Board of Trustees v. Roche Molecular Systems Inc.: Negotiating the web of competing ownership claims to inventions arising from government-funded academic-industry collaboration

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I. INTRODUCTION

In Board of Trustees v. Roche, the Supreme Court is poised to rule on the disposition of rights to inventions arising out of academic-industry collaborations funded in part by U.S. government research grants and thereby covered by the Bayh-Dole Act (BDA). Central to this case is the contentious issue over multiple and inconsistent assignments of patent rights claimed by both Stanford University and Cetus, a biotech company where crucial aspects of the invention were developed in its labs. This case speaks to collaborations between universities and businesses, in which employees and know-how flow freely between partners, financing for which is partly based on federal research grants. The ruling implicates public policy goals including: recent government policy initiatives supporting innovation and invention, academic entrepreneurship along with its associated economic and

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1 583 F.3d 832 (Fed. Cir. 2009), vacating and remanding, 583 F. Supp.2d 1016 (N.D. Cal. 2008).


3 Cetus, one of the first biotech companies, was a faculty start-up, spun-off from University of California at Berkeley based on inventions from its labs.
competitiveness consequences, and the continuing vitality of the historic doctrine that patent rights vest first with inventors.

Should the Court award rights to the university-contractor whose assignment is first in time though the language concededly lacks precision? Or should the Court award rights to the company whose assignment while second in time is clear as to intent and rights? What of the inventor, the presumed owner? How to construe the BDA, whose main purpose was to incent invention and innovation through commercialization of government-funded research? Its stunning success has had the effect of converting billions of taxpayer dollars for basic research into commercial applications, jobs, companies and wealth. While the BDA language focuses mainly on allocating and tiering rights of contractor-universities and the government, it lacks clarity as to the inventor's rights or partnering companies' rights for it does not explicitly repudiate American patent law.

This case significantly impacts universities that seek to commercialize their faculties' research into patentable inventions and highlights their risk exposure well in relation to collaborations with businesses that partner or share knowledge with universities. This exposes the tensions as to control or ownership of inventions inherent in collaborations between research universities and commercial entities and points to another thicket of complications for universities' faculty relationships. The Court will issue its opinion at the end of the Term and it will be the first time the Court has construed this aspect of the Bayh-Dole Act.

II. CASE BACKGROUND

A. The Invention

The patent rights in question claim methods for quantifying HIV in human blood samples and correlating those measurements to the therapeutic effectiveness of anti-retroviral drugs. The claimed methods use the polymerase chain reaction (PCR) to measure ribonucleic acid (RNA) from HIV in the blood plasma of patients. The PCR exponentially amplifies the sample to show detectable levels of the nucleic acids. The three patents (5,968,730, the '730 patent; 6,503,705, the '705 patent; and 7,129,041, the '041 patent) derive from a parent application and share the same title, 'Polymerase Chain Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the Treatment of Acquired Immunodeficiency Syndrome.' Three
Stanford researchers, Mark Holodniy, Thomas Merigan, and David Katzenstein, are named inventors on all three patents. A fourth inventor, Michael Kozal appears on just one of the patents.

The legal complications arose because one of the inventors signed multiple and inconsistent agreements defining his obligations to assign his invention rights. First, in 1988 when Mark Holodniy joined Merigan’s lab at Stanford as a Research Fellow, he signed a Copyright and Patent Agreement (CPA) obligating him to assign any inventions to Stanford. In the CPA, Holodniy acknowledges that Stanford enters into contracts or grants with third parties, including the government, and that he may “conceive or first actually reduce to practice” various inventions. Specifically paragraph 2 provides: “I agree 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.”

October 19, 1999: 1. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising: (i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent; (ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and (iii) testing for the presence of HIV-encoding nucleic acid, in the product of the PCR; in which the absence of detectable HIV-encoding nucleic acid correlates positively with the conclusion that the antiretroviral agent is therapeutically effective.

U.S. Patent No. 6,503,705 (Kozal, Merigan, Katzenstein and Holodniy, inventors), issued on January 7, 2003: 1. A method of evaluating the effectiveness of anti-HIV therapy of an HIV-infected patient comprising: a) collecting statistically significant data useful for determining whether or not a decline in plasma HIV RNA copy numbers exists after initiating treatment of an HIV-infected patient with an antiretroviral agent by: (i) collecting more than one plasma sample from the HIV-infected patient at time intervals sufficient to ascertain the existence of a statistically significant decline in plasma HIV RNA copy numbers; (ii) amplifying the HIV-encoding nucleic acid in the plasma samples using HIV primers via PCR for about 30 cycles; (iii) measuring HIV RNA copy numbers using the products of the PCR of step (ii); (iv) comparing the HIV RNA copy numbers in the plasma samples collected during the treatment; and b) evaluating whether a statistically significant decline in plasma HIV RNA copy numbers exists in evaluating the effectiveness of anti-HIV therapy of a patient.

And U.S. Patent No. 7,129,041 (Merigan, Katzenstein and Holodniy, inventors), issued on October 31, 2006: 1. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising: correlating the presence or absence of detectable HIV-encoding nucleic acid in a plasma sample of an HIV infected patient with an absolute CD4 count, wherein the presence or absence of said detectable HIV-encoding nucleic acid is determined by (i) collecting a plasma samples from an HIV-infected patient who is being treated with an antiretroviral agent; (ii) amplifying HIV-encoding nucleic acid that may be present in the plasma sample using HIV primers via PCR and; (iii) testing for the presence of HIV-encoding nucleic acid sequence in the product of the PCR.

