

Stanford v. Roche, the Bayh-Dole Act, and the Possibility of Unintended Consequences

Introduction

Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems et al. involves a question of whether the Bayh-Dole Act prevents an employee of a university from assigning rights in an invention that arose, at least in part, from federally-funded research.¹ The Federal Circuit held that it does not and, applying standard contract principles, found that the Roche defendants had acquired equitable title to inventions arising from federally-funded research as a result of a Stanford employee's unilateral assignment of the inventions to a Roche predecessor. Stanford petitioned for *certiorari*, and the Supreme Court granted the petition. Oral argument was held on February 28, 2011, and a decision is expected shortly.

This may be a case of “be careful what you ask for” for Stanford. That is to say, there is a risk that—if Stanford succeeds—its own freedom to contract with respect to federally-funded research could be substantially restricted. Though perhaps counterintuitive, such a result may provide a good example of the law of unintended consequences, *i.e.*, that an intervention in a complex system (*e.g.*, that of the allocation of intellectual property rights arising from federally-funded research) always creates unanticipated and often undesirable outcomes. For better or worse, the Bayh-Dole Act put in place a system that has governed interactions between the Federal Government, contractors, and their inventors for the last thirty years. Stanford's attempt to overturn the Federal Circuit's opinion, while potentially beneficial for Stanford in the instant case, may also serve to inject uncertainty into an otherwise relatively stable system with relatively established expectations.

More specifically, in future situations where Stanford may desire to assign rights associated with federally-funded research, such as in the sale of a business or the settlement of an infringement or interference dispute, Stanford may find that uncertainty in the allocation of the rights at issue may make such an assignment agreement difficult to come by. In short, if Stanford is successful, the fact that Bayh-Dole Act may trump the university's own contractual rights may make industry less confident about entering into agreements with universities and researchers.

The Facts of *Stanford v. Roche*

The relevant facts in *Stanford* are fairly straightforward. A Stanford employee conducting federally-funded research used polymerase chain reaction (“PCR”) materials from Cetus, a Roche predecessor, and received technical advice and other information from Cetus scientists, to develop methods for quantifying Human Immunodeficiency Virus (“HIV”) in human blood samples. When a patent issued from the researcher's work, Stanford sued Roche, and, in response, Roche claimed title to the patent based on a prior agreement between the researcher and Cetus.²

Three types of agreements govern the respective rights in the patents-in-suit:

1. An employment agreement, including a “Copyright and Patent Agreement” (“CPA”) between the researcher and Stanford, under which the researcher “agree[d] 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.”

2. A “Visitor’s Confidentiality Agreement” (“VCA”) that states that the researcher “will assign and do[es] hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements” that the researcher may devise “as a consequence of” work at Cetus.

3. Multiple “Materials Transfer Agreements” that permitted Stanford to use the PCR-related materials and information supplied by Cetus. These agreements provided Cetus with licenses to technology that Stanford created as a result of access to Cetus’s materials.

Also of note was Stanford’s invention rights policy which stated: “[u]nlike industry and many other universities, Stanford’s invention rights policy allows all rights to remain with the inventor if possible.”³

The Federal Circuit Opinion

The Federal Circuit held that the researcher’s CPA with Stanford was only a promise to assign rights to any future inventions and, at best, gave the promisee, *i.e.* Stanford, equitable rights.⁴ The Federal Circuit had previously held that such an agreement to assign is not an actual assignment and requires a subsequent written instrument to complete the assignment.⁵ Indeed, it would appear that any other interpretation of Stanford’s CPA would be inconsistent with Stanford’s invention rights policy, which expressly allowed “all rights to remain with the inventor if possible.”

By contrast, the VCA with Cetus, signed by the inventor/researcher, contained an unambiguous, actual, assignment.⁶ Cetus gained equitable title with the execution of the VCA, and legal title vested with the filing of the parent application.⁷ As such, the researcher’s later attempt to assign rights to Stanford failed.

