

No. 09-1159

JUN - 5 2010

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,
ROCHE DIAGNOSTICS OPERATIONS, INC.,
Respondents.

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

PETITIONER'S REPLY BRIEF

RICARDO RODRIGUEZ
Counsel of Record
STEPHEN C. NEAL
LORI R.E. PLOEGER
MICHELLE S. RHYU
BENJAMIN G. DAMSTEDT
COOLEY LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, California 94306
(650) 843-5000
rr@cooley.com

June 5, 2010

Blank Page

TABLE OF CONTENTS

INTRODUCTION 1

I. ROCHE OFFERS VIRTUALLY NO DEFENSE ON THE MERITS OF THE FEDERAL CIRCUIT’S CONSTRUCTION OF THE BAYH-DOLE ACT. 2

II. THIS COURT’S REVIEW IS URGENTLY NEEDED. 4

 A. Roche Cannot Minimize the Importance of the Federal Circuit’s Decision. 4

 1. Roche focuses on irrelevant details while ignoring the broad implications of the Federal Circuit’s decision. 4

 2. A research institution’s rights flow from the statutory framework of the Bayh-Dole Act, not contractual assignment language. 5

 3. The problems created by the Federal Circuit’s decision cannot be avoided by using different contractual assignment language. 7

 B. The Federal Circuit’s Decision Deprives the Government of Rights Granted by the Bayh-Dole Act. 8

 C. The Court Should Not Await a Circuit Conflict. 9

III. ROCHE'S APPEAL TO EQUITIES IS MISPLACED AND UNSUPPORTED BY THE FACTS.	10
IV. ROCHE IGNORES THE ENORMOUS ONE-SIDED BURDEN OF DISRUPTING THE PATH TO CLEAR TITLE UNDER THE BAYH-DOLE ACT.	12
CONCLUSION.	13

TABLE OF AUTHORITIES

Cases

Central Admixture Pharmacy Services, Inc.
v. Advanced Cardiac Solutions, P.C.,
482 F.3d 1347 (Fed. Cir. 2007) 3, 4

Statutes

28 U.S.C. § 1295(a)(1) 9
35 U.S.C. § 202(a) 3, 5, 11
35 U.S.C. § 202(b) 5
35 U.S.C. § 202(c)(1) 8
35 U.S.C. § 202(c)(7)(C) 11
35 U.S.C. § 202(d) 1, 2, 3, 5, 8
42 U.S.C. § 5908(a) 3

Blank Page

INTRODUCTION

The Brief in Opposition ignores the statutory language, structure, and historical background of the Bayh-Dole Act. As Roche acknowledges, the fundamental premise of the Federal Circuit's holding, and of Roche's position, is that "the Bayh-Dole Act nowhere alters an inventor's basic freedom to assign his own rights in [a federally funded] invention to a third party." Opp. Br. 2. Yet Roche fails to even mention section 202(d), the Bayh-Dole provision specifically limiting how inventors may obtain rights in federally funded inventions. Nor does Roche rebut the showing by Stanford and over 60 amici that Congress intended Bayh-Dole to provide a clear, statutory right to title in federally funded inventions to university contractors. Statutory rights to federally funded inventions do not depend on assignment language in employment contracts or invention agreements. The only rights implicated by such agreements are ones that exist *after* the application of the Act.

Before Bayh-Dole, the government, not individual inventors, held title to federally funded inventions. Because the government underutilized these inventions for decades, the Act reallocated the primary right to title to universities. Neither Roche nor the Federal Circuit identified any support in the statute or legislative history for the notion that Congress intended to allow individual inventors to assign rights in federally funded inventions outside this statutory structure.

Although Roche argues that this case is unique, the Federal Circuit's decision reaches far beyond

Stanford's dispute with Roche. As the extensive amicus briefing has shown, the issues presented here have widespread and profound implications for billions of dollars provided annually for government-sponsored research throughout the nation.

This Court's review is urgently needed. Because of the Federal Circuit's exclusive jurisdiction over patent appeals, other circuits will not likely consider the issue. Moreover, the Federal Circuit's decision casts immediate doubt on research institutions' title under Bayh-Dole for past and new inventions arising from federally funded research. As history demonstrates, without clarity of title, those inventions will go undeveloped, and the principal purpose of the Bayh-Dole framework will be frustrated.

I. ROCHE OFFERS VIRTUALLY NO DEFENSE ON THE MERITS OF THE FEDERAL CIRCUIT'S CONSTRUCTION OF THE BAYH-DOLE ACT.

Roche's Brief rests on the faulty premises that (1) individual inventors own patent rights in federally funded inventions independent of the Bayh-Dole Act, (2) they have the right to assign such inventions to third parties outside the statutory scheme, and (3) that third parties are free to receive such assignments, regardless of the Act or whether the university or federal government agrees.