6 Board of Trustees, 583 F.3d at 837.
7 Id.
8 Id. at 841.
Holodniy further promised in the CPA to “not enter into any agreement creating copyright or patent obligations in conflict with this agreement.”

Since Holodniy had no prior experience with PCR techniques, in 1989 he began regular visits to Cetus, a private company whose PCR work had matured by then. Merigan, Holodniy’s supervisor at Stanford directed him to work with Cetus and himself executed a number of Materials Transfer Agreements with Cetus allocating some intellectual property rights. Cetus Company Policy required all visitors to sign agreements. Accordingly Holodniy signed Cetus’s “Visitor’s Confidentiality Agreement” (VCA). The primary purpose of Cetus’s VCA was to maintain confidentiality of all aspects of company operations. Though characterized by the company as a confidentiality agreement, additionally it featured an assignment clause that figures prominently into this litigation: specifically Holodniy agreed that “[I] will assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements” devised as a consequence of his work with Cetus. This purportedly effects a present transfer of future invention rights. This collaborative research yielded results: the research produced an assay that became the basis of the invention and further, Holodniy co-authored a paper with Cetus employees and subsequently returned to work further with Stanford colleagues on clinical studies that led to the patented invention.

Also adding to the mix of issues, Stanford applied for and received government funding from the National Institutes of Health to conduct HIV research. Federal funding is commonly sought to support research of small businesses and non-profits. Congress passed the Bayh-Dole Act (BDA) to promote research and development and to ensure that it obtains sufficient rights in federally funded inventions. The Act allows the Government to elect to take title to inventions, or the contractor universities, or inventors may elect title if the Government does not. Should universities elect to take title to inventions, the Government nevertheless reserves “march-in” rights under certain conditions.

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9 Id. at 843.
10 Id.
11 Id. at 842.
12 Id. at 837.
13 Id. at 838.
14 Id. at 844. See infra Part II for a complete rendering of the statutory provisions.
15 Board of Trustees, 583 F.3d at 844; see also 35 U.S.C. section 203 (2006).
B. Competing Claims of Ownership

In December 1991, Roche purchased Cetus, including its agreements with Stanford researchers through an Asset Purchase Agreement.16 Thereafter, Roche began manufacturing HIV detection kits employing the RNA work.17

In May 1992, Stanford filed the parent application to which these patents claim priority.18 (The '730 patent issued on Oct. 19, 1999; the '705 patent on Jan. 7, 2003; and the '041 patent on Oct. 31, 2006, after this litigation began.) Stanford is the assignee of all three patents.19 In June 1992, Stanford filed an invention disclosure with the NIH.20 In November 1994, Stanford formally notified the Government that it elected to retain title to the invention under the Bayh-Dole Act, confirming the grant of a "nonexclusive, nontransferable, irrevocable, paid-up license."21

In May 1995 Holodniy signed a second agreement with Stanford, this time executing an assignment of rights in the parent application to Stanford.22 In April 2000, Mr. Luis Mejia a Senior Licensing Associate in Stanford’s Office of Technology Licensing conducted a slide presentation at Roche that purported to establish Stanford’s ownership of the HIV RNA invention, at which time he offered Roche a license to the patents.23 This meeting put Roche on notice that Stanford claimed ownership of Holodniy’s work, that Stanford patented the invention relating to the Holodniy-Cetus collaboration, that Stanford continued to file related patent applications, and that Stanford expected Roche to license the technology. Roche disputed this, claiming that it owns all of Holodniy’s rights pursuant to the VCA signed in 1989.24

C. Litigation over Competing Claims

In 2005, Stanford filed suit in the United States District Court for the Northern District of California alleging that Roche’s HIV detection kits infringed its patents.25 Roche answered and counterclaimed arguing inter alia, that Stanford lacked standing to sue because Roche “possesses ownership, license, and/or shop rights to the patents through Roche’s

16 Board of Trustees, 583 F.3d at 837-88.
17 Id. at 838.
18 Id. at 842.
19 Id. at 838.
20 Id.
21 Id.
22 Id. at 842.
23 Id. at 847.
24 Id.
25 Id. at 838.
acquisition of Cetus’s PCR assets.”26 Roche pleaded its ownership theory in three forms: as a declaratory judgment counterclaim, an affirmative defense, and challenge to Stanford’s standing to sue for infringement.27 The parties cross-motioned for summary judgment on Roche’s rights in the patents. The district court denied Roche’s motion in full and granted Stanford’s motion in part. After briefing and a hearing, the court construed several claim terms.28 At this point, Roche moved for summary judgment on grounds that the asserted claims were invalid. The district court granted Roche’s motion though based on its conclusion that the claims failed the non-obviousness requirement and the parties filed a cross-appeal.29

On appeal to the Court of Appeals for the Federal Circuit (CAFC), Stanford appealed the judgment of invalidity; Roche cross-appealed the judgment as to the parties’ respective rights in the patents. The court first considered Roche’s claims of ownership as a bar to Stanford’s standing and began with a review of the chain of title to the invention. Conceding that interpreting contracts is normally a state law matter (the question here was whether the patent assignment clause created an automatic assignment or merely an obligation to assign), the court retained jurisdiction since the contracts were so closely linked to the patent case.30

The court of appeals initially ruled that the district court abused its discretion when it incorrectly declined to consider Roche’s affirmative defense based on ownership of the invention.31 Thereafter the court construed each agreement chronologically. It interpreted the ‘I agree to assign’ language of the 1988 Holodniy-Stanford agreement, “I agree to assign...right, title and interest...in such inventions....” to be merely a promise to assign rights in the future in contrast to an immediate transfer of any interest.32 Relying on other cases as well as on Stanford’s Administrative Guide that provided, “Unlike industry and many other universities, Stanford’s invention rights policy allows all rights to remain with the inventor if possible,” the court ruled that the 1988 agreement did not effect a transfer of the invention to Stanford.33