Stanford argued that it was a *bona fide* purchaser under 35 U.S.C. § 261 because Cetus/Roche did not record its assignment within three months after the subsequent assignment to Stanford.⁸ But actual or constructive notice precludes a *bona fide* purchase, and the Federal Circuit found that Stanford was on notice of the assignment via its agent/employee (*i.e.*, the researcher).⁹

The Federal Circuit also rejected Stanford’s argument that the Bayh-Dole Act negated the researcher’s assignment and allowed Stanford a “right of second refusal” to the patents after the Government refrained from exercising its rights.¹⁰ The Federal Circuit found that, at most, the Government had a discretionary option to the researcher’s rights and could claw back any rights assigned to Roche.¹¹ The Court found that the Bayh-Dole statutory scheme did not automatically void the rights that Cetus received from the researcher.¹² Notably, however, the Federal Circuit “express[ed] no opinion as to whether [the researcher’s] execution of the VCA violated any provisions of the Bayh-Dole Act, or whether the Act provides the Government or Stanford some other legal recourse to recover [the researcher’s] rights.”¹³

Finally, Federal Circuit rejected Stanford’s argument that the VCA unlawfully restrained the researcher from “engaging in a lawful profession, trade or business” and was void under the California Business and Professions Code § 16600.¹⁴ The Federal Circuit noted that the California provision applies to “employment restrictions on departing employees, not to patent assignments.”¹⁵

Arguments Submitted to the Supreme Court

Stanford sought *certiorari* on the Federal Circuit's decision under the Bayh-Dole Act. The Government filed an amicus brief asserting that the Bayh-Dole Act requires that all rights to any federally-funded inventions are either vested in the Government or retained by the contractor (e.g., Stanford).¹⁶ To make this argument, the Government had to ignore the various references to the "inventor" throughout the Bayh-Dole Act. Instead of using the "inventor" language from the Bayh-Dole Act, the Government suggested that Act refers to a "recipient of federal funds under a funding agreement."¹⁷

The Government further asserted that the researcher possessed only a contingent interest in obtaining title to the invention if (a) Stanford waived or failed to exercise its rights under the Act and (b) the Government then authorized the researcher to retain title.¹⁸ Because Stanford "elected to retain title and complied with the statutory requirements for doing so," the Government reasoned that the contingent interest was "of no practical value."¹⁹ According to the Government, the researcher "could not assign to Cetus any higher priority in the federally funded inventions than [the researcher] himself would have possessed," which in this case was none.²⁰

From a policy stand-point, the Government made the argument that the commercialization of government-funded projects may be jeopardized if rights to such projects could be lost due to an inventor's prior, unilateral, assignment.²¹ The Government also asserted that, if patent rights *do not* automatically vest with contractors, a substantial increase in due diligence costs may result²² and the security of existing and pending patents may be at risk.²³

Additional amicus briefs were filed. The American Intellectual Property Law Association ("AIPLA") argued that such fears are unjustified.²⁴ The AIPLA emphasized that, while due diligence may be costly, universities are currently able to adequately protect non-federally funded research.²⁵

The Pharmaceutical Research and Manufacturers of America ("PhRMA") emphasized what is, perhaps, the most challenging aspect of Stanford and the Government's position: the widespread practice of requiring individual inventors to execute documents in which they assign their existing and prospective intentions to their employers.²⁶ PhRMA's brief details these practices and the extent to which agencies have consistently required such assignments.²⁷

Intel Corporation warned that if patent rights *do* automatically vest with contractors, universities could simply provide small amounts of government funding for any project and, as a result, legally own all rights to any invention produced therefrom.²⁸ Intel suggested that this would "damage . . . industrial-academic collaborations."²⁹

However, the nonprofit BayhDole25³⁰ argued that the Bayh-Dole Act does not allow government rights to federally-funded inventions to be defeated by the "whims of individual inventors who, according to the Federal Circuit opinion, have the unfettered right to assign their federally funded inventions without regard to Bayh-Dole's statutory provisions."³¹ The American Association of University Professors made the counterpoint that professors are not "for-hire" inventors.³² Further, the University Professors noted that if the Bayh-Dole Act made the process of assignment unnecessary, as suggested by Stanford, universities would not have been conducting "the very

process—acknowledging faculty ownership of inventions born from scholarly research and effectuating technology transfer of that ownership” for the past thirty years.³³

Oral Argument Before The Supreme Court

At oral argument, a number of justices raised questions that generally seemed to suggest favor for Roche’s position. Justice Ginsburg noted that the problem here seemed to be Stanford’s employment agreement, which did not automatically assign its employees’ rights to the university:³⁴

The whole thing that was wrong here is that Stanford, instead of drafting the agreement “I agree to assign,” should have said “I hereby assign” and then there would be no case.

