

The National Institutes of Health, Patents, and the Public Interest: an Expanded Rationale of Justice Breyer's Dissent in *Stanford v. Roche*

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**The National Institutes of Health, Patents, and the
Public Interest: an Expanded Rationale of Justice
Breyer’s Dissent in *Stanford v. Roche***

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I. INTRODUCTION

In February 2010, the Alzheimer’s Institute of America (AIA) filed a patent infringement lawsuit against Jackson Laboratory, the largest repository of research mice in the world.¹ AIA sued Jackson Laboratory for infringing on AIA’s patent covering a DNA mutation linked to Alzheimer’s disease.² Jackson Lab allegedly violated that patent by distributing mice especially bred for Alzheimer’s research.³

1. See *National Institutes of Health Intervenes to End Patent Infringement Suit Against the Jackson Laboratory Concerning Alzheimer’s Disease Research Mouse Models*, INTELLECTUAL PROPERTY TODAY (Sep. 23, 2011), www.iptoday.com.

2. *Id.*

3. *Id.*

AIA also sued a number of other parties for infringing upon this same patent. However, in August 2011, only the case against Jackson Laboratory was dismissed.⁴ What caused the dismissal of the lawsuit against Jackson Laboratory? The answer is simple: the National Institutes of Health (NIH) had funded Jackson Laboratory's research with the mice in question since 2003.⁵ And due to the NIH's significant interest in the research, it retroactively granted Jackson Laboratory authorization and consent to distribute the mice.⁶

It is easy to see why Jackson Laboratory, and arguably the public, benefited from NIH's rare decision to intervene.⁷ Currently, the NIH holds various patent rights that date back to the federal government's long-term vision of the agency.⁸ Many of these rights come from the amendments to the Patent and Trademark Act, or more commonly referred to as the Bayh-Dole Act.⁹

Today, it seems like this vision falls seamlessly in line with the NIH's broader goals within the medical research community. For example, Francis Collins, the Director of the NIH, released a letter explaining the agency's decision to support Jackson Laboratory against the infringement suit.¹⁰ He stated that it was not only to aid Jackson Laboratory, but also to effectuate the NIH's broader policy on access to research tools.¹¹ Specifically he stated, "[t]his is great news not only for those involved in Alzheimer's disease research, but for the entire biomedical research community . . . [a]t [the] NIH, we believe that science advances most rapidly when new technologies and research tools resulting from federal

4. *Id.*

5. *Id.*

6. See Letter from Francis S. Collins, Director, National Institutes of Health, to David Einhorn, House Counsel, The Jackson Laboratory (Jun. 17, 2011) (on file with the National Institutes of Health) [hereinafter Letter from Francis S. Collins].

7. The public has a significant interest in scientific research and development of a disease that currently does not have a cure and affects millions of Americans daily. See <http://www.alz.org/> (5.4 million Americans are currently living with Alzheimer's). See also CENTERS FOR DISEASE CONTROL AND PREVENTION, *Alzheimer's Disease*, <http://www.cdc.gov/Features/Alzheimers/>.

8. See generally, Mary Eberle, Comment: *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 MARQ. INTELL. PROP. L. REV. 155 (1999).

9. WENDY H. SCHACHT, CONG. RESEARCH SERV., RL 32076, THE BAYH-DOLE ACT: SELECTED ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY (2011) (stating that the government's "interest in facilitating U.S. technological innovation led to the passage of P.L. 96-517, amendments to the Patent and Trademark Act (commonly referred to as the Bayh-Dole Act after is two main sponsors.)"). Thus, throughout this article, the author will refer to the Amendments to the Patent and Trademark Act as the "Bayh-Dole Act."

10. See Letter from Francis S. Collins, *supra* note 6.

11. *Id.*

funding are made available to others.”¹²

In addition to having some authority over patents, the NIH has an underlying mission to uncover new knowledge that will lead to improved public health.¹³ The Office of Technology Transfer, under the NIH, has a primary function to transition basic medical research into commercially successful inventions that will improve public health.¹⁴ With such a stated mission, the NIH does not take this responsibility lightly and is heavily involved in balancing the interests of the public with those of the private sector.¹⁵

It is with this backdrop that this Comment analyzes the recent Supreme Court case *Board of Trustees of Leland Stanford University v. Roche Molecular Systems, Inc. (Stanford v. Roche)*.¹⁶ In *Stanford v. Roche*, the Court sets forth an interpretation of the Bayh-Dole Act with regards to patent ownership and holds that patent ownership can vest beyond the initial recipient of federal funding.¹⁷ This Comment discusses the dissenting viewpoint set forth by Justice Breyer, who claimed that the majority’s holding will adversely affect the carefully thought-out balance of interests between the public and private sector.¹⁸ This Comment agrees with the dissenting opinion in *Stanford v. Roche* and seeks to assuage Justice Breyer’s concern over this balance of interests by using the NIH as an example of how the government is actively seeking to balance this interest, even if the Court is not.

Section II of this Comment will discuss the historical rationale behind creating the NIH and its enabling authority. Specifically, this Section will delve into the two opposing viewpoints leading up to the passage of the Bayh-Dole Act. Section III will briefly discuss the Bayh-Dole Act and the implications the Act has on the NIH’s patent authority. Section IV will focus on the recent Supreme Court decision in *Stanford v. Roche*. Finally, Section V of this Comment will argue that Justice Breyer’s dissenting opinion in *Stanford v. Roche* highlights an important public interest viewpoint on patent ownership. This Section will then argue that this

12. *Id.*

13. See UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH, www.nih.gov (last visited February 15, 2012) [hereinafter NATIONAL INSTITUTES OF HEALTH]. See also UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH, OFFICE OF TECHNOLOGY TRANSFER, www.ott.nih.gov (last visited February 15, 2012) [hereinafter OFFICE OF TECHNOLOGY TRANSFER].

