to avoid and survive strokes and heart disease, and magnetic resonance imaging (MRI) has made it easier to diagnose and treat many ailments.

Owning inventions enables universities to enjoy returns if those inventions are commercialized, and royalties from licenses have contributed significantly to universities' research and educational missions.

* All parties have consented to the filing of this brief. No party or counsel for a party authored any portion of this brief or made a monetary contribution intended to fund its preparation or submission. No one other than *amici*, their members, and their counsel have made such a monetary contribution. *Amici* notified respondents' counsel of their intention to file this brief more than 10 days before its due date.

But *amici's* interest goes far beyond that. As shown below, the Bayh-Dole Act of 1980 granted universities and other nonprofit research institutions initial title to federally funded inventions in order to promote the transfer and commercialization of federally funded research for the benefit of the public.

SUMMARY OF ARGUMENT

The Federal Circuit's decision is wrong and, if not reversed, will return the world to the pre-1980 era when uncertainty over ownership of federally funded inventions impeded their transfer and commercialization. If, as the Federal Circuit has held, individual researchers initially own federally funded inventions and may unilaterally transfer their interests to third parties, the Bayh-Dole Act will have been negated and decades of public benefits from transfer of university-developed research will be in jeopardy.

Review should be granted now and should not be deferred until another case. The effects of the decision below will be vast and immediate. The Bayh-Dole Act was designed to clarify title to federally funded inventions. With this decision, the Federal Circuit has clouded the title to a host of inventions, inevitably discouraging licensing and commercialization as well as spawning needless litigation. Because the Federal Circuit has nationwide jurisdiction, the effect will be nationwide and a split in the circuits is unlikely to develop.

At a minimum, the Court should call for the views of the Solicitor General so that the federal government can confirm the errors in the court of appeals' construction of the statute and the importance of the issues to both the government and the nation.

ARGUMENT

A. The Court of Appeals Misunderstood and Misconstrued the Bayh-Dole Act

This case turns on the Bayh-Dole Act, 35 U.S.C. §§ 200 et seq., and its effect on who owns rights in inventions made with federal funding. The Federal Circuit held that an individual inventor (Holodniy) owned initial title to a portion of an invention that he and other Stanford employees jointly made using federal funding, and that the inventor could and did transfer those rights to a private company (Cetus, predecessor to Roche) because neither the funding agency (NIH) nor the contracting research institution (Stanford) had claimed patent rights previously. Pet. App. 18a–21a. Although the Federal Circuit recognized that Stanford disclosed the invention and claimed title within the statutory time period, the court held that “claiming title under Bayh-Dole does not override prior assignments.” *Id.* at 21a.

The Federal Circuit fundamentally misunderstood the Bayh-Dole Act. As shown below, the statute is clear: title to federally funded inventions originally vests in the contracting *research institution*, not the inventor or third-party collaborators. In this case, Stanford timely disclosed the invention to the funding federal agency and timely elected to retain its statutory ownership rights. Holodniy had no rights to assign to Cetus, and Stanford had standing to sue Roche for infringement.

Before 1980, the federal government—not individual inventors and not contracting research institutions—owned default rights to inventions made using federal research funds. Different agencies had

different policies about transferring those rights, and the resulting lack of clarity and conformity hampered commercialization of federally funded research. *See* S. Rep. No. 96-480, 96th Cong., 1st Sess. 2-3 (1979) (“Senate Report”) (noting dozens of conflicting agency policies and that only 4% of federal patents had been successfully licensed; concluding that “ineffective patent policies regarding ownership of potentially important discoveries” were preventing “deliver[y of] new inventions and processes from [federal] research and development programs to the marketplace where they can benefit the public”).

The Bayh-Dole Act, adopted in 1980, changed the landscape by clearly vesting ownership of inventions made in whole or in part with federal funds in the contracting institutions. Individual inventors are entitled to a share of any royalties, but they cannot own title to the invention unless the institution waives title and the government agency consents.