Justice Kagan echoed Justice Ginsburg’s point when she asked:³⁵

[I]s this a Stanford-specific problem or is it a more general problem? In other words, are there many universities that have agreements like Stanford’s that would be subject to the Federal Circuit’s ruling? Or is this just an example of one university that unfortunately has a bad agreement?

Justice Kagan also asked the Government:³⁶

So why doesn’t the Federal Government just require assignments from employees to the university?

Either an improved agreement according to Justice Ginsburg, or a federally mandated assignment according to Justice Kagan, would avoid the problems Stanford faces in this case.

Justice Alito noted that there are two facts that “seem to me to cut pretty strongly against” Stanford’s argument: (1) “that it has long been the rule that inventors have title to their patents initially, even if they make those inventions while working for somebody else” and (2) the Bayh-Dole Act says that the contractor can “elect to retain title, which means hold onto a title that the—organization already has. ‘Retain’ does not mean obtain.”³⁷ In other words, where a contractor has failed to take proper steps to assure that it obtains rights to its employees’ inventions in the first place, the contractor may not be said to have rights to “retain.”

Justice Sotomayor also questioned:³⁸

Does the—as a practical matter, when a university is seeking a patent, doesn’t it have to identify the inventors and get their—proof of their assignment before it can claim ownership of the patent?

Justice Scalia concurred with Justice Sotomayor’s sentiment:³⁹

If—if the government was going to make such a huge change from normal patent law where the inventor owns his invention until he assigns it to his employer, why wasn’t that set forth clearly?

Justice Kennedy, in turn stated:⁴⁰

What you're asking for, based on submissions to us of amici, of amicus briefs, means a very great change in how—how—how patents are held.

Justice Breyer, on the other hand, noted case law cited by the amicus brief submitted by the Association of American Universities and the Advancement For Science and the Council on Education, held that third-party assignments in an analogous situation—a government employee who has an obligation to assign an invention to the government—were void as against public policy.⁴¹ Chief Justice Roberts also noted that relying on funding agreements to require the contractor to get assignments from the inventors may yield the patchwork of arrangements across government agencies that the Bayh-Dole Act was intended to avoid.⁴²

Thoughts as We Await the Supreme Court's Decision

At issue, of course, is not just the rights of industry vis-à-vis researchers, universities and the Government, but also the rights of universities and researchers vis-à-vis the Government. The interpretation of the Bayh-Dole Act proposed by Stanford may well come back to haunt Stanford's own future attempts at administration of its own intellectual property. As noted in the various arguments before the Supreme Court, Stanford's interpretation of the Bayh-Dole Act, in at least some significant respects, appears inconsistent with settled practice of the last thirty years. As a result of disturbing the somewhat established system of allocation of intellectual property rights under thirty years of the Bayh-Dole Act, Stanford may, as an unintended consequence, increase industry reluctance to enter into agreements with Stanford and other similarly situated universities and researchers. The outcome Stanford seeks may well also stifle interchange of information between industry and researchers such as Cetus' and the Stanford employee's activities here.

Contrary to the Government's position, the Federal Circuit's decision does not appear to affect a substantial number of colleges or universities or other federally-funded institutions. As Justice Ginsburg and Justice Kagan noted at oral argument, the real problem with Stanford's position was the clearly problematic language of its employment agreement. A simple rewording of the employment agreement would have avoided the problem altogether. Accordingly, the issues raised in this case do not appear to be significant, systematic, problems that require a new interpretation of the Bayh-Dole Act and a substantial revision of the expectations regarding who owns the rights to inventions.⁴³

Christopher D. Butts prepares and prosecutes patent applications, conducts legal research, and provides technological advice in support of validity, infringement, and patentability analyses, and litigation matters for universities and high-tech companies in the electrical engineering field.

[@mbhb.com](mailto:cbutts@mbhb.com)

Endnotes

1. 583 F.3d 832 (Fed. Cir. 2009).
2. For a more thorough discussion of the agreements relevant to this case, see *id.* at 837-838.
3. *Id.* at 841.
4. *Id.* at 841-842. The Federal Circuit commented that, "[w]hile Stanford might have gained certain equitable rights against [the researcher], Stanford did not immediately gain title to [the researcher]'s inventions as a result of the CPA, nor at the time the inventions were created." *Id.*
5. See *IpVenture, Inc. v. Prostar Computer, Inc.*, 503 F.3d 1324, 1327 (Fed. Cir. 2007).