14. OFFICE OF TECHNOLOGY TRANSFER, *supra* note 13.

15. *Id.*

16. Bd. of Trs. of Leland Stanford Univ. v. Roche Molecular Sys., 131 S. Ct. 2188 (2011).

17. *Id.* at 2196.

18. *Id.* at 2200–02.

viewpoint is a valid public policy concern that could tip the carefully balanced interests between the public and private sector, which are currently in place to facilitate patent innovation. This Section will lastly use the NIH to exemplify how the government uses existing statutory authority to balance this public-private interest.

II. HISTORICAL BACKGROUND OF THE NATIONAL INSTITUTES OF HEALTH AND PATENT AUTHORITY

The NIH received its enabling authority from the passage of the Public Health Service Act (PHS Act).¹⁹ Throughout the 1930s, the federal government began granting funds to states and local health departments and expanded their involvement throughout national health care.²⁰ Congress initially passed the PHS Act in two pieces of legislation; first in 1943 and then in 1944 when it codified its authority and strengthened its role.²¹ Functioning through four main authorities: “the Office of the Surgeon General, the National Institute of Health, a new Bureau of Medical Services, and a new Bureau of State Services,”²² the PHS Act was the first piece of legislation unifying already existing programs and federal activities into a “linear relationship between investment in the supply of knowledge and health services and [the] reduction in the burden of disease.”²³ It essentially set up a new approach to public health in the United States.²⁴

A. *Two Decades of Careful Planning Created the National Institutes of Health*

Before the end of World War II, public health officials began laying the groundwork for a postwar medical research effort.²⁵ Thus, during the 1930s, the NIH worked hard to be a part of that effort.²⁶ Congress

19. See Lynne Page Snyder, *Passage and Significance of the 1944 Public Health Service Act*, 109 PUBLIC HEALTH REPORTS 721 at 723 (1944).

20. *Id.*

21. *Id.* at 723.

22. Lynne Page Snyder, *A New Mandate for Public Health*, 109 PUBLIC HEALTH REPORTS 469, 469 (1944).

23. Daniel M. Fox, *The Public Health Service and the Nation's Health Care in the Post-World War II Era*, 109 PUBLIC HEALTH REPORTS 725, 725 (1994). See Rebecca Goulding, et. al., *Alternative Intellectual Property for Genomics and the Activity of Technology Transfer Offices: Emerging Directions in Research*, 16 B.U. J. SCI. & TECH. L. 194, 217–18 (2010).

24. Snyder, *supra* note 22, at 471.

25. Donald C. Swain, *The Rise of a Research Empire: NIH, 1930 to 1950*, SCIENCE, NEW SERIES, Dec. 14, 1962, at 1233.

26. Donald S. Fredrickson, *The National Institutes of Health Yesterday, Today, and Tomorrow*, 93 PUBLIC HEALTH REPORTS 642, (1978); see also NATIONAL INSTITUTES OF HEALTH,

carefully crafted legislation to provide maximum flexibility for the NIH.²⁷ While the PHS had initially proposed solely intramural research, research conducted by the agency's own scientists and in their own laboratories,²⁸ other proposals believed that the government should limit its own research programs and award grants-in-aid to university scientists.²⁹ Slowly, this idea took off with the creation of the National Cancer Institute, which was the first institute to award grants-in-aid and fellowships to able researchers in institutions outside of the PHS.³⁰ This approach proved to be cost effective and successful as the NIH became "the principal biomedical and behavioral research agency within the Federal Government."³¹ Now, as the premier public health agency, the NIH was ready for more power, principally in the patent arena.

B. The Department of Health Education and Welfare

Many post World War II U.S. presidents attempted to unify a patent policy across federal agencies, however, both sides of the debate were compelling, and Congress could not agree.³² Thus, agencies followed ad hoc patent titles and licensing for many years.³³ The Department of Health, Education, and Welfare (HEW)³⁴ was one of the first agencies to negotiate an agreement with universities regarding technology transfer.³⁵ These agreements were known as Institutional Patent Agreements.³⁶ HEW specifically wanted to grant exclusive patent licenses and was the first agency to do so absent explicit statutory authority.³⁷ Under the financial umbrella of HEW, the NIH also granted patent titles in a similar fashion.³⁸ This approach to technology transfer of information was significant because the NIH controlled "nearly half of all federal financing

supra note 13.

27. Fredrickson *supra* note 26, at 643.

28. *Id.* at 646.

29. *Id.* See Gil Van Bokkelen, *The Role of the Federal Government in Overseeing Medical Research*, 20 J.L. & HEALTH 299, 300-04, (2006).

30. *Id.*

31. *Id.* See OFFICE OF TECHNOLOGY TRANSFER, *supra* note 13. See also Deepak Hegde, *Political Influence Behind the Veil of Peer Review: An Analysis of Public Biomedical Research Funding in the United States*, 52 J. LAW & ECON. 665 (2009).

32. White Paper, *The Bayh-Dole Act* at 25, 19 (Apr. 17, 2006), http://www.bayhdolecentral.com/BayhDole25_WhitePaper.pdf [hereinafter White Paper].

33. *Id.*

34. *Id.* (The HEW is currently the Department of Health and Human Services).

