

Stanford v. Roche: Confirming The Basic Patent Law Principle That Inventors Ultimately Have Rights In Their Inventions

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In June 2011, the Supreme Court ruled in *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.* that the Bayh-Dole Act did not deprive inventors to the rights in their inventions. While this may seem like a basic proposition of patent law, it has created some uncertainty for entities covered by the Bayh-Dole Act, including universities. This article will discuss the history of the Bayh-Dole Act, the lower court and Supreme Court decisions in the *Stanford* case and the potential implications of the Supreme Court decision and practice tips.

History of the Bayh-Dole Act

Prior to 1980, ownership of inventions arising from federally-funded research was determined by the agency that was sponsoring the research.² Many agencies retained ownership of these inventions. Moreover, because the government retained the rights to these inventions,³ government funded research was rarely commercialized.⁴ This was troubling to Congress for several reasons, including the state of the economy in the 1970s and because the public was paying for research without receiving any benefit.⁵

Congress attempted to rectify this problem in 1980 with the passage of the Bayh-Dole Act.⁶ The Bayh-Dole Act, codified at 35 U.S.C. §§ 200-210, provides that certain organizations, including universities, may elect to retain the patent rights in inventions developed with federal funds.⁷ In order to retain these rights, the university must comply with certain

statutory requirements, including disclosing the invention to the federal agency sponsoring the research within a reasonable amount of time and electing to pursue patent protection for the invention.⁸ Additionally, should the university successfully obtain a patent, the government retains a non-exclusive, non-transferrable, irrevocable, paid-up license in the patent.⁹

The Bayh-Dole Act contemplates that the inventor may be able to retain rights. Specifically, the Bayh-Dole Act provides that “[i]f a contractor does not elect to retain title to a subject invention... 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.”¹⁰

Further, the Bayh-Dole Act provides the government with march-in rights in certain circumstances.¹¹ These march-in rights allow the government to require the patentee to grant a license to a third party.¹² This license may be exclusive, partially exclusive or non-exclusive.¹³ If the patentee refuses to grant the license, the government may grant the license.¹⁴ The government may exercise the march-in rights if: (i)

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1. 131 S. Ct. 2188, 2192 (2011).

2. See Chester G. Moore, *Killing the Bayh-Dole Act's Golden Goose*, 8 TUL. J. TECH. & INTELL. PROP. 151, 153-54 (2006).

3. See Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1378 (2006-2007).

4. Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J. L. SCI. & TECH. 395, 397 (2006).

5. See Moore, *supra* note 2, at 151-54.

6. *Id.* at 152-53.

7. See generally 35 U.S.C. § 200 et seq.

8. 35 U.S.C. § 202(c).

9. 35 U.S.C. § 202(c)(4).

10. 35 U.S.C. § 202(d).

11. 35 U.S.C. § 203(a).

12. *Id.*

13. *Id.*

14. *Id.*

the patentee has not taken and is not expected to take steps to achieve a practical application of the invention;¹⁵ (ii) action is necessary to alleviate health or safety needs;¹⁶ (iii) action is necessary to meet requirements for public use as specified by federal regulations;¹⁷ or (iv) the patentee has not agreed to or has not licensed the patent to an entity that substantially manufactures the invention in the U.S.¹⁸ As of 2007, the government had not exercised its march-in rights.¹⁹

The Bayh-Dole Act is considered to be a great success.²⁰ It has allowed the commercialization of many inventions that otherwise would never have seen the light of day.²¹ It has also changed the way that universities look at inventions. Since enactment of the Bayh-Dole Act, the number of patents awarded to universities has increased dramatically.²² For example, the number of patents issued to universities rose from 264 in 1979 to 3,680 in 2004.²³ Additionally, many universities have set up technology transfer offices to evaluate university inventions and decide whether to pursue patent protection.²⁴ Such offices were rare prior to passage of the Bayh-Dole Act.²⁵