Inventions subject to the Act include “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a [federal] funding agreement,” such as a grant. 35 U.S.C. § 201(e). Under section 202(a), ownership rights to all such “subject inventions” are allocated to contracting research institutions if those institutions elect to “retain title” to them:

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).¹

Section 202(a) nowhere states or suggests that individual inventors own initial title or can defeat the contracting research institution's right to retain title. The statute provides that the research institution may waive title by not disclosing the invention, by not electing in writing to retain title to it, or by not filing a timely patent application. *See* 35 U.S.C. § 202(c). Moreover, the statute gives the federal government certain license and "march-in" rights and limits assignments. *See* 35 U.S.C. §§ 202(c), 203(a), 204. But the institution's title is not subject to rights or claims of individual inventors.

Other provisions of the Bayh-Dole Act confirm that research institutions own original title to the fruits of their federally funded research and that individual inventors have only contingent, secondary rights if the institution waives its ownership rights. Under 35 U.S.C. § 202(d), individual inventors may claim patent rights *only* if the contracting institution does not elect to retain title *and* the funding agency then consults with the institution and grants the inventor's request:

If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provi-

¹ Section 202(a) contains a proviso allowing a federal agency to specify otherwise in a particular funding agreement if one of four specific circumstances applies. Those circumstances are rare, however, and irrelevant to this case.

sions of this Act and regulations promulgated hereunder.

Moreover, under 35 U.S.C. § 202(c)(7)(B), institutions are to “share royalties with the inventor,” confirming that the basic right to royalties belongs to the institutions. *See also* 35 U.S.C. § 202(c)(7)(C) (contractor expected to use royalties remaining after expenses, including such payments to inventors, for the support of scientific research or education).

Furthermore, Congress dictated that funding agencies must approve all assignments of rights in inventions made under contracts with nonprofit organizations such as Stanford, thereby setting a high bar to assumption of ownership by others. *See* 35 U.S.C. § 202(c)(7)(A) (excepting only assignments to invention management organizations). The governing regulations confirm that “the ownership provisions ... remain applicable in any invention ‘conceived or first actually reduced to practice in performance’ of the project,” regardless of whether other sources provided supplemental research funding. 37 C.F.R. § 401.1. The statutory limits on assignments would be pointless if, as the Federal Circuit has held, individual inventors owned initial title and could freely assign away their ownership rights through side agreements that neither the research institution nor the funding agency has reviewed and approved.

Finally, the legislative history of the Bayh-Dole Act confirms that it was intended to grant initial title to contracting research institutions, not individual inventors. The Senate Report accompanying the Act noted that “Section 202 establishes the basic framework for the disposition of rights in [federally

funded] inventions” and that “Section 202(a) provides that as a normal rule small business firms and nonprofit organizations are to have the *right to elect to retain worldwide ownership* of their inventions by making an election within a reasonable time after they disclose the invention.” Senate Report at 31 (emphasis added); *see also id.* at 29 (bill would “allow [university and nonprofit] contractors to retain patent rights on these discoveries while allowing the funding agencies to have free access to them”). Later, the Senate Report included findings of the Congressional Budget Office, which summarized the bill as “*automatically grant[ing] small businesses and non-profits title to inventions arising from Government-supported research unless the contracting agency could justify, through specified procedures, holding title to the invention.*” *Id.* at 36 (emphasis added).

In short, initial patent rights in federally funded research belong to the funded contractors. Individual researchers and third parties may not bypass that allocation unilaterally. That principle is clear from both the text of the statute and its legislative history, and that principle was understood and accepted in the research community until this case.²

² Contrary to the Federal Circuit’s suggestion, *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1352–53 (Fed. Cir. 2007), merely recognized that a party may waive title to an invention. The court stated that “title remains with the named inventors or their assignees” until the government chooses to void it for non-compliance with the Act. *Id.* But the reference to “named inventors” reflected the unusual facts: the researcher there obtained title after (1) the university had abandoned the invention and (2) the funding agency had granted his request for title under 35 U.S.C. § 202(d). *Id.* at

B. Ownership of Patent Rights to Federally Funded Inventions Is a Question of Great Importance

The Bayh-Dole Act is vitally important to our economy. Indeed, the *Economist* once called it “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century,” one that “helped to reverse America’s precipitous slide into industrial irrelevance.” *Innovation’s Golden Goose*, THE ECONOMIST (Dec. 12, 2002).