35. *Id.*

36. *Id.*

37. *Id.* at 13.

38. *Id.*

of academic research.”³⁹ Eventually, the HEW became a premier example of how the government could facilitate patent innovation that benefitted both the public and private sectors.

C. Two Opposing Perspectives: The Bush-Kilgore Debates

During the debates prior to the passage of the Bayh-Dole Act, the conversation focused on whether the government should have a uniform patent policy and who should primarily retain title to patents that were discovered in part through the use of public funding.⁴⁰ Prior to 1980, the government maintained full control of all patents resulting from government sponsored research.⁴¹ Although this approach ensured that patents would be available to the public and fall in line with the goals of the PHS Act and the NIH, this approach prevented federally financed technology to translate into successful commercial products.⁴² This often stifled innovation, and it was thought that “public ownership of research results was equivalent to ‘dead-hand’ control, and [that] the public domain was a treacherous quicksand pit in which discoveries [sunk] beyond reach of the private sector.”⁴³ Without a uniform policy across all agencies, the government “lacked a consistent approach to determining who held clear title to federally-financed research.”⁴⁴

Congress had been debating this issue for decades; however, the concerns over agreeing on a uniform government patent policy were becoming more pertinent due to a “massive expansion of federal [research and development] during World War II, [where] patents [became] a central point of contention during the Bush-Kilgore debates over the shape of . . . science and technology policy.”⁴⁵

One prominent side of the debate was led by Senator Harley Kilgore, a representative from West Virginia.⁴⁶ He believed and emphatically

39. *Id.*

40. Bhaven N. Sampat, *Patenting and US Academic Research in the 20th Century: The World Before and After Bayh-Dole*, 35 RESEARCH POLICY 772, 777 (2006). See generally, SCHACHT, *supra* note 9 (“cited studies suggest that companies which do not control the results of their investments, either through ownership of patent title, exclusive license, or pricing decision, tend to be less likely to engage in related R&D.”)

41. White Paper, *supra* note 32, at 12.

42. *Id.* at 10.

43. Rebecca S. Eisenberg, Symposium, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1664 (1996).

44. White Paper, *supra* note 32; See Edward C. Walterscheid, *The Need for a Uniform Government Patent Policy: The D.O.E. Example*, 3 HARV. J.L. & TECH. 103 (1990).

45. Sampat, *supra* note 40, at 777.

46. For further explanation on Senator Kilgore’s position see Robert F. Maddox, *Senator Harley M. Kilgore and Japan’s World War II Business Practices* (1996).

argued that titles to patents should be retained by the federal government when funded with federal research dollars; that way they would primarily be kept in the interest of the public domain.⁴⁷ Senator Kilgore's main concern with large corporations retaining title to patents was that taxpayers would be "double taxed". Essentially, taxpayers' dollars are used to develop federally funded patents, and then taxpayers pay again as a consumer once the patents are commercialized.⁴⁸ Instead, with patent titles retained in the government domain, the public would benefit without being "double taxed."⁴⁹

Vannevar Bush, the Director of the Wartime Office of Scientific Research and Development, held the opposing argument.⁵⁰ He strongly believed that technology and innovation played a critical part in the war effort and, particularly, in winning the war.⁵¹ In 1945, Bush presented a report to Congress, which was a request from President Roosevelt, detailing his "support of basic science to the goal of stimulating the economy."⁵² His position and influence led to strengthening agencies like the NIH, whose primary mission was to fund basic science for the benefit of the public domain.⁵³ Bush's argument focused on retaining title to patents in the hands of contractors or individuals, even though the funding was backed by federal dollars.⁵⁴ He believed it would be beneficial to consumers to retain title in the private sector because it would otherwise be "difficult to attract qualified firms to perform government research..."⁵⁵ Additionally, an "absence of title would reduce incentives to invest in commercial development of these inventions."⁵⁶ This position eventually won and legislators were careful to craft the policy to balance the interests of both the public domain and private sector.

47. *Id.*

48. *Id.*

49. *Id.*

50. For further explanation on Vannevar Bush's position see A REPORT TO THE PRESIDENT BY VANNEVAR BUSH, DIRECTOR OF THE OFFICE OF SCIENTIFIC RESEARCH AND DEVELOPMENT (1945).

51. White Paper, *supra* note 32, at 8.

52. *Id.*

53. *Id.*

54. *Id.*

55. Sampat, *supra* note 40, at 777.

56. *Id.* See Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J.L. SCI. & TECH. 393, 394 (2006).

III. THE BAYH-DOLE ACT AND ITS IMPACT ON THE NATIONAL INSTITUTES OF HEALTH

The Bayh-Dole Act (Act) has a long, mired history and, as stated previously, had two very distinct viewpoints forming the debate prior to its passage.⁵⁷ Passed in 1980, the country was at a distinct disadvantage in the technological arena.⁵⁸ The Act proved to be the nation's most effective investment in technology transfer to date, and impacted many government agencies to facilitate new innovation.⁵⁹

A. *The National Institutes of Health and Its Patent Authority*

The NIH has broad discretion in its ability to manage its intellectual property rights.⁶⁰ The NIH can “invoke additional legal authorities for advancing its interest related to research tools,” and it can assist in improving access to research tools and ultimately patents in the public domain.⁶¹ Specifically, the NIH has intramural authorities and grant authorities under the Act; all of which are given to any research oriented federal agency.⁶²

The Act sets out a framework for many government agencies, including the NIH, that are involved in technology transfer. It allows grantees of federal contracts to “elect title to patentable ‘subject inventions’ that arise within the use of federal funds.”⁶³ Even if the grantee chooses to elect title to the invention, the federal agency still has residual rights to the subject inventions.⁶⁴ For example, the NIH can intervene and elect title itself or limit the grantees right to title if it sees fit under the circumstances.⁶⁵ Specifically, the NIH can intervene “in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives.”⁶⁶ The primary purpose to use the power to elect in exceptional circumstances is to

57. *See supra* Section I C.

58. Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004, available at www.ott.nih.gov/policy/meeting/Senator-Birch-Bayh.pdf.

59. *See* Margo A. Bagley, *Academic Disclosure and Proprietary Rights: Putting Patents in their Proper Place*, 47 B.C. L. REV 217, 220 (2006).

60. REPORT OF THE NIH WORKING GROUP ON RESEARCH TOOLS, ANALYSIS OF NIH OPTIONS UNDER CURRENT LAW, PRESENTED TO THE ADVISORY COMMITTEE TO THE DIRECTOR (1998).

61. *Id.*

62. *Id.*

63. *Id.*

64. *See* 35 U.S.C. § 202 (2006).

65. *Id.*

66. 35 U.S.C. § 202(a) (2006).

promote the broad dissemination of research tools for the benefit of the public, however, the NIH has yet to utilize this power over inventions.⁶⁷ The NIH also has the ability to use any patented research tools that arise from federally sponsored research without the liability of patent infringement.⁶⁸

Under 35 U.S.C. section 203, the Act provides government agencies with a “march-in” authority or a mandatory licensing authority.⁶⁹ The primary purpose of this authority is to “prevent the underutilization of federally funded inventions.”⁷⁰ Again, this right only applies to research tools that are defined as patentable subject inventions, per statute language.⁷¹ Although the right has a beneficial use to improve access to particular research tools, the process is cumbersome and thus seldom used.⁷² Before exercising this right, the NIH must determine that it is necessary to intervene because the grantee or licensee has not taken proper steps to achieve a practical application of the invention in a particular field of use, to satisfy health or safety needs, or to meet requirements for public use specified by Federal regulations.⁷³ Although the triggers to permit an intervention seem broadly defined, “the NIH has only received march-in petitions four times” and has yet to exercise the right.⁷⁴ The benefit of this right is that its power is utilized only if it would be beneficial to the government.⁷⁵ That is, the government could intervene so that a third party could license the patent and manufacture the product to make it available to the public domain.⁷⁶

There are many rights the NIH has apart from those proscribed under

67. REPORT OF THE NIH WORKING GROUP ON RESEARCH TOOLS, ANALYSIS OF NIH OPTIONS UNDER CURRENT LAW, PRESENTED TO THE ADVISORY COMMITTEE TO THE DIRECTOR (1998).

68. *Id.*

69. 35 U.S.C. § 203 (2006).

70. REPORT OF THE NIH WORKING GROUP ON RESEARCH TOOLS, ANALYSIS OF NIH OPTIONS UNDER CURRENT LAW, PRESENTED TO THE ADVISORY COMMITTEE TO THE DIRECTOR (1998); Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 BERKELEY TECH. L.J. 1095, 1104 (1999).

71. *Id.*

72. *Id.*

73. See 35 U.S.C. § 203(a)(1) (2006).

74. John Conley, *Government Refuses to March-In Under Bayh-Dole Act*, GENOMICS LAW REPORT (Jan. 18, 2011), <http://www.genomicslawreport.com/index.php/2011/01/18/government-refuses-to-march-in-under-bayh-dole-again/>.

75. REPORT OF THE NIH WORKING GROUP ON RESEARCH TOOLS, ANALYSIS OF NIH OPTIONS UNDER CURRENT LAW, PRESENTED TO THE ADVISORY COMMITTEE TO THE DIRECTOR (1998). For further discussion on March-in Rights under Bayh-Dole see John H. Raubitschek & Norman J. Latker *Reasonable Pricing—A New Twist for March-in Rights Under the Bayh-Dole Act*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 149, 155–160 (2005).

76. *Id.*

the Bayh-Dole Act. One falls under 28 U.S.C. section 1498, which provides a limitation on remedies for patent infringement against a governmental agency.⁷⁷ Under this provision, the NIH has the right to use and manufacture any patented invention regardless of whether it was developed with federal funding.⁷⁸ Further, the NIH can use the patent without a license, although it is subject to limited liability for doing so.⁷⁹ Specifically, the provision states:

[w]henever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.⁸⁰

A recent example of this right being asserted by the NIH was on June 17, 2011.⁸¹ The NIH granted Jackson Laboratory "with the government's authorization and consent . . . to all use and manufacture of any invention described in and covered by a United States patent."⁸² The NIH's authority to allow Jackson Laboratory to continue using a patent that the Alzheimer's Institute of American had claim over was from 28 U.S.C. section 1498, which states:

the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm or corporation for the Government and with authorization or consent of the Government, shall be construed as use or manufacture for the United States.⁸³

This right can be differentiated from other rights the NIH holds, specifically under the Bayh-Dole Act, in three ways. First, it provides the NIH with a compulsory license over all U.S. patents.⁸⁴ Thus, its right is not limited to whether the federal agency provided the funding and

77. 28 U.S.C. § 1498 (2006).

78. *See* 28 U.S.C. § 1498 (2006).

79. *Id.*

80. 28 USC § 1498(a) (2006).

81. *See supra* Introduction.

82. Letter from Francis S. Collins, *supra* note 6.

83. 28 USC § 1498 (2006).