6. *Stanford*, 583 F.3d at 842. The Federal Circuit noted that, “Paragraph 3 of the VCA recites: ‘I will assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements.’ In contrast to the CPA, the VCA’s language of ‘do hereby assign’ effected a present assignment of [the researcher]’s future inventions to Cetus.” *Id.* (internal citations omitted).
7. *Id.* As the Federal Circuit explained, upon execution of the VCA “CETUS immediately gained equitable title to [the researcher]’s inventions . . . Cetus’s equitable title converted to legal title no later than the parent application’s filing date.” *Id.*
8. *Id.* at 842-843.
9. *Id.* at 843. The Federal Circuit noted that although “Stanford contends . . . that Stanford received no notice of [the researcher]’s countervailing assignment to CETUS . . . Stanford’s argument fails because there can be no genuine dispute that Stanford had at least constructive or inquiry notice of the VCA.” *Id.*
10. *Id.* at 844-845.
11. *Id.* at 844.
12. *Id.*
13. *Id.* at 844 n.1, citing *Cf. Cent. Admixture*, 482 F.3d at 1353.
14. *Id.* at 845-846.
15. *Id.* at 846.
16. See Brief for the United States as Amicus Curiae in Support of Petitioner on Writ of Certiorari at 6. The Government urged that “[t]he Act creates a presumption that title to federally funded inventions will vest in the contractor, as opposed to the government or the inventor . . . The government ‘may receive title to any subject invention’ when the contractor does not timely disclose the invention, elect to retain the invention, elect to retain title, or seek patent protection for the invention. 35 U.S.C. 202(c)(1)-(3).” *Id.*
17. *Id.* at 5.
18. *Id.* at 18.
19. See Brief for the United States as Amicus Curiae on Petition for a Writ of Certiorari at 13-14.
20. *Id.* at 14.
21. See Brief for the United States as Amicus Curiae in Support of Petitioner on Petition for a Writ of Certiorari at 30-31.
22. Stanford made a similar argument: It is no answer to suggest that a contractor like Stanford can alleviate such uncertainties by combing through the files of each faculty member, graduate student, or employee who may be an inventor and seeking documents from all of the third parties with whom those people may have interacted. Even such due diligence cannot prove a negative. Absolute assurance that a contrary assignment does not exist is impossible. Brief of Petitioner at 47.
23. See Brief for the United States as Amicus Curiae in Support of Petitioner on Petition for a Writ of Certiorari at 30-31 (emphasis added); see also Brief of Amici Curiae Association of American Universities, *et al.* at 36.
24. See Brief of Amicus Curiae American Intellectual Property Law Association in Support of Neither Party at 28–32.
25. See *id.* at 28.
26. See Brief for the Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Respondent at 13-18.
27. See *id.*
28. See Brief of Intel Corporation, *et al.*, as Amici Curiae in Support of Respondents at 18-19.
29. See *id.* at 19.
30. “BayhDole25 is a not-for-profit educational and research organization created to study the U.S. Bayh-Dole Act of 1980, as well as similar U.S. and international technology transfer legislation and related issues. BayhDole25 performs independent, non-partisan research projects and provides educational materials relating to technology transfer legislation and its role in the successful commercialization of science and technology through public-private partnership.” About BayhDole25, <http://www.bayhdole25.org/about> (last visited May 31, 2010).
31. See Brief of Amicus Curiae Bayhdole25, Inc. in Support of Petitioner at 9.
32. See Brief of Amici Curiae American Association of University Professors, *et al.* in Support of Affirmance at 11.
33. *Id.* at 19.
34. Transcript of Oral Argument at 36.
35. *Id.* at 24.
36. *Id.* at 18.
37. *Id.* at 14-15.
38. *Id.* at 20.
39. *Id.* at 15.
40. *Id.* at 23.
41. *Id.* at 28-30. Justice Breyer referred to *Li v. Montgomery*, No. 99-5106, 2000 WL 815992 (D.C. Cir. May 15, 2000), an unpublished decision of the D.C. Circuit.
42. See *id.* at 35.
43. As Justice Kennedy remarked at oral argument, “why can’t we resolve this case in a simple way . . . If we can resolve this case on a simple contract basis, why not do it?” *Id.* at 23.