Strikingly, while repeatedly claiming that Bayh-Dole addresses only the rights of the government and universities and not inventors' rights, Roche never addresses section 202(d), which specifically limits how

inventors may obtain rights in federally funded inventions:

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

35 U.S.C. § 202(d). Retention of patent rights by an inventor—and thus the ability to assign them away—is strictly controlled, and is neither presumed nor automatic. And section 202(d)'s requirements were indisputably not met in this case.

Moreover, Roche's position rests on the mistaken assumption that before Bayh-Dole was enacted, an inventor had the same patent rights in a federally funded invention as in other inventions. That is not true. As detailed by the amici, before Bayh-Dole, the federal government—not individual inventors—held all such invention rights. *Br. of Ass'n of Am. Univs. et al. as Amici Curiae in Support of Petitioner 11-15* (citing, *e.g.*, 42 U.S.C. § 5908(a) (1976)). Bayh-Dole altered the statutory scheme to give universities the right to retain title. 35 U.S.C. § 202(a). The Act did not grant default invention rights in federally funded inventions to individual inventors.

Roche also misapprehends the Federal Circuit's decision in *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347 (Fed. Cir. 2007). If *Central Admixture* establishes anything, it is that Bayh-Dole governs inventors' rights

in federally funded inventions: after the university waived its statutory right to the invention, the inventor applied for the rights as required under Bayh-Dole, and the federal agency approved the application. *Id.* at 1351. The case *applied* the Act, and did not hold that the inventor had rights independent of Bayh-Dole.

II. THIS COURT'S REVIEW IS URGENTLY NEEDED.

A. Roche Cannot Minimize the Importance of the Federal Circuit's Decision.

Roche's contention that this case is "highly unusual" (Opp. Br. 14-16) is contradicted by the grave concerns detailed by more than 60 university and university association amici. The Federal Circuit's opinion creates an immediate and widespread harm to universities and other research institutions that receive federal funding for research. Clarity of title is essential to achieving the goals of the Bayh-Dole Act. Absent that clarity, companies will be unwilling to pay to license federally funded inventions, and universities will be unable to commercialize those inventions. This was the state of affairs before Bayh-Dole.

1. Roche focuses on irrelevant details while ignoring the broad implications of the Federal Circuit's decision.

Roche contends that this case does not present the question of whether an inventor can unilaterally terminate a university's rights under Bayh-Dole because Stanford still possesses rights from Dr. Holodniy's co-inventors. Opp. Br. 11-13. Roche further argues that shared ownership of the invention is

appropriate here because of Cetus's purported contribution to the invention. *Id.* 12-13, 24. Both arguments are red herrings.

As Roche recognizes, the premise of the Federal Circuit's decision is that "the Bayh-Dole Act nowhere alters an inventor's basic freedom to assign his own rights in [a federally funded] invention to a third party." Opp. Br. 2. It directly follows that, if Holodniy were the sole inventor, he could have assigned the entirety of the rights to a third party, thus wholly depriving Stanford (and the federal government) of any rights in the invention. Moreover, under the Federal Circuit's analysis, Holodniy could have assigned rights to a third party that had no prior contact with Dr. Holodniy or knowledge of the invention. Thus, Cetus's alleged involvement and Stanford's ownership of the co-inventors' rights are pure happenstance unrelated to the logic or reach of the Federal Circuit's holding.¹

2. A research institution's rights flow from the statutory framework of the Bayh-Dole Act, not contractual assignment language.

A research institution's right to elect to retain title under the Bayh-Dole Act does not turn on whether an inventor has made an assignment to the research institution. The Act itself gives Stanford the right to elect to retain title in the federally funded invention, and has specific requirements that must be met for an inventor to obtain title. 35 U.S.C. § 202(a)-(b), (d). By making title to federally funded inventions depend on

¹ Indeed, the Federal Circuit's decision would allow inventors to assign rights to themselves, in violation of Section 202(d).

the ad hoc assignments of title by individual inventors, the Federal Circuit has introduced a lack of clarity that is anathema to the statutory scheme.

This very case is a troubling example of the pitfalls of making Bayh-Dole dependent on inventor assignments. Stanford's employment agreement with Dr. Holodniy expressly gave Stanford the right to government-funded inventions, to secure compliance with the Bayh-Dole framework. App. 118a-119a. Despite this right, the Federal Circuit gave priority to the later executed VCA's "present assignment" provision, App. 12a-15a, while giving no effect to the prior-existing agreement with Stanford. *Id.* The court provided no explanation why a later present assignment should terminate a prior contractual commitment, and there is none.