84. REPORT OF THE NIH WORKING GROUP ON RESEARCH TOOLS, ANALYSIS OF NIH OPTIONS UNDER CURRENT LAW, PRESENTED TO THE ADVISORY COMMITTEE TO THE DIRECTOR (1998).

further, is not limited to a specific funding agency. Second, the provision requires that the government pay a reasonable compensation to the patent holder.⁸⁵ This is particularly important to note because it can be costly to the government when implemented. Thus, it is a rare occurrence when the government steps in, and this power is only used when it is essential because a license is not otherwise available. Further, seldom does the need outweigh the cost. Third, as exemplified by the Jackson Laboratory case, the NIH is able to authorize and consent to the use of a patent on behalf of third parties. The NIH believes that “[r]esearchers, patients, and caregivers look to the NIH to support the development and dissemination/sharing of critical research resources and to pursue aggressively new insights and innovative therapies to alleviate suffering.”⁸⁶ The NIH weighed the costs of intervening and granting Jackson Laboratory a compulsory license with the public benefit, and the public benefit won because, it is “critical to the advancement of our understanding of Alzheimer’s disease and to the development of new diagnostics and treatments.”⁸⁷ Therefore, the broad authority that the government granted the NIH within the patent realm has proven useful and has been utilized to primarily benefit the public.

B. The Passage of the Bayh-Dole Act

Most government investment into patent research and development produced only a small percentage of what was reaching consumers in the market.⁸⁸ Prior to the Act, the government held onto patent rights, which tended to frustrate the private industry, and often it had no reason or incentive to invest in research.⁸⁹ The belief by Congress was that the “government typically funds the inspiration [while the] industry the perspiration.”⁹⁰ At a time when the United States was concerned about the country’s technological competitiveness in the global arena, legislation that finally addressed these concerns and unified the federal government’s patent authority was necessary. The Act allows inventors to retain title to inventions that are the result of federally funded research. Subsequently, it allows them to license their inventions to the

85. *Id.*

86. Letter from Francis S. Collins, *supra* note 6.

87. *Id.*

88. See Rachael A. Ream, *Nonprofit Commercialization Under Bayh-Dole and the Academic Anticommons*, 58 CASE W. RES. 1343, 1355 (2008).

89. April L. Butler, *Stealing Thunder From Government Contractors: Thwarting the Intent of the Bayh-Dole Act in Campbell Plastics v. Brownlee*, 31 DAYTON L. REV. 477, 491 (2006).

90. Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004, available at <http://ott.od.nih.gov/Meeting/Senator-Birch-Bayh.pdf>.

private market to facilitate commercialization.⁹¹ The Act contains two salient rights that the government retained to make sure patent owners use government-sponsored inventions for the benefit of the public. This Comment will discuss these rights specifically within the context of the NIH and its patent authority.

IV. BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY V. ROCHE MOLECULAR SYSTEMS, INC.

The American federal court system has recently heard a number of public health patent cases that seem to be reigniting the debate regarding who should retain patent ownership.⁹² Although each case addresses a slightly different public health viewpoint, there is an underlying theme that courts are wary of patents that affect the public when kept in the hands of the private sector. One of the principles of the Bayh-Dole Act and the focus of the debates was retaining government ownership of a patent when it was beneficial to the public. Last year, the Supreme Court addressed this issue when it decided the *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.* (“*Stanford v. Roche*”).

When an invention is conceived, it is generally presumed to be owned by the inventor under U.S. patent law.⁹³ The case of *Stanford v. Roche* addressed the issue of patent ownership in the context of federally funded research.⁹⁴ The issue brought before the Supreme Court was whether, in the context of federally funded research, the ownership of the invention first arises with the federal contractor (i.e., Stanford) or with the inventor under the Bayh-Dole Act.⁹⁵ Further, the Court discussed whether the inventor can interfere with that right by assigning the invention to a third party.⁹⁶ Addressing this issue was significant because a large part of the debate prior to the passage of the Bayh-Dole Act focused on the issue of patent ownership and who holds that right.

In general, allowing a person to retain ownership of a patent is considered a strong right. For example, ownership of a patent gives the

91. BAYH-DOLE ACT, 35 U.S.C. § 202 (2006).

92. For example, *Lab. Corp. v. Metabolite Labs. Inc.*, 548 U.S. 124, (2006); *Ass’n for Molecular Pathology v. United States Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011).

93. 35 U.S.C. section 101 states: “[w]hoever invents or discovers a new and useful [invention] may obtain a patent.”

94. See *Bd. of Trs. v. Roche Molecular Sys.*, 131 S. Ct. 2188 (2011).

95. 35 U.S.C. §§ 200–212 (2011).

96. *Bd. of Trs. v. Roche Molecular Sys.*, 131 S. Ct. 2188, 2196 (2011).

patent owner the right to exclude others from making, using, offering for sale, selling, or importing into the United States the invention claimed in the patent.⁹⁷ Thus, holding that one party has the right over another has strong implications that can offset the carefully balanced interests of the public and private sectors; a balance already in place to further patent innovation.