Factual History of *Stanford v. Roche* and the Inventions of the Patents-in-Suit

In 1985, Cetus, a California research company, began to develop methods for quantifying blood borne levels of human immunodeficiency virus (HIV), the virus that causes AIDS.²⁶ A vital part of Cetus efforts was the development of the Nobel Prize winning technique polymerase chain reaction, or PCR.²⁷ PCR allows billions of copies of DNA sequences to be made from a small initial blood sample.²⁸

Cetus started to collaborate with scientists at Stanford University's Department of Infectious

Diseases to test the efficacy of new AIDS drugs in 1988.²⁹ Around that time, Dr. Mark Holodniy joined Stanford as a research fellow in the department.³⁰ When Holodniy joined the department, he signed a Copyright and Patent Agreement (CPA) stating that he "agree[d] to assign" to Stanford his "right, title and interest in" inventions resulting from his employment at the University.³¹

While at Stanford, Holodniy worked on the development of an improved method for quantifying HIV levels in patient blood samples using PCR.³² Because Holodniy was not entirely familiar with PCR, his supervisor arranged for him to conduct research at Cetus. As a condition to access Cetus, Holodniy signed a Visitor's Confidentiality Agreement (VCA) stating that Holodniy "will assign and do[es] hereby assign" to Cetus his "right, title and interest in each of the ideas, inventions and improvements" made "as a consequence of [his] access" to Cetus.³³

Holodniy conducted research at Cetus for nine months.³⁴ Along with Cetus employees, Holodniy developed a PCR-based procedure for calculating the amount of HIV in a patient's blood.³⁵ That technique allowed doctors to determine whether a patient was benefiting from HIV therapy.³⁶

After this development, Holodniy returned to Stanford where he and other University employees tested the HIV measurement technique.³⁷ Stanford then obtained written assignments of rights from its employees involved in refinement of the technique, including Holodniy, and filed several patent applications related to the procedure.³⁸ Stanford obtained three patents on the HIV measurement process.³⁹

In 1991, Roche Molecular Systems, which specializes in diagnostic blood screening, acquired Cetus PCR-related assets, including all rights Cetus had obtained through agreements like the VCA signed by Holodniy.⁴⁰ Subsequent to conducting clinical trials on the HIV quantification method developed at Cetus,

15. 35 U.S.C. § 203(a)(1)

16. 35 U.S.C. § 203(a)(2)

17. 35 U.S.C. § 203(a)(3)

18. 35 U.S.C. § 203(a)(4)

19. See Larena, *supra* note 3, at 1392.

20. See Pulsinelli, *supra* note 4, at 410.

21. See Moore, *supra* note 2, at 155-56.

22. See Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1708 (1996).

23. See Larena, *supra* note 3, at 1381 note 49.

24. *Id.* at 1412.

25. *Id.*

26. Stanford, 131 S. Ct. at 2192.

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

Roche commercialized the procedure. Today, Roche's HIV test is used across the globe.⁴¹

The Lower Court Decisions

In 2005, the Board of Trustees of Stanford University sued Roche Molecular Systems, Inc., Roche Diagnostics Corporation, and Roche Diagnostics Operations, Inc. (collectively Roche), alleging that Roche's HIV test kits infringed Stanford's patents.⁴² Roche responded by asserting that it was a co-owner of the HIV quantification procedure, based on Holodniy's assignment of his rights in the VCA.⁴³ Because of this assignment, Roche argued, Stanford lacked standing to sue Roche for patent infringement.⁴⁴ In response, Stanford claimed that Holodniy had no rights to assign because the University's HIV research was federally funded, giving the school superior rights in the invention under the Bayh-Dole Act.⁴⁵