The court then considered the effect of the 1989 Holodniy-Cetus agreement (that Roche is a successor in interest to) that stated, “I will

26 Id.
27 Id.
28 Id.
29 Board of Trustees, 563 F. Supp.2d 1016 (N.D. Cal. 2008).
30 Board of Trustees, 583 F.3d at 841.
31 Id. at 840.
32 Id. at 841.
33 Id. at 841-42.
assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions....” and distinguished this language from that used in the 1988 Holodniy-Stanford agreement. Holding that the 1989 agreement effected a present transfer of Holodniy’s future inventions to Cetus, at the moment it was signed, Cetus gained equitable title to Holodniy’s future inventions.34 (Once the invention is made and the patent is filed, legal title would be in the assignee.) While Stanford filed the patent application on May 1992, Holodniy had already conceived his contribution to the invention by then, with Cetus automatically gaining legal title before Stanford filed. Even though Holodniy purported to assign his rights to Stanford in 1995, he had no rights to assign according to the court’s interpretation of the multiple contracts.35

The court rejected Stanford’s attempt to overcome what it found was a defective chain of title as to the university. Stanford’s assertion that it was an innocent, bona fide purchaser of Holodniy’s rights did not resonate with the court because the university was on notice where, even though he was employed by them, they knew his PCR work at Cetus was directly related to the Stanford project, and the Materials Transfer Agreement highlights this point.36 Stanford’s second assertion — that Holodniy was an agent of the university and lacked authority to sign away valuable patent rights — was likewise rejected based on the court’s conclusion that Holodniy signed away his, not Stanford’s rights, as he was the inventor.37

Noting that since the federal government as another potential party-in-interest did not seek title to the invention, the court ruled that title vested in Holodniy since in its opinion, the original Holodniy-Stanford agreement was insufficiently definite on an assignment date and instead was better characterized as an indefinite obligation to assign potential future rights. Therefore Holodniy retained rights — until he transferred them to Cetus, more than six years before Stanford formally notified the Government of its election to retain title as provided by the Bayh-Dole Act.38

Finally as to Roche’s counterclaim for a judgment of ownership of the three patents, the court ruled that challenge was time-barred by the statute of limitations and the district court correctly dismissed Roche’s claim.39 Stanford’s inability to establish that it possessed Inventor

34 Id. at 842.
35 Id.
36 Id. at 843-44.
37 Id. at 844 (emphasis in original).
38 Id.
39 Id. at 846-47.
Holodniy's interest in the patents-in-suit defeated its right to assert its cause of action against Roche. While Roche's failure to timely seek a judgment of ownership defeated its counterclaim, this did not alter the fact that Stanford had no title, and therefore it lacked standing to assert claims of patent infringement against Roche.\textsuperscript{40}

In considering competing claims of ownership, the CAFC recognized fundamentally that rights vested first in the inventor rather than in either of his employers. The court then crafted a bright line rule based on its interpretation of contract language and with reference to patent law precedent holding that patent rights to this federally funded research vested first in the inventor rather than the university contractor even though work had begun at Stanford University, and that these rights were effectively assigned to Cetus in priority to rights claimed by Stanford.\textsuperscript{41} Under this construct, an inventor's present assignment of an invention trumps an inventor's promise to assign future, as-yet undiscovered inventions, considered by the court to be too remote for rights to vest. This opinion potentially undermines the goals for enacting the BDA. Moreover it greatly complicates technology transfer since it is exceedingly difficult to discover assignments as there is no uniformity to the language of rights transfers nor is there any central repository for recordation of these rights for all to see. Therefore it is not practically possible to effectively assess the assignments for validity or relevancy as to proposed deals and this leads to a great deal of uncertainty in the legal environment. The CAFC's decision altered the settled expectations of university contractors and significantly disrupted the present model under which contractors commercialized inventions based on basic research funded by the federal government.

The Supreme Court heard arguments in this case on February 28, 2011. Construing rights in this case is problematic and for this, the Court heard from the Deputy Solicitor General of the United States in addition to Petitioner and Respondent. In granting certiorari, the Court framed the question as, “whether a federal contractor university’s statutory right under the Bayh-Dole Act, 35 U.S.C. sections 200-212, in inventions arising from federally funded research can be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor’s rights to a third party.”\textsuperscript{42}

During Oral Arguments Mr. Donald Ayers representing Stanford asserted such rights could not be terminated unilaterally because the research was covered by the BDA and therefore the Stanford employee

\textsuperscript{40} Id. at 848-49.

\textsuperscript{41} Id. at 848.