Contrary to Roche's assertion (Opp. Br. 22), the Federal Circuit's lack of deference to the Bayh-Dole statutory framework over a new application of its present assignment law is unprecedented. The Federal Circuit never previously concluded that a present assignment clause terminates prior contractual obligations, much less obligations directed to Bayh-Dole compliance. Whether through the allocation of inventorship rights under Bayh-Dole or his prior agreement with Stanford, Dr. Holodniy had no invention rights in any government-funded inventions to give to Cetus, whether through present assignment or otherwise.

3. The problems created by the Federal Circuit's decision cannot be avoided by using different contractual assignment language.

Roche suggests that Stanford is uniquely harmed by the Federal Circuit's decision because few universities use the "agree to assign" language used in Stanford's agreement. Opp. Br. 15-16. Roche's suggestion is meritless. Many universities have inventors' agreements using similar language. *See, e.g.,* Univ. of Cal., State Oath of Allegiance, Patent Policy, and Patent Acknowledgement, available at <http://www.ucop.edu/ott/genresources/patentac.html>; Univ. of Wis. Sys., Patent Policy (G34), available at <http://www.uwsa.edu/fadmin/gapp/gapp34.htm#appndx1>.

Ensuring clarity of title is hardly the simple matter of changing a few words as Roche would have the Court believe. Contrary to Roche's contention, universities cannot "easily" change their agreements to avoid the Federal Circuit's decision. Opp. Br. 15. Further, changing future contracts does nothing to remedy the confusion created by the Federal Circuit's decision as to the many years of already ongoing or completed research. Nor do prospective changes remedy problems caused by assignment agreements into which inventors may have entered with third parties prior to making an assignment to a university.

It would wholly frustrate the purpose of Bayh-Dole to have a university's ownership of a federally funded invention turn on a battle of contractual assignment clauses. This is particularly true in the context of

academic research, where the existence, dates, and terms of any competing assignment by the individual researcher cannot be known with certainty.

B. The Federal Circuit's Decision Deprives the Government of Rights Granted by the Bayh-Dole Act.

Roche's contention that the Federal Circuit's opinion will not affect government rights (Opp. Br. 13-14) ignores the opinion's necessary implications and Roche's own sweeping arguments about inventors' rights outside the statutory scheme.

Most immediately, the decision eliminates the government's statutory right to control whether an individual inventor will have rights in a federally funded invention. Under the Act, inventors have rights in federally funded inventions *only* if the federal government consents after consultation with the research institution. 35 U.S.C. § 202(d). This is the only means through which Holodniy could have obtained the rights purportedly transferred to Roche in this case. It is the federal government that succeeds to the rights of the research institution if the research institution fails to comply with the Act's disclosure and election requirements. *See* 35 U.S.C. § 202(c)(1).

Although there was no such consent in this case, the Federal Circuit nonetheless gave Dr. Holodniy exclusive rights to his federally funded work, which the Federal Circuit then held were transferred to Cetus. The Federal Circuit's decision in effect creates a new category of statutory rights of individual inventors in federally funded inventions that exist

independent of the statutory scheme and do not require governmental consent under Section 202(d).

Roche next argues that the Federal Circuit “did not rule out the possibility” that the government might have other remedies.² No such remedies would be necessary if compliance with the Bayh-Dole Act is required.

Roche finally submits that this Court should not “presume that this case will implicate any important federal interest.” Opp. Br. 14. If there is any doubt, Stanford suggests it would be appropriate for this Court to call for the views of the Solicitor General.

C. The Court Should Not Await a Circuit Conflict.

The lack of a Circuit split does not counsel against review in this case. The Federal Circuit has pronounced a broad rule of law applicable to federally funded programs throughout the country, and declined to rehear the issue *en banc*. Although the issue could theoretically arise in another Circuit, as a practical matter the issue is most likely to arise in the Federal Circuit, which has exclusive jurisdiction over patent appeals. *See* 28 U.S.C. § 1295(a)(1). Because the harm

² Roche’s suggestion that the government may have remedies against a university is contrary to the Act’s purpose to further research and foster commercialization of federally funded inventions. Its further suggestion that a university should sue the inventor is illusory: the idea that an individual inventor could make the university whole has no basis in reality.

from the Federal Circuit's decision is real and immediate, the question should be heard now.³

III. ROCHE'S APPEAL TO EQUITIES IS MISPLACED AND UNSUPPORTED BY THE FACTS.

Roche's statement of the facts relies heavily on innuendo, suggesting that the Court should deny certiorari because the equities somehow favor Roche. The equities alleged by Roche are not only irrelevant, but also contradict the factual record.

Initially, as shown above, the broad rule announced by the Federal Circuit does not depend on the particular facts here. Under that rule, an individual inventor is free to assign rights in a federally funded invention regardless of either the level of contributions by third parties, or whether the university retains some rights through other co-inventors. Indeed, the Federal Circuit's reasoning compels the same result had a single inventor assigned all rights in a federally funded invention to a holding company that did nothing more than purchase and license patents.