The District Court decided in favor of Stanford.⁴⁶ Although the District court held that the "VCA effectively assigned any rights that Holodniy had in the patented invention to Cetus," and thus to Roche, because of the operation of the Bayh-Dole Act, "Holodniy had no interest to assign."⁴⁷ The District Court thus concluded that the Bayh-Dole Act "provides that the individual inventor may obtain title" to a federally funded invention "only after the government and the contracting party have declined to do so."⁴⁸

On appeal, the Federal Circuit reversed the District Court.⁴⁹ The Federal Circuit concluded that Holodniy's initial CPA with Stanford constituted a mere promise to assign rights in the future, unlike Holodniy's VCA with Cetus, which itself assigned Holodniy's rights in the invention to Cetus.⁵⁰ As a matter of contract law, Cetus had therefore obtained Holodniy's rights in the HIV quantification technique through the VCA.⁵¹ The Federal Circuit also reasoned that the Bayh-Dole Act "does not automatically void *ab initio* the inventors' rights in government-funded inventions" and that

the "statutory scheme did not automatically void the patent rights that Cetus received from Holodniy."⁵² The Federal Circuit held that "Roche possess[ed] an ownership interest in the patents-in-suit" that was not extinguished by the Bayh-Dole Act, thereby "depriv[ing] Stanford of standing."⁵³ Ultimately, the Federal Circuit remanded the case with instructions to dismiss Stanford's infringement claim.⁵⁴

In November 2010, the Supreme Court granted *certiorari*.⁵⁵

The Supreme Court Decision

On June 6, 2011, the United States Supreme Court issued its opinion affirming the Federal Circuit.⁵⁶ The question before the Court was whether the Bayh-Dole Act "displaces the norm and automatically vests title to federally funded inventions in federal contractors."⁵⁷ The Court held that it does not.⁵⁸ In so doing, the Court reaffirmed the accepted rule that "rights in an invention belong to the inventor."⁵⁹

At the outset of the Majority Opinion, written by Justice Roberts, the Court briefly reviewed basic principles of patent law.⁶⁰ Citing to the Patent Act of 1790, *Gayler v. Wilder*, 51 U.S. (10 How. 477), 493, 13 L. Ed. 504 (1851), *Solomons v. United States*, 137 U.S. 342, 346 (1890) and *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 188 (1933), as well as 35 U.S.C. § 101, the Court stated that patent law has consistently recognized that the rights in an invention belong to the inventor.⁶¹ While an inventor may transfer ownership to others by written assignment, any interest others acquire "must trace back to the inventor."⁶² According to the Court, with respect to employer's rights in their employees' inventions, "unless there is an agreement to the contrary, an employer does not have rights in an invention 'which is the original conception of the employee alone.'"⁶³

41. *Id.*

42. *Id.* at 2193

43. *Id.*

44. *Id.*

45. *Id.*

46. *Bd. of Trustees of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 487 F.Supp.2d 1099, 1117 (N.D. Cal. 2007).

47. *Id.* at 1117, 1119.

48. *Id.* at 1118.

49. *Bd. of Trustees of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 836-37 (Fed. Cir. 2009).

50. *See id.* at 841-842.

51. *Id.*

52. *Id.* at 844-845.

53. *Id.* at 836-837.

54. *Id.* at 849.

55. *Bd. of Trustees of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 131 S. Ct. 502 (2010).

56. *Stanford*, 131 S. Ct. at 2199. The Supreme Court decision was 7-2, with Justice Sotomayor filing a concurring opinion and Justice Breyer filing a dissenting opinion. *Id.*

57. *Id.* at 2192.

58. *Id.*

59. *Id.* at 2192, 2195-97.

60. *Id.* at 2194-95.

61. *Id.*

62. *Id.* at 2195.

63. *Id.* (citing *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 189 (1933)).