\textsuperscript{42} See supra note 2.
lacked the power to transfer title to the future invention.\textsuperscript{43} He suggested that the cost of this free basic research money is a restricted right to inventions by the employee inventors - that individuals who participate in projects with BDA money have correspondingly limited rights subject to contractors' election to retain ownership. Chief Justice Roberts refuted this claim reminding counsel that title initially vests in inventors even if the work is done on behalf of an employer.\textsuperscript{44} Further the Chief Justice suggested that Stanford and other such contractors could advance their own interests at the expense of those of the United States' while cloaking themselves as guardians or stewards of this public interest.\textsuperscript{45}

The Deputy Solicitor General Mr. Malcolm Stewart appeared on behalf of the United States in support of Petitioners, acknowledging that while its interests are aligned with the contractor/Stanford's in the instant case, this may not be so in future similar cases.\textsuperscript{46} Mr. Stewart's main points related to concerns over individual inventors' ability to retain title as this is prejudicial to advancing goals of the BDA. His proposed solution is to craft a rule in which federal BDA government funding of university contractors automatically takes precedence over contractual arrangements with commercial partners.\textsuperscript{47}

Mr. Mark Fleming argued on behalf of Roche, focusing on the gaps in understanding of commonly accepted definitions of statutory language in the BDA. For example, the BDA does not explicitly state that it supersedes patent law, though its provisions are inconsistent with patent law.\textsuperscript{48} The Justices had zeroed in on this as well during Respondent's arguments earlier.\textsuperscript{49} For contractors electing to 'retain title' when they do not yet have it according to patent law, evidences a chasm in the parties' understanding, one that was overlooked by Congress, and is now left to the Court to interpret. Mr. Fleming repeatedly questioned whether this was even BDA-funded research\textsuperscript{50} and further cautioned that should Stanford prevail, Roche, a good faith successor-in-interest, would be completely unprotected, and it is possibly more in the nature of a takings case.\textsuperscript{51}

\textsuperscript{43} Transcript of Oral Argument at 3, 9-10, Board of Trustees v. Roche, 2010 U.S. LEXIS 8553 (U.S. Nov. 1, 2010) (No. 09-1159).
\textsuperscript{44} Transcript, \textit{supra} at 12-13.
\textsuperscript{45} \textit{Id.} at 42.
\textsuperscript{46} \textit{Id.} at 17-18.
\textsuperscript{47} \textit{Id.} at 24.
\textsuperscript{48} \textit{Id.} at 27.
\textsuperscript{49} \textit{Id.} at 14-15, 36, 48.
\textsuperscript{50} \textit{Id.} at 54-55.
\textsuperscript{51} \textit{Id.} at 9-10, 54-55.
Petitioner Stanford University is seeking an expansive interpretation of the BDA, citing the overarching policy goals and public benefits accruing from the Act. Stanford however, needs to overcome two primary concerns. First, that its position effectively negates individual inventors’ rights and it will have to convince the Court that the BDA’s intent supersedes patent law governing vesting of title. Second, Stanford needs to overcome concerns about the obvious shortcomings in its assignments clauses, by convincing the Court that the BDAs intent supersedes contract principles too.

Respondent Roche Molecular Systems faces other perhaps more daunting hurdles, mainly related to public policy and technological progress. Roche needs to overcome concerns that should it prevail, a precedent is created in which a company may effectively privatize taxpayer-funded basic research and thereby limit technological development, or at least diffusion of it. Further, this potentially diminishes the government’s rights and public benefits thereby frustrating all that the BDA was intended to foster, simply because of a contract outlining a different set of assignment rights the Federal Circuit construed to be better drafted.

It is unclear what direction the Justices are poised to take, though during Oral Arguments it appeared that Justices Breyer and Kennedy focused on the value of a broad recognition of rights created by the BDA. At one point Justice Breyer opined, “[if] the Federal Government paid for it, they should have the invention...[t]here is a statute here that really seems to assume, though not explicitly say, that the universities will have title - - that...an effort to assign by the employee in contravention of what this statute takes as its basic assumption, and a contract , is void as a matter of public policy, because the exclusive license is assumed...to be assigned to the university....”52 On the other hand, Justices Ginsburg, Alito, Sotomayor and Kagan focused on the private contracts and assignments and this suggests a resistance to recognizing a broad interpretation of the BDA for expediency simply to reach a result for a contractor whose own assignments were lacking in clarity.53 Justice Scalia pointed out the problematic provisions concerning university-contractors’ rights to elect to retain title, when there is no such accepted definition of this new language Congress crafted for the BDA, especially since it adds uncertainty over the disposition of rights.54 Chief Justice Roberts observed that there are

52 Id. at 29-30.
53 Id. at 9, 36-37, 39, 45.
54 Id. at 16-17; compare id. at 48 (Mr. Fleming takes exception to a reading that ‘retain’ means to automatically ‘get’ title as Stanford would have it) with id. at 57-58 (Mr. Ayers suggesting that ‘retain’ could only be construed in its common sense meaning in relation to
many entanglements contractors can find themselves in and they can possibly work around BDA restrictions with private companies, or even carve out special deals for superstar researchers, and thereby contravene the goals of the BDA.\textsuperscript{55}

A dozen amicus curiae briefs were received by the Supreme Court for this case as well.\textsuperscript{56} The circuit court opinion and the grant of certiorari triggered a great deal of uncertainty and speculation throughout university communities, start-ups, spin-outs, and even the more established biotech, life science labs that perform the critical work of translating basic research into commercial applications for goods and services.

III. LAW AND POLICY: THE BDA AND THE PRESENT BUSINESS ENVIRONMENT

\textit{A. The Bayh-Dole Act (BDA)}

The University and Small Business Patent Procedures Act of 1980, better known as the Bayh-Dole Act (BDA), was passed in an effort to foster the development and diffusion of government-sponsored research.\textsuperscript{57} Described as “possibly the most inspired piece of legislation to be enacted in America in the past half-century,”\textsuperscript{58} and referred to as innovation’s “golden goose.” The BDA created an effective formula to translate basic research and reversed a legacy of underutilized government-owned research stalled or squandered for lack of a comprehensive or uniform government policy to leverage research for commercial applications. The BDA provides a series of incentives and unleashes the potential of these taxpayer-financed inventions by shifting intellectual property ownership rights away from the government and towards institutions amenable to taking a stewardship role in fostering marketable opportunities.