Federal agencies such as the National Institutes of Health, the National Science Foundation, and the Office of Naval Research sponsor much of the research performed at universities today. Before Bayh-

1351. The court nowhere suggested that title had not vested initially with the university.

University of Pittsburgh v. Townsend, No. 3:04–CV–291, 2007 WL 2263079 (E.D. Tenn. Aug. 3, 2007), *aff’d*, 542 F.3d 513 (6th Cir. 2008), also cited by the Federal Circuit, also sheds no light. It was an unpublished trial court decision that addressed a different issue (the statute of limitations) and cursorily distinguished the district court’s decision in this case on a variety of grounds. The court did not analyze the Bayh-Dole Act.

Finally, *Fenn v. Yale University*, 393 F. Supp. 2d 133 (D. Conn. 2004), dealt with whether the Bayh-Dole Act preempted a university’s state law tort counterclaims against a former faculty member. In passing, the court observed that the Act’s “primary purpose” was “to regulate relationships of small business and nonprofit grantees with the Government, not between grantees and the inventors who work for them.” *Id.* at 141–42. The point, however, was that the Act was not designed to benefit individual researchers and thus did not preempt institutions’ claims against them.

Dole, title to the inventive fruits of that research was often unclear and subject to the vagaries of agency policies. When title was clear, it was often held by funding agencies that were ineffective at licensing the inventions and fostering their commercialization. See Senate Report at 2–3.

By granting research institutions clear initial title to federally funded inventions, Congress encouraged licensing and commercialization of those inventions. The result was a boom in the transfer of the results of federally supported research through patenting and licensing by universities, the establishment of technology transfer offices at many institutions, and the development of public-private partnerships around the country.³ University-owned inventions have become a major engine of economic growth. Indeed, a recent report estimates that university licensing contributed between \$108.5 and \$457.1 *billion* to the U.S. economy from 1996 to 2007.⁴ In contrast, little licensing of federally funded inventions occurred before 1980. Senate Report at 2.

³ See generally David Roessner et al., *The Economic Impact of Licensed Commercialized Inventions Originating in University Research, 1996–2007: Final Report to the Biotechnology Industry Organization* (Sept. 3, 2009) (“BIO Report”); Howard Bremer et al., *The Bayh-Dole Act and Revisionism Redux*, 78 PAT., TRADEMARK & COPYRIGHT J. 483 (Aug. 14, 2009). “[G]rowth during the 1970s in patenting, licensing, licensing income, or in the establishment of independent technology transfer offices, was dwarfed by the surge in all of these activities after 1981.” BIO Report, *supra*, at 18 (citing David C. Mowery, *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL’Y 99, 104 (2001)).

⁴ BIO Report, *supra* note 3, at 34.

The Federal Circuit's opinion threatens to undermine these advances. The success of the Bayh-Dole Act stems from its carefully crafted and balanced statutory scheme: universities and other research institutions receive ownership of federally funded inventions in exchange for a commitment to use their best efforts to commercialize the inventions for the benefit of the public. The fundamental premise of the statute—that clarifying who owns and can license federally funded inventions will encourage their development and exploitation—is now in jeopardy.

Simply put, the Federal Circuit's opinion eliminates the certainty of title that has been the cornerstone of university-industry relationships under the Bayh-Dole Act for nearly 30 years. Until this case, research institutions and corporations alike understood that title to federally funded inventions belongs to the contracting institution unless the institution has disclaimed ownership or failed to follow the terms of the statute. Indeed, "[t]he most significant feature of the Act was that it changed the presumption of title to any invention made ... through the use, in whole or in part, of government funds from the government to the contractor-grantee."⁵ Under the court of appeals' decision, that presumption of title has disappeared: title may belong to individual inventors or to whomever those inventors may have assigned it (advertently or inadvertently).