The Court then turned to the Bayh-Dole Act to ascertain if any language in the Act controverted this basic patent law principle to vest title *ab initio* in a federally funded contractor.⁶⁴ The Court found significant that fact that the Bayh-Dole Act contained no language which unambiguously deprived inventors of their rights in federally funded inventions.⁶⁵ Instead, the Court stated, “the Act provides that contractors may ‘elect to retain title to any subject invention.’ 35 U.S.C. § 202(a). A ‘subject invention’ is defined as ‘any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.’”⁶⁶

Next, the Court reviewed the language from the Bayh-Dole Act that Stanford relied upon in support of its argument that it had superior rights to Holodniy’s invention.⁶⁷ Stanford first argued that the Act’s phrase “invention of the contractor” in the definition of “subject invention” should be read to include “all inventions made by the contractor’s employees with the aid of federal funding.”⁶⁸ The Court disagreed, explaining that this reading could not possibly be correct since it would “subtly set aside two centuries of patent law in a statutory definition.”⁶⁹ The Court was “confident that if Congress had intended such a sea change in intellectual property rights it would have said so clearly...”⁷⁰

Moreover, according to the Court, Stanford’s interpretation would “render the phrase ‘of the contractor’ superfluous,” since interpreting “inventions of the contractor” to mean “all inventions” would give it the same meaning as “any...invention conceived or first actually reduced to practice in the performance of work under a funding agreement.”⁷¹ The Court expressed a reluctance to approve of any construction that treats statutory terms as surplusage.⁷²

To the Court, a more acceptable construction would interpret the phrase “inventions of the contractor” as referring “to a particular category of inventions conceived and reduced to practice under a funding agreement.”⁷³ The Court reasoned that this lead to

the conclusion that “[o]nly when an invention belongs to the contractor does the Bayh-Dole Act come into play.”⁷⁴ According to the Court, this interpretation was fully consistent with the purpose of the Act, which was “to clarify the order of priority of rights between the Federal Government and a federal contractor in a federally funded invention that already belongs to the contractor. Nothing more.”⁷⁵ The Court further reasoned that since the Bayh-Dole Act does not apply to inventions belonging to an inventor, it did not even address, let alone dictate, displacement of the inventor as the original title holder to his invention.⁷⁶

Stanford also argued that the word “retain” in the phrase “may elect to retain title” in the Bayh-Dole Act meant “acquire” and “receive,” and that this phrase allowed a federal contractor to elect to acquire title to a federally funded invention.⁷⁷ The Court disagreed.⁷⁸ According to the Court, Stanford’s interpretation of “retain” to mean “acquire” or “receive” was not the common meaning of the word.⁷⁹ Citing to three dictionaries, the Court determined that “retain” implied preexisting possession.⁸⁰ The Court went on to reason that “[y]ou cannot retain something unless you already have it” and, according to the Court, the Act’s “may elect to retain title” language “does not confer title to federally funded inventions on contractors or authorize contractors to unilaterally take title to those inventions; it simply assures contractors that they may keep title to whatever it is they already have.”⁸¹

Finally, the Bayh-Dole Act’s lack of procedural protections for inventors and third parties—for example, to contest a claim that an invention was federally funded—also aided the Court in confirming the Act’s limited scope.⁸² According to the Court, the lack of procedural protections would ordinarily be “deeply troubling,” but it “makes perfect sense” if “there is no need to protect the inventor’s rights because the only rights at issue are those of the contractor and the Government.”⁸³

The dissent, written by Justice Breyer, cast the Bayh-Dole Act in a different light. Justice Breyer

64. *Id.* at 2196-98.

65. *Id.* at 2196.

66. *Id.*

67. *Id.* at 2196-98.

68. *Id.* at 2196.

69. *Id.* at 2196.

70. *Id.* at 2198-99.

71. *Id.* at 2196.

72. *Id.* (citing *Duncan v. Walker*, 533 U.S. 167, 174 (2001)).

73. *Id.* at 2196.

74. *Id.* at 2197.

75. *Id.*

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.* at 2198.