The BDA provides recipient universities (the contractors) of federal research funds the option of electing to retain rights to inventions created with the research grants.\textsuperscript{59} The academic institutions then

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\textsuperscript{55} Id. at 35.


\textsuperscript{58} Opinion, Innovation’s Golden Goose, The Economist at 3 (2002).

\textsuperscript{59} 35 U.S.C. sections 200-212 (2006). The Department of Commerce administers the program, and promulgated regulations, rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and
possess a bundle of rights with certain restrictions to commercialize, or license out these inventions to entities that can effectively commercialize the work. This academic-industry alliance, backed by government funding is a tremendously successful platform for all participants and provides significant benefits to the public just as the patent system is intended to function. The BDA dramatically changed the paradigm as between contracting universities and the government because heretofore the government retained title to federally sponsored research.

Congress devised this Act to promote collaboration between the academic and business sectors and as a way to commercialize the underutilized, even dormant basic research and patents owned by the government. The General Accounting Office (GAO) found that prior to 1980 only five percent of patents on federally sponsored inventions were used. Furthermore, there were twenty-six different federal agency policies on using results from such research. Negotiating title and licensing rights to federally sponsored research was clearly a complicated endeavor. Without rational policies, businesses lacked incentives to exploit this technology by taking on such risk, and therefore potentially innovative research languished. By this time moreover, federal expenditures on research expanded from the modest funding of World War II era research projects to reach $8 billion by 1980.

B. Background on the pre-BDA environment:

To add valuable context to the BDA’s importance, it is helpful to consider government-sponsored research policies before 1980. During World War II, the U.S. government initiated and funded a series of research projects, establishing the National Defense Resources Committee “to coordinate, supervise, and conduct scientific research on the problem underlying the development, production and use of mechanisms and devices of warfare.” Initial projects focused on cooperative agreements, 37 C.F.R. sections 401.1-401.17 (2010).


Id. at 4.

MIT’s Radiation Laboratory made substantial contributions to radar, anti-aircraft and other electronics, and Columbia University sponsored the Manhattan Project. Funding continued to rise even beyond the Cold War era. See Scott Shane, Academic Entrepreneurship 46-47 (2004).


Id. at 7.
challenges with urgent and sensitive military, defense, computing or medical requirements so complex that they exceeded the scope and resources of private entities. The Office of Scientific Research and Development replaced the NDRC in 1941 lead by MIT President Karl Compton and Dean of Engineering Vannevar Bush.66 These government initiatives, most especially work on radar and the Manhattan Project were transforming achievements dramatically altering the course of the war.67

Dean Vannevar Bush's report to Congress in 1945, Science: The Endless Frontier, was visionary in that he linked “government support of basic science to the goal of stimulating the economy.”68 Government backing continued to build for basic research in the form of a number of new agencies, notably the National Science Foundation and National Institutes of Health, though many other existing institutions received government research support as well. Federal expenditures on research reached $8 billion by 198069 and the government held title to approximately 30,000 patents.

Yet, there were many distressing signs that such investments were yielding meager returns. The technology was not being transferred to the marketplace and the U.S. economy languished during the 1960's and 70's, lagging in science and other invention benchmarks. The government practiced and commercialized fewer than 5% of patents on inventions it sponsored.70 Businesses that could possibly commercialize the subject inventions found that the transactional costs were too high. This was due to the fact that there was no central government office or mechanism for the transfer of rights to these inventions. Each agency it turns out developed its own particular procedures, set of rights as well as licensing and royalty schedules for inventions they sponsored, so that businesses had to in some instances, negotiate with multiple government organizations for receipt of varying rights to inventions that were interconnected. By 1980 there was a maze of 26 different sets of agency regulations with varying terms and levels of support covering the use of government-funded research by private companies.71

To remedy this stall Congress held extensive hearings on how to leverage inventions and harmonize the interests of businesses, inventors, universities and funding agencies. A “solid bipartisan consensus had formed that the federal government should at least try a

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66 Id. at 8.
67 Id.
68 Id. n.13
69 Id. at 7-8.
70 Id. at 25 & n.25; see also GAO Rep't, supra note 61, at App. III, p.21.
71 See The Bayh-Dole Act at 25, supra note 64, at 19 & n.37.
new approach."\(^\text{72}\) The BDA was signed into law by then-President Carter on Dec. 12, 1980.

C. The Bayh-Dole Act statutory provisions

The BDA acts as a catalyst to invention and diffusion of basic research through providing a framework for cooperation between the government, universities (the contractors), inventors, and businesses in recognition that inventions thrive in a collaborative ecosystem with the right supports. For this, the BDA legislation makes two significant improvements. First it establishes a policy for uniform grant contracts applicable to all funding agencies that speeds commercialization. Second, it re-allocates rights as between the parties reversing the presumption of title so that now contractors are first in right and may claim title to government-funded research, thus providing a superior incentive scheme for successful commercialization. The sections in more detail:

Section 200: This section states the goals of the legislation and evidences Congress’s objectives including: to promote competition, commercialization and diffusion of basic research; to ensure that the government retains sufficient rights for itself as a means to protect the public against non-use or unreasonable use of inventions, while minimizing costs of program/agency administration.\(^\text{73}\)

Section 201: This provision describes the contracting parties and defines subject inventions as those that comprise any invention (whether first conceived or reduced to practice) funded in whole or in part under a government funding agreement (emphasis added).\(^\text{74}\)

Section 202. This section is covered in more detail due to its relevance and importance to the case-in-chief. Section 202 addresses ownership of inventions created with government funding. The provisions do not exactly square with the tiered structure of rights enunciated under the Patent Act and therein is the challenge as to whether these two legislative pronouncements can be read together.