The Supreme Court held in *Stanford v. Roche* that an inventor is still presumed to be the owner of a patent when the patent resulted from federally funded research.⁹⁸ The Supreme Court specifically addressed the issue of whether the ownership of the invention automatically arises with the federal contractor or with the individual inventor within the context of the Bayh-Dole Act.⁹⁹ Further, the majority opinion held that an inventor could even assign an invention to a third party.¹⁰⁰ The majority discerns that this viewpoint falls in line with the original intent of the bill and is the manner in which the government should view patent ownership.¹⁰¹

In contrast, Justice Breyer, along with Justice Ginsburg, wrote an extensive dissenting opinion that disagreed with Chief Justice Roberts.¹⁰² Specifically, Justice Breyer contended that the Court's holding turned on matters that were not fully briefed in the majority opinion.¹⁰³ More importantly for the purposes of this Comment, the dissenting opinion discusses an interesting viewpoint that the public interest is lost when ownership is transferred. Interestingly, his argument largely parallels the post-World War II national debates prior to the passage of the Bayh-Dole Act.

Justice Breyer begins his dissent by discussing the age-old debate over patents and their effectiveness in promoting innovation. He quotes two of America's founding fathers, Thomas Jefferson and James Madison, who were both concerned about "the difficulty of drawing a line between the things which are worth it to the public, the embarrassment of an exclusive patent, and those which are not."¹⁰⁴ Thus, allowing a patent owner to have a "monopoly" interest was "compensation" for the

97. 35 U.S.C. § 154(a)(1) (2006).

98. *Bd. of Trs.*, 131 S. Ct. at 2188.

99. *Id.* at 2189.

100. *Id.* at 2193.

101. *Id.* at 2203.

102. Chief Justice Roberts delivered the opinion of the court in which Justices Scalia, Kennedy, Thomas, Alito, Sotomayor, and Kagan joined. Justice Sotomayor filed a separate concurring opinion.

103. *Bd. of Trs.*, 131 S. Ct. at 2200.

104. *Id.* at 2200.

community's "benefit." Justice Breyer explained:

the importance of assuring this community 'benefit' is reflected in legal rules that may deny or limit the award of patent rights where the public has already paid to produce an invention, lest the public bear the potential costs of patent protection where there is no offsetting need for such protection to elicit that invention.¹⁰⁵

This point is alleging that, since the public pays taxes that contribute in part to federal patent grants, the public has a stake in patents, and their interests should not be outweighed for the sake of commercialization and profit.¹⁰⁶

V. RATIONALIZING THE DISCUSSION RAISED IN JUSTICE BREYER'S DISSENTING OPINION

The United States Constitution states, in Article I, Section 8, Clause 8, that "Congress Shall Have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and discoveries."¹⁰⁷ Essential to the definition of Congress' authority to promote patents is the underlying right of the public to access the innovation.¹⁰⁸ Further, the U.S. patent system is often referred to as "a social contract between the inventor and society that encourages innovation and promotes increased knowledge in the public domain."¹⁰⁹ Justice Breyer's dissenting opinion in *Stanford v. Roche* discusses this underlying right of the public in the context of the Bayh-Dole Act and ownership rights.¹¹⁰ His concerns lie in the transfer of ownership rights from the initial recipient of federal funds to a third party. And further, whether this transfer of ownership defeats the purpose behind the Bayh-Dole Act ultimately defeating the benefit to the community.¹¹¹

105. *Id.* at 2200-01.

106. See KALI MURRAY, *A POLITICS OF PATENT LAW: CRAFTING THE PARTICIPATORY PATENT BARGAIN* (Routledge Press 2012).

107. U.S. CONST. art. I § 8.

108. Cynthia Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601, 610, (2000); See Stephen W. Chen, Marina Len, & Seth D. Levy, *Patent Protection in Medicine and Biotechnology: An Overview*, 4 J. HEALTH & LIFE SCI. L. 106 (2011).

109. *Id.* at 60.

110. For the purposes of this article, the author is narrowing her argument to focus on solely the "public interest" analysis mentioned in Justice Breyer's dissent and will not address the larger issues presented in the majority and dissenting opinion.

111. Because the public has already "paid" for the patent through federal funding,

This Section will argue that the public's interest in patents invented with federal funding is lost when an ownership interest vests beyond the initial recipient of the federal funding; thus, validating Justice Breyer's viewpoint. This Comment will first argue that key policy debates prior to the enactment of the Bayh-Dole Act sought to preserve a balance between private and public interests. One solution to this balance of interests was to maintain the interest of investors by allowing them to retain ownership of title to a patent. Thus, allowing ownership to vest beyond the initial investor or recipient of federal funding defeats the purpose underlying the passage of the bill.¹¹² Second, in lieu of the majority opinion clearly setting precedent for patent ownership in future litigation, this Section will offer Justice Breyer a case study of a government agency currently maintaining a balance of interests between investors ownership rights and the public domain. This section will use the National Institutes of Health as an example of how the government asserts its authority to intervene in the patent process when the public interest is at stake, while remaining cognizant of private sector interests.¹¹³

*A. Allowing Ownership of Title to Vest beyond a Federally Funded Investor
Could Tip the Scale*

The current patent ownership arrangement is a strategic attempt to balance the interests of federally funded private investors with the interests of the public. Veering from this balance could tip the scale in the wrong direction. Patent investment would be at stake. Furthermore, it is clear that from the significant policy debates, outlined in Section 1C of this Comment, that the government had a difficult time structuring the current system (where the government and the private sector successfully continue to innovate and develop patents).

One of the major debates prior to the passage of the Bayh-Dole Act was how to balance the interests of individuals who retain ownership of the patent. The only way to encourage the private sector to further innovate was to have title to the patent vest in the initial recipient of

Justice Breyer is concerned that any interest the public might have in vesting ownership of the patent is lost when the transfer of the patent to a third party no longer ensures that the government can intervene on behalf of the public's interest, per statutory authority.