³ Roche also argues that even if Stanford has standing, Roche would still have other defenses, including the purported invalidity of the patent. Opp. Br. 17. That Roche could later prevail on other grounds is no reason for the Court to decline review of the important legal question presented. The Court often grants review to resolve important legal questions, even where the petitioner may ultimately lose on other legal or factual grounds. In any event, Stanford has a strong position on the merits, including patent validity issues that were briefed to, but not reached by, the Federal Circuit.

In any event, Roche paints a misleading and dramatically skewed picture of this case. For example, Roche ignores that its claim to patent ownership rests on Dr. Holodniy signing a Visitor's Confidentiality Agreement ("VCA") in which the intellectual property clause was buried. Roche also brushes past the fact that this VCA was signed 15 years before Roche asserted any ownership rights. Stanford and Roche negotiated for years in an attempt to reach an acceptable license arrangement. Far from seeking to prevent Roche from commercializing the technology, Stanford simply seeks fair compensation for Roche's longstanding, unlicensed use of Stanford's patented technology.⁴

Roche also ignores that Cetus made no contribution to the clinical work that resulted in Stanford's inventions. Roche argues that Dr. Holodniy performed laboratory work on an assay at Cetus, Opp. Br. 3-4, but does not dispute that the clinical work was performed exclusively at Stanford without Cetus's input. See App. 39a-40a ("Cetus was not involved in these experiments."). Nor does Roche dispute that Holodniy's assay work at Cetus was published in abstracts months before the Stanford clinical research began. App. 37a. Holodniy—just like the rest of the HIV research community—was entitled to rely freely on this publicly available information. Moreover, the assay Roche attempts to equate with the claimed inventions was described in a published scientific article that the Patent Office considered before

⁴ Thus, Roche's argument regarding exclusive commercialization (Opp. Br. 13) is inapposite. Further, the Act gives research institutions—not private concerns—the right to retain title, and resulting royalties benefit the public by funding further research. 35 U.S.C. § 202(a), (c)(7)(C).

granting Stanford's patent. Roche's attempts to conflate the publicly disclosed assay with Stanford's inventions should be rejected.

Finally, Roche's claim that Stanford "secretly" patented the claimed inventions is baseless. Opp. Br. 6-7. Dr. Holodniy disclosed the prior assay work to Cetus, but Cetus declined to pursue any patents based on that assay, and the assay work was thereafter published. App. 37a-38a. Further, after performing the later clinical work resulting in the inventions, Stanford published the results and methodology widely. App. 40a. Cetus personnel learned of this clinical work shortly thereafter, but never made any claim to ownership or contribution. *Id.* Indeed, both courts below held that because Roche knew of Stanford's claims to sole title over the clinical invention for many years before this suit, Roche is time-barred from pursuing any affirmative ownership claim. App. 22a-27a, 45a-51a.

IV. ROCHE IGNORES THE ENORMOUS ONE-SIDED BURDEN OF DISRUPTING THE PATH TO CLEAR TITLE UNDER THE BAYH-DOLE ACT.

Roche also avoids the Federal Circuit's failure to take into account relative burdens in establishing its new rule, contending that it is an issue of agency law for state legislatures. Opp. Br. 24. But this misses the point. Whether Stanford had actual or constructive knowledge of the VCA is a hotly contested issue,⁵ but

⁵ Roche's assertion (without citation) that Stanford does not dispute that Dr. Holodniy acted as Stanford's agent in signing the VCA (Opp. Br. 23), is false. *See, e.g.*, App. 16a-18a.

it was undisputed that Cetus had actual knowledge of Holodniy's status as a Stanford employee and the Bayh-Dole Act. Yet the Federal Circuit placed the entire burden on Stanford (and any prospective licensee of the university) to make sure that Holodniy did not purposely or inadvertently give away rights to Bayh-Dole inventions. The Federal Circuit's holding would require universities to so heavily police their researchers as to require an enormous administrative load, or to wholly preclude beneficial collaborations between researchers and third parties. Ultimately, the Federal Circuit's opinion turns on its head one of the Bayh-Dole Act's principal objectives—establishing a uniform and clear path for establishing title to inventions arising from federally funded research at universities.

CONCLUSION

The petition should be granted.

Respectfully submitted,

RICARDO RODRIGUEZ
Counsel of Record

STEPHEN C. NEAL

LORI R.E. PLOEGER

MICHELLE S. RHYU

BENJAMIN G. DAMSTEDT

COOLEY LLP

Five Palo Alto Square

3000 El Camino Real

Palo Alto, California 94306

(650) 843-5000

Counsel for Petitioners

June 5, 2010

Blank Page