Sub-section (a) attempts to allocate rights to inventions. The language specifically provides, "[e]ach...organization...may, within a reasonable time after disclosure [of the invention to the funding agency] elect to retain title to any subject invention."\(^\text{75}\) It implies contractor-

\(^{72}\) Id. at 19.


\(^{74}\) 35 U.S.C. section 201 (2006). Through this provision the government evidenced its intent to capture 100% of the value of inventions for which any government money fund was given.

organizations have a first option to claim title - and notably absent is mention of inventors’ right and title to inventions in whom rights first vest under U.S. patent law.\textsuperscript{76}

Sub-section (b) identifies conditions under which the government may exercise rights to the invention.\textsuperscript{77}

Sub-section (c) outlines the provisions that are to be included in funding agreements, as well as the contractor’s responsibility to disclose inventions, file patent applications, and so forth. Notably, notwithstanding the contractor’s title to an invention, the government retains a residual right to a nonexclusive, nontransferable, irrevocable paid-up license to practice the invention.\textsuperscript{78}

Sub-section (d) allocates rights as between the government, the contractors and inventors providing that if contractors “do 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....”\textsuperscript{79}

Section 203 delineates conditions under which the government may require the contractor to grant rights to other, third parties (known as march-in rights).\textsuperscript{80}

The Department of Commerce is charged with issuing regulations clarifying terms and other conditions for contractors working under contract with funding agencies.\textsuperscript{81}

\textbf{D. Commercialization: translating basic research into inventions for market-ready goods and services - the present business environment}

By all benchmarks, the BDA is an overwhelming success. At its essence, the BDA is meant to encourage the translation of abstract or theoretical ideas into socially useful inventions. The BDA can be characterized as a meta-idea, so-named by economist Paul M. Romer, because these are “ideas about how to support the production and transmission of other ideas.”\textsuperscript{82} He wrote, “...the country that takes the

\textsuperscript{76} See 35 U.S.C. sections 101, 115 (2006) (outlining rights of inventors to obtain patents in their inventions). The Supreme Court recognized this right as early as 1851 in \textit{Gaylor v. Wilder}, 10 How. 477, 493 (1851), and further established that inventions are the personal property of the inventor in \textit{United States v. Dubilier Condenser Corp.}, 289 U.S. 178, 188 (1933). This case recognized that the invention belongs to the employee initially and not the employer. \textit{Id.} at 189.

\textsuperscript{77} 35 U.S.C. section 202(b) (2006); see also 37 C.F.R. section 401.6 (2010).

\textsuperscript{78} 35 U.S.C. section 202(c) (2006).


\textsuperscript{81} See 37 C.F.R. sections 401.1 - 401.17 (2010).

lead in the twenty-first century will be the one that implements an innovation that more effectively supports the production of new ideas in the private sector." To paraphrase the General Accounting Office (GAO), the BDA is good policy and good for the economy. The GAO estimates that "federal support accounts for over half of the research conducted at colleges and universities" now in the billions of dollars that are translated into commercialized inventions, responsible for the formation of thousands of companies, jobs, and economic growth. Funding to agencies that will also ultimately fund other research is in the range of $147 billion in fiscal year 2010.

Recipients (the contractors) of federal funding for research sign an agreement with the funding agency under the terms and conditions of the statute and federal regulations. Contractors have created licensing and technology transfer offices to manage the process that starts with the results from basic research and perhaps end with a product that produces revenue. An entire industry has been created out of the need to bridge the divide between idea and market. Technology transfer is the process of transferring a method, know-how, application, technology and so forth - to entities that are most able to commercialize it for use in products or services, thereby promoting progress and maximizing the social benefit of government funding. Technology transfer describes the process of entering into agreements and managing licensing for the technology. Each university must build a technology evaluation and licensing team to manage government agency funding agreements, disbursal of funds, disclosure reporting to funding agencies, patenting, and to determine whether to seek licensing opportunities or develop a business model by using the technology as a start-up, and so forth. A professional organization, the Association of University Technology Managers exists to represent members' interests and support academic technology transfer. For fiscal year 2009, the AUTM Summary highlights the following:

- 658 new commercial products introduced
- 5,328 total licenses and options executed
- 596 startup companies formed based on university technology
- 3,423 startups still operating as of the end of FY2009

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83 Id.
84 See GAO Rep't, supra note 61, at App. III, p.21.
85 See GAO Rep't, supra note 61, at 1.
20,309 disclosures received

To appreciate the impact of Bayh-Dole on just one contractor, consider MIT by way of example. In fiscal year 2010, it made 530 invention disclosures to the government. It filed 184 patents. It granted over 50 licenses to companies to commercialize some of these patents. MIT was responsible for starting 16 companies, and its gross revenue exceeded $75 million. The primary method that revenue is generated is from straight licensing fees in which universities license inventions directly to existing companies for them to produce and distribute. More recently among universities there is a trend towards a more entrepreneurial approach that is at its essence a riskier strategy: spinning off start-up companies (such as was the case of Stanford and Google) based on university-owned inventions with backing from the venture capital community. In this approach, contractor-universities stand poised to benefit in two ways from the tech transfer: through its underlying equity stake in the company in addition to the potential revenue from licensing fees for the technology.