112. See Benjamin K. Sovacool, *Placing a Glove on the Invisible Hand: How Intellectual Property Rights May Impede Innovation in Energy Research and Development (R&D)*, 18 ALB. L.J. SCI. & TECH. 381, 401 (2008).

113. The author chose the National Institutes of Health as an example because of its unique history of maintaining the private sector's interest in patent development while also intervening on behalf of the public when necessary.

federal funding.¹¹⁴ Allowing title to vest in private ownership, as opposed to the government, has proven exponentially beneficial to facilitating the innovation of patents.¹¹⁵ For example, “[t]he Director of Stanford University’s Office of Technology Licensing . . . noted that exclusivity is what motivates firms to invest financial and human resources in technology development.”¹¹⁶ Why else would the private sector want to invest its resources and technology into developing patents that could potentially take years to come to fruition? It is clear, simply by looking at the number of patents that are now developed by the private sector that patent innovation would come to a halt if not for this motivation. In 1980, universities were awarded only 390 patents. By contrast in 2008, universities were awarded 3,042 patents, a significant increase.¹¹⁷

Even though the private sector has ownership rights to the patent, this arrangement for patent ownership rights eventually benefits the public as well. This is due to the underlying purpose behind the Bayh-Dole Act, which is to effortlessly transition the results of government funded research into a benefit, in part, for the public domain.¹¹⁸ By increasing the commercialization of patents the public is able to use information and technology that might never have reached the public domain.

The government strongly considered whether more needed to be done to keep an equal balance of interests instead of one that heavily favored the private sector.¹¹⁹ Many were worried that the private sector could simply use government, and essentially tax payer funds, to facilitate patent innovation and then keep all the profits once the patent became lucrative.¹²⁰ One concept that would alleviate this concern was the idea of recouping government funds once the patent became profitable.¹²¹ Thus, “recoupment is based upon the argument that the government should be reimbursed for research and development expenses provided

114. See April L. Butler, *Stealing Thunder From Government Contractors: Thwarting the Intent of the Bayh-Dole Act in Campbell Plastics v. Brownlee*, 31 DAYTON L. REV. 477, 490–91 (2006).

115. United States General Accounting Office, *Technology Transfer: Administration of the Bayh-Dole Act by Research Universities*, RCED-98-126, May 1998, 2.

116. SCHACHT, *supra* note 9, at 9.

117. WENDY H. SCHACHT, CONG. RESEARCH SERV., RL 32324, FEDERAL R&D, DRUG DISCOVERY, AND PRICING: INSIGHTS FROM THE NIH-UNIVERSITY-INDUSTRY RELATIONSHIP, 16–17 (2011); see Risa L. Lieberwitz, *Education Law: The Corporatization of Academic Research: Whose Interests Are Served?*, 38 AKRON L. REV. 759, 764–65 (2005).

118. Butler, *supra* note 89.

119. SCHACHT, *supra* note 9, at 14.

120. *Id.*

121. *Id.*

to a contractor if the resulting product is brought to the market and generates profits.”¹²²

In theory, this concept makes sense. The government is investing in the private sector with taxpayer dollars and should be reimbursed once the investment reaches profitability, especially considering the number of other strong patent rights the owner receives.¹²³ However, in practice, recoupment cuts at the very reason the private sector is willing to invest in patent innovation. The “economic incentive to realize a return on investment provided by a patent is necessary to stimulate companies to provide the often substantial financial commitment to turn federally-funded R&D into marketable technologies and techniques.”¹²⁴ Further, the government realized there was an anticipated return on investment, for the public benefit, through “increased revenues from taxes on profits, new jobs created, improved productivity and [overall] economic growth.”¹²⁵ Thus, the government strongly considered adding recoupment provisions to the Bayh-Dole Act. However, the larger implications and increased burden that it would place on stifling innovation outweighed any benefit the concept would bring.¹²⁶

The government carefully crafted the current arrangement where patent ownership vests in the initial recipient of federal funds. Therefore, allowing title to vest beyond the initial recipient of federal funds is an inaccurate assumption of the purpose behind the passage of the Bayh-Dole Act and could result in a disincentive for the private sector to continue to invest.

B. The National Institutes of Health: What Are They Doing Right?

The majority opinion in *Stanford v. Roche* held that ownership rights stem initially from the inventor instead of the initial recipient of government funding, i.e. often times the university.¹²⁷ This Comment argues that this interpretation was not the intent of the Bayh-Dole Act, and ultimately agrees with and validates Justice Breyer’s dissent.¹²⁸ The

122. *Id.*

123. See 35 U.S.C. § 261 (2002) (Patent protection offers the patent owner twenty years ownership from the filing of a patent application, protection against independent invention or reverse engineering, and protection against any similar or identical device.).

124. SCHACHT, *supra* note 9, at 14.

125. *Id.* at 15.

126. See Bernadette M. Broccolo, *Today's Conflict of Interest Compliance Challenge: How Do We Balance the Commitment to Integrity with the Demand for Innovation?* 1 J. HEALTH & LIFE SCI. L. 4 (2008).

127. See *Bd. of Trs.*, 131 S. Ct. 2188.

128. See *id.* at 2200.

majority's interpretation of the Bayh-Dole Act will pose challenges for future recipients of government funding hoping to invest in patent innovation and could possibly stifle future innovation. This Section offers an example of how the government plays, and already is playing, a critical role in maintaining the balance of public and private interests, even if the courts have chosen to tip this balance in favor of private interests. The NIH is an excellent example of how a government agency is balancing the interests of the public with the interests of the marketplace in order to foster patent development and innovation, precisely in the arena of patent ownership.