83. *Id.*

stated that the right outcome would have been to vacate the Federal Circuit's decision.⁸⁴ Joined by Justice Ginsburg, he maintained that existing laws and regulations reflected the desire to avoid having the public pay twice for the cost of a federally funded invention.⁸⁵ The dissent stated that various federal statutes prevented the inventor—who had already received the benefit of federal funds—from hindering the distribution of the new invention by means of a patent by allowing the government to take title to such inventions.⁸⁶ According to the dissent, the Bayh-Dole Act, consistent with this legal framework, had left the rights in such inventions to the recipient of federal funds for the specific objective of encouraging institutions like Stanford to commercialize their inventions.⁸⁷ The dissent argued that it was consistent with the objectives of the Bayh-Dole Act to read the statute as requiring “an assignment of patent rights by the federally funded employee to the federally funded employer.”⁸⁸

Justice Breyer also took issue with the Federal Circuit's interpretation of the “agree to assign” and “do hereby assign” language in the CPA and VCA, respectively, asserting that in 1988 when the CPA was executed “patent law appears to have long specified that a present assignment of future inventions (as in both contracts here) conveyed equitable, but not legal, title.”⁸⁹ From this perspective, Stanford had the superior equitable interest because it executed the CPA with Holodniy first and later received written assignment of Holodniy's rights to the invention.⁹⁰ Justice Breyer added that the Federal Circuit's reasoning disregarded the intention of the parties to the CPA.⁹¹

Implications of the Supreme Court's Decision and Practice Tips

The Supreme Court's grant of *certiorari* for this case came as a surprise to many intellectual property attorneys who did not believe that the Bayh-Dole Act changed the centuries old proposition that inventors ultimately have rights in their patents. As a result, the

Supreme Court's decision certainly reassured inventors, as well as all those involved in the practice of law involving inventions, that their longstanding belief that the ownership rights in inventions belong first and foremost to inventors is correct. The extensive history of practice built on “the premise that rights in an invention belong to the inventor”—and the corollary that an employer does not automatically own the rights to an invention conceived by its employee—remains unchanged under the Bayh-Dole Act.⁹²

In its *Petition for a Writ of Certiorari*, Stanford dramatically argued “[t]he impact of the Federal Circuit's decision is without question: it immediately triggered a wave of discussion and commentary and grave concern among the universities . . . At stake is the ownership of countless inventions made over 30 years.”⁹³ This is an overstatement. Roche countered this argument by pointing out that “not one of Stanford's many amici” stated that it had used the disputed “agree to assign” language found in Stanford's agreements.⁹⁴ Whether Stanford's predicted upheaval will occur remains to be seen. Thus far there have been no reports of it in the press.

After the Supreme Court decision, if university technology transfer offices want to assure that they “retain title” to their federally funded employees' inventions they must obtain these rights in the present, by written agreement, and not rely on a promise to grant rights in the future. To be safe, they should use the language in the Stanford VCA, which has been blessed by the Federal Circuit, stating that the “signor will assign and does hereby assign” his/her inventions.⁹⁵

Finally, when arranging for its employees to conduct research at the facility of a collaborating company, a university would be well advised to negotiate in advance the ownership of any resultant inventions and have both parties sign a written agreement memorializing the results of the negotiation. ■

84. *Id.* at 2204-05.

85. *Id.* at 2200-01.

86. *Id.* at 2201-02.

87. *Id.*

88. *Id.* at 2203.

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.* at 2192, 2199.

93. *Bd. of Trs. of Leland Stanford Univ. v. Roche Molecular Sys., Inc., Petition for a Writ of Certiorari*, 2010 WL 1138571 (U.S.) at *3-4.

94. *Bd. of Trs. of Leland Stanford Univ. v. Roche Molecular Sys., Inc.*, Brief in Opposition to Petition for a Writ of Certiorari 2010 WL2173781 (U.S.), at *16.

95. *Bd. Of Trs.* 131 S.Ct. at 2204; *Stanford*, 583 F.3d at 844-45.