E. The Impact of this Case on the Bayh-Dole Act and Future Technological Developments Meant to Promote the Public Interest

This is an auspicious age for R&D as government support is increasing for academic-industry collaboration and entrepreneurship. The BDA created a powerful platform for building out these relationships and the benefits clearly continue to accrue. The Supreme Court’s interpretation on how to best balance rights to make private contracts with the public’s interest in taxpayer-financed research will surely influence technological progress, risk-taking job creation and

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91 President Barack H. Obama, State of the Union Address (Jan. 25, 2011) ("The first step in winning the future is encouraging American innovation. None of us can predict with certainty what the next big industry will be or where the new jobs will come from. Thirty years ago, we couldn’t know that something called the Internet would lead to an economic revolution. What we can do — what America does better than anyone else — is spark the creativity and imagination of our people. We’re the nation that put cars in driveways and computers in offices; the nation of Edison and the Wright brothers; of Google and Facebook. In America, innovation doesn’t just change our lives. It is how we make our living."). Further, the President announced the Startup America Partnership initiative, with information is available at http://www.startupamericapartnership.org/ (last visited June 21, 2011).
economic growth. There are a number of considerations in this respect as the Court grapples with this challenge.

R&D is maximized and best accomplished through networks that result in partnering and collaborating:

To the extent R&D needs a cohort of skills, motivation and financing, it becomes clear that this is not a lone endeavor. There is in these fields a high mobility index. The case in chief is a striking example of this professional mobility. Recall that co-inventor Thomas Merigan had ties to both Stanford and Cetus. During Merigan's tenure at Stanford, he joined the Cetus Board in 1979 and signed a number of consulting agreements with Cetus agreeing to share research and know-how. The collaboration at issue in this case began in 1988 between Merigan and Cetus. When research fellow Mark Holodniy began working for Merigan at Stanford, Merigan arranged for him to spend time at a Cetus lab bench with full access to its assets in order to perfect needed scientific techniques for their Stanford-based lab research to advance. The ease with which academic and industry professionals are able to move between workplaces is striking. There are low fences and an open-door policy among contacts in the clubby cohesive world of networked academics and professionals in highly specialized industries.

This type of collaboration will necessarily increase since in many respects the "easy work" is done. Further research suggests more complexity and reaching deeper into the nature of that scientific discipline (math, computer science, chemistry, biology and so forth). Scientists are attempting to extract more knowledge from smaller, more complex samples and in this process will more frequently need to collaborate beyond traditional borders of disciplines. Collaboration is a necessity for progress at this point in time. For example, biotechnologists must work with nanotechnologists to develop the right scale for prototypes. Just one report title underscores this point, 'Convergence of Biotechnology, Information Technology, and

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92 Board of Trustees v. Roche, 487 F. Supp. 2d 1099, 1099-1102 (N.D. Cal 2007) (noting that Merigan signed numerous consulting agreements with Cetus and served on its Scientific Advisory Board while employed by Stanford as a Professor of Medicine with a research focus on infectious diseases).

93 Id. (noting that Merigan had a right "to use Cetus' proprietary materials and information in exchange for a non-exclusive, royalty-free license to Cetus for any intellectual property developed as a result of the" Materials Transfer Agreements between the parties).

94 Id.

Nanotechnology: A NASA Perspective. The next article in this volume focuses on technology transfer, and so forth. In a broad sense, one isolated company almost cannot invent alone in this increasingly complex inventing and regulatory environment.

Furthermore the amount of money needed between idea and marketplace make development so exceedingly expensive and therefore risky for just one company, that it has further accelerated the trend toward partnering. In recognition of this complicated backdrop, strategic partnerships have developed. Intel is reportedly investing $100 million to create research centers on college campuses in its effort to create a hybrid business model in which its in-house researchers will collaborate more closely with academic peers. Merck and Harvard Medical School signed an agreement to jointly advance research. And more often than not, academic researchers with which industry collaborates will have antecedent government funding agreements for the same, or similar work - meaning that the university is a contractor under the Bayh-Dole Act and accordingly its requirements must be met, irrespective of the peripheral contracts or partnership with commercial entities.

This ever more complicated R&D-to-commercialization trend suggests that in a future with combinations and permutations of funding agencies, research teams, universities, business partners, grad students, fellows, and other possible inventors, the process of discerning, or even

96 10 Aerospace Technology Innovation 6 (July-Aug. 2002).
100 Maureen Martino, Press Release: Harvard Medical School and Merck Announce Research Agreement, FierceBiotech, Sept. 14, 2007, available at http://www.fiercebiotech.com (last visited June 21, 2011) (Harvard Medical School’s Chief Technology Development Officer noted that this “represents an important new model to collaborate with an industry leader, as well as an essential means to provide our investigators with the resources required to advance their work and translate their research findings into what we hope will one day culminate in new therapeutic modalities that address important unmet medical needs”).
granting title to ownership of technology will become fraught with more complex difficulties.\textsuperscript{101} It will be a challenge to create a ‘bright-line’ rule defining rights ahead of time as projects and project members change. And as the project members change, so do the assignments and rights within those assignments. In the case-in-chief for example, recall that Merigan needed more expertise in one discreet area, and the project team changed right at this moment - the point at which Cetus became involved thus forming the basis for its claim of title to the invention at issue.