The NIH is using its explicit authority under the Bayh-Dole Act to protect the public when the private sector is inefficiently or ineffectively using federally funded inventions.¹²⁹ For example, as previously discussed, the "march-in" right allows the NIH to intervene in the ownership rights of a private patent owner under certain discretionary guidelines.¹³⁰ If the patent owner is not using the patent in its best possible way, the government can exercise its march-in rights and license the patent to another company. Essentially, "[m]arch-in rights to protect the public's interest were developed to take care of and address . . . [a] contractor's windfall profits . . . and detrimental effects to competition."¹³¹ Thus, even though the courts have chosen to interpret the Bayh-Dole Act's ownership provisions in favor of private sector ownership, the government's authority under the Act will maintain a balance of interests on behalf of the public.

The Act authorizes the Department of Commerce to create regulations to implement the provisions contained within the Act; this includes guideline procedures for agencies on how to assert their march-in authority.¹³² Although such procedures exist, they are often critiqued as being too "detailed and time-consuming, and may make it difficult to initiate a march-in proceeding."¹³³ Others have stated "that the clause is just a 'dummy clause' and [that] the government has no desire to ever use it."¹³⁴ Moreover, no government agency has ever exercised any authority

129. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-742, INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 2 (2009); Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: The Bayh-Dole Reform and the Progress of Biomedicine*, 66 *Law & Contemp. Prob.* 289, 292-93 (2003).

130. See *supra* Section III B.

131. Tina K. Stephen, *Asian Initiatives on Bayh-Dole, With Special Reference to India: How Do We Make it More "Asian"?*, 10 *CHI.-KENT J. INTELL. PROP.* 44, 61 (2010).

132. Bayh-Dole Act, 35 U.S.C. § 203 (a)(1) (2002).

133. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-742, INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 7 (2009).

134. Stephen, *supra* note 131, at 62.

under march-in rights, and further, the NIH has formally been petitioned to exercise this right on three separate occasions but each time determined it did not meet the statutory requirements.¹³⁵

As such, how is the interest of the public actually being protected by the government when the march-in provision is commonly ridiculed as useless? The agencies believe quite the opposite and hold that the authority is highly valued, even without being exercised, “because, together with other tools, it provides them leverage to promote commercialization of federally funded inventions.”¹³⁶ Therefore, the NIH does not need to explicitly exercise march-in rights because they are consistently looming as a bargaining chip in the background of negotiations, implementation procedures, and reporting requirements with private actors.¹³⁷ Furthermore, one anecdote commented on how the mere presence of the NIH in such discussions was enough leverage to encourage commercialization without actually exercising the authority.¹³⁸

In addition, the government heavily relies on the public to regulate and track federally-funded inventions. The public is more apt to know sources of information that could lead to a march-in proceeding. Further, the NIH awards thousands of grants each year and “[m]onitoring such a large number of awards and institutions would be very resource intens[ive].”¹³⁹ To complicate the matter even more, grants can be licensed out for multiple uses and often are. This would pose significant problems for the government if it were to inquire about every contract or license agreement to assess whether the government should exercise its march-in authority.¹⁴⁰

The NIH is effectively using the public as a resource in maintaining a balance of interests in the marketplace. Justice Breyer’s dissenting opinion in *Stanford v. Roche* is concerned with how the public’s interests will be offset given the implications of the majority opinion, which tips the interest in favor of the private sector. However, the NIH is utilizing its patent authority to effectuate the balance between the rights of the private sector with the rights of the public domain.

135. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-09-742, INFORMATION ON THE GOVERNMENT’S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 7 (2009).

136. *Id.*

137. *Id.*

138. *Id.* at 12.

139. *Id.* at 10.

140. *Id.*

VI. CONCLUSION

The NIH holds salient rights within the patent realm that allow it to maintain a balance of interests between the public and private domain; namely, when patents affect the public health. This authority under the NIH directly addresses one of Justice Breyer's main concerns in his dissenting opinion in *Stanford v. Roche*. Interestingly, Justice Breyer addresses a valid public policy concern that largely parallels the exact concerns legislators, private investors, small businesses, and universities discussed prior to the passage of the Bayh-Dole Act and subsequent legislation. At that time, the government was concerned with facilitating an investment in research and development in patents without throwing the interests of the public out the window.¹⁴¹ They carefully crafted legislation so that both interests would be best served; however, the Supreme Court now offsets this balance in the majority holding in *Stanford v. Roche*. The holding interprets the Bayh-Dole Act's ownership provisions so that they weigh slightly in favor of private interests over public interests.

In lieu of the recent court decision, however, the government is adequately taking on the responsibility of maintaining a balance in favor of the public sector and will remain to do so. Many of the provisions under Bayh-Dole grant the government authority to intervene on behalf of the public when their interests are at stake. Thus, although Justice Breyer holds a legitimate concern regarding the majority's holding, his concern regarding whether there are adequate measures in place to protect the public's interest are assuaged by specific agency practices and procedures outlined in this Comment.

NIDA SHAKIR*

141. SCHACHT, *supra* note 9. Current legislation includes "the research and experimentation tax credit, the National Cooperative Research Act, the small business technology transfer program, the advanced technology program, and cooperative R&D agreements established by the Stevenson Wydler Technology Innovation Act." For more information on current laws governing ownership of inventions made with federal funding see Mark R. Wisner, *Recent Development: Proposed Changes to the Laws Governing Ownership of Inventions Made with Federal Funding*, 2 TEX. INTELL. PROP. L.J. 193 (1994).

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