⁵ Howard Bremer, *University Technology Transfer: Evolution and Revolution*, in COUNCIL ON GOVERNMENTAL RELATIONS, 50TH ANNIVERSARY J. OF PAPERS 13, 20 (1998).

The practical problems that will result from the Federal Circuit's misreading of the Bayh-Dole Act are obvious. Consider a case involving four university employees working on federally funded biotechnology research. One visits the laboratory of a private company and signs an access/confidentiality agreement addressing invention rights. The second acquires research equipment from another company and signs a form purporting to assign ownership of any inventions conceived or made through the use of the equipment to that company. The third obtains supplemental research funding under a contract with a third company that also addresses intellectual property rights. The fourth assigns any intellectual property rights that she may own to a start-up company in which she holds equity.⁶

Under the Federal Circuit's opinion, it will be virtually impossible to know who has what rights to exploit the invention because any of the inventors' agreements could override the Bayh-Dole Act's assignment of ownership to the university. If a valuable invention were developed, the result would be a battle of the forms, with lawyers parsing contracts to determine who transferred what rights and whether such assignments technically occurred before or after the employees assigned ownership to the university under the terms of their employment contracts. Alternatively, and more likely, nothing valuable would be developed because everyone would conclude that title to the invention was too uncertain or too

⁶ This hypothetical may seem extreme, but it is nonetheless representative. Most universities now encourage faculty members to consult with the private sector, and such collaborations are beneficial for society as a whole.

splintered to justify investing in refining and commercializing the invention. The Bayh-Dole Act was designed to prevent that result.

In fact, this hypothetical is optimistic because it assumes full information. Historically, a company wanting a license understood that it needed to contract with the university that received the federal funds. The university and industry could rest assured that no side deals or unknown agreements would affect the rights negotiated. For example, an exclusive licensee knew that it was the only private party with rights to exploit the invention. Under the decision below, however, neither the university nor its licensee can know whether a third party will claim a license or superior ownership rights based on some obscure agreement that neither knew existed. Again, the result would be the uncertainty and concomitant disincentives for university-industry partnerships that Congress aimed to avoid.

In short, “[t]he certainty of title in the universities to inventions made with government funds afforded by the Bayh-Dole Act ... provided the major impetus to new and expanding university-industry relationships.”⁷ The Federal Circuit’s decision would destroy that certainty and roll back decades of progress. Equally troubling, the court of appeals’ reading would allow private companies to gain the benefits of federal funds (in effect a taxpayer subsidy), yet avoid the conditions that the Act imposes on research institutions in the public’s interest.

It is no answer to suggest that universities can avoid such results by policing employees and forbid-

⁷ H. Bremer, *supra* note 5, at 21.

ding them from signing agreements assigning patent rights. Even if faculty remembered the edict in their haste to pursue research, most are not intellectual property experts. It is impractical and impracticable to expect them to understand nuances of legalese.

This case is a good example. Signing a visitor's confidentiality agreement does not obviously implicate the legal rights between a researcher and his or her university, much less the university's ability to obtain and license a patent on resulting inventions. Moreover, requiring universities to police faculty-industry partnerships would drain scarce resources, and effective policing would inevitably inhibit or at least delay fruitful collaborations. Nothing in the legislative history suggests that Congress intended such inefficient transaction costs, or that unauthorized acts by researchers would undermine invention management by universities.

Nor is it any answer to say that universities should simply draft employment agreements that presently convey rights rather than terms requiring faculty members to execute assignments after each invention is made. To begin with, that would still leave decades of inventions whose ownership would remain clouded by the panel opinion. As Stanford notes (Pet. 17–18), many universities' standard faculty employment contracts contain "agree to assign" language. In any event, except as trumped by federal laws such as the Bayh-Dole Act, patent ownership is a matter of state law. No one knows for sure whether the courts would uphold the enforceability of mandatory employment contracts that purport to assign ownership of inventions that do not exist at the time. Universities may face a Catch-22.

Finally, apart from its economic consequences, the panel opinion threatens academic freedom. When universities license their patent rights, they ordinarily preserve the right to conduct further research. Under the decision in this case, however, a company may entice a researcher to assign away ownership rights, obtain a patent, and then dictate whether that researcher—or anyone else—may continue to conduct research in the field. That is so because the Federal Circuit has narrowly construed the “experimental use” exception to patent infringement, reasoning that “research projects with arguably no commercial application whatsoever” can infringe merely because they “educat[e] and enlighten[] students and faculty” and “increase the status of the institution.” *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002). The specter of interference with academic research is yet another reason why this Court should ensure that title to federally funded inventions belongs initially to research institutions and not to individual researchers.

C. Review Needs to Be Granted Now and Cannot Await Another Case

The Court may be tempted to wait and see how the consequences of the decision play out. *Amici* urge the Court not to do so.

To begin with, this case presents an appropriate vehicle to decide the question presented. The legal issue is squarely and starkly presented, and the judgment is final.

Second, delay will only cause the damage to mount. The effects of the Federal Circuit’s decision have been great and immediate. As discussed above,

the Bayh-Dole Act was designed to clarify research institutions' title to federally funded inventions. This decision now re-clouds the title to thousands of patents, many of which have already been licensed and commercialized. More litigation over ownership of existing patents and standing to sue on them will inevitably result.⁸ Worse, doubts about universities' title to current and future patents will dissuade licensees and investors, inhibiting the technology transfer and university-industry partnerships that Congress strove to promote. The effects will be doubly pernicious because those effects will be largely invisible: when title is uncertain, transactions simply will not happen.

Finally, further "percolation" in the lower courts will be minimal. Litigation will normally arise in conjunction with patent lawsuits, and the Federal Circuit has exclusive and nationwide jurisdiction over all actions arising under all statutes relating to patents. *See* 28 U.S.C. §§ 1295(a)(1), 1338(a). The Federal Circuit has denied rehearing *en banc*, and it is unlikely to change its mind in the near future.

There is no reason to wait.

D. The Court Should at Least Call for the Views of the Solicitor General

For the reasons discussed above, *amici* submit that this Court should grant certiorari and reverse without further ado. Nevertheless, if the Court has any doubt about whether review is warranted, *amici*

⁸ Litigation over ownership of federally funded inventions was rare before this case because research institutions' ownership rights were so well recognized.

urge the Court to call for the views of the Solicitor General, who can confirm the legal errors and practical consequences of the decision below, including the consequences for the federal government itself.

The federal government has an obvious and substantial interest in who owns the rights to exploit federally funded inventions. Federal agencies spend tens of billions of dollars each year supporting academic research.⁹ Moreover, the Bayh-Dole Act itself confirms the federal interest in ensuring that inventions enabled by federal funds inure to the public good. *See* 35 U.S.C. § 200 (stating Congress’s policies and objectives).

Furthermore, although the court of appeals purported not to decide whether an individual inventor’s assignment may override the government’s rights under the Bayh-Dole Act (*see* Pet. App. 20a n.1), there is no basis to distinguish between the statutory rights of agencies and research institutions. For example, if an individual inventor holds initial title in a federally funded invention and assigns away his or her rights, leaving the research institution with no title, then the federal government likewise will have no paid-up license under 35 U.S.C. § 202(c)(4), no march-in rights under 35 U.S.C. § 203(a), and so forth. The Court should at least consult the Solicitor General before countenancing that dangerous result.

⁹ *See* National Science Board, SCIENCE AND ENGINEERING INDICATORS 2010, at 5-9 & appendix table 5-2, *available at* <http://www.nsf.gov/statistics/seind10/> (reporting that the federal government “accounted for about 60% of the \$51.9 billion of R&D funds expended by universities and colleges in FY 2008”).

CONCLUSION

Stanford's petition for a writ of certiorari should be granted. At a minimum, the Court should call for the views of the Solicitor General.

Respectfully submitted,

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