\textit{Due Diligence challenges - inventors’ rights, assignments and strategic partnerships as stealth wild cards that create uncertainty in the business environment:}

Another related aspect to sorting rights in academic-industry collaborations is the due diligence problem. There is a paper trail of agreements concerning different aspects of projects being performed in distributed locations without a central repository of documentation. Aspects of a project may be funded differently, interested parties are not always the same for each aspect, and therefore in such a laddered-out crazy quilt of funding and inventing, there are bound to be troublesome aspects. Behind the inconsistent assignment phenomenon is fact that language of assignments is highly variable since parties are drafting customized agreements in contract to standard-form agreements easily capable of uniform interpretation, nor have they recorded agreements for ‘all the world’ to recognize and evaluate. In one stark example (though not covered by the BDA), Dana Farber Cancer Institute and Novartis Pharmaceutical Corp. partnered on cancer studies and entered into a Collaborative Research Agreement. They agreed that in return for certain funding provided to Dana-Farber, Novartis would be entitled to certain rights to the resulting work. The case was filed as a Declaratory Judgment action by Dana-Farber seeking the court’s help on an inconsistent assignment case.\textsuperscript{102} Dana-Farber allegedly assigned the same rights to two competing entities: Novartis, as well as Gatekeeper Pharmaceuticals (a start-up by Dana Farber’s own employees). It seems that assigning entities lack a clear understanding even of the fact that antecedent agreements exist. Neither the parties,


nor the facts and subject matter of these cases lend themselves to simple or straightforward resolution.

This uncertain contracting environment is further complicated because of inventors’ rights that are possibly still in force. Recall from Part II above, that the BDA statutory scheme neglects to explicitly address these rights and addresses just those rights as between the government and the university contractor. Note that BDA section 202(a) provides that contractors may ‘elect to retain title’ to the invention; and that under section 202(d) the BDA recognizes inventors’ rights, in a limited way in that they are subject to a first right of refusal by the contractor.103 This suggests that inventors’ rights are inferior to university contractors’ and the government’s rights though this is not dispositive because the Patent law scheme has not been repudiated. Interestingly U.S. patent law differs from almost every other countries’ patent law in this respect. The U.S. awards a patent to the first to invent that subject matter, while in other countries, a patent is awarded to the first inventor to file a patent application for that subject matter.104 There is more clarity regarding title, and assignments are thereby rendered unnecessary. Harmonizing these two statutes should clearly be a priority. Resolving priority of inventorship rights cases with individuals who have not yet signed invention assignment agreements, or even for those who have, will increase tremendously for this case calls into question instances in which an assignment has been executed. Employee status is not always clear and questions will further arise since the employment relationship has evolved to encompass less formal arrangements, including: those who work for hire, or as consultants, temps, interns, or perform contract work, and so forth.

In this increasingly stratified employment construct, establishing priority of inventorship rights absent a clear unequivocal invention assignment agreement will be troublesome. “In general, under varying applicable state and federal laws where the university employs the individual in question, there is a presumption that the employee owns the...IP, even though it may have been created during the course of their employment.”105 This general rule is subject to the following caveats: (1)

103 See Part II, supra.
105 Raymond Millien, Within a University Community, Who Owns Newly-Created IP?
in general, if the employee sign an invention assignment agreement with the employer, the employer owns the IP; (2) the IP is assumed to belong to the employer who hires the employee to invent in this field; and (3) if an explicit assignment does not exist, the employee owns the underlying invention, and the employer nevertheless concurrently holds shop rights to it - a non-exclusive, non-transferable royalty-free license to use the employee’s invention.\textsuperscript{106} This further reinforces the sense that reliance on assignment agreements is not necessarily a solid strategy for promoting an effective scheme of establishing or transferring rights.

IV. CREATING A RATIONAL PLATFORM FOR TECHNOLOGY DEVELOPMENT AND TRANSFER

The present interpretation of the BDA by the circuit court stands as an obstacle to the accomplishment of the full purpose and objectives Congress expressed when it enacted the BDA.\textsuperscript{107} While its decision was understandable under these facts, the net effects are decidedly unfavorable. This decision promotes parties’ private contracts over the public benefits; it promotes the notion that an individual employee’s interests are never aligned with those of his or her employer; it presumes there is no relationship of trust or accountability for projects funded by taxpayer contributions, that the invention is just another property to be leveraged or sold; and it gives no consideration to that remaining dormant right: the government retains the right to march-in should the invention languish or be subject to misuse. This is not to say that contractor universities, such as Stanford in this case, are the most able stewards for leveraging basic research, but the formal first-party agreement between the government and the contractor confirms these points and values.

The Supreme Court has shown a great deal of interest in patents recently, especially since Chief Justice Roberts’s tenure, demonstrating a willingness to re-consider precedent and thereby alter the patent landscape.\textsuperscript{108} This apparent newfound interest in patent cases “perhaps

\textsuperscript{106} Gerald Ferrera et al., CyberLaw Text & Cases 299-328 (2012).

\textsuperscript{107} See Bayh-Dole Act at 25, supra note 64, at 22 (“Congress passed Bayh-Dole at a time of widespread concern over America’s relative economic decline. Making it easier to commercialize successful academic research was intended to facilitate technology transfer so as to stimulate economic development. The Bayh-Dole structure made it far easier for universities to own the technology developed in their research facilities, and equally importantly, allowed researchers themselves to profit from successful commercialization of their research”).

\textsuperscript{108} Robert C. Scheinfeld & Parker H. Bagley, The Roberts Supreme Court Takes on Patent
stems from a recognition of the growing importance of intellectual property to the nation's information-based economy." Inventing and innovating are the linchpins of the U.S. economy and our future - they represent the technology that forms the basis of company formation and job creation. For example, Google started from a government-funded research project that resulted in an algorithm that yielded better search results for a digital library collection. During this cycle of technology development and deployment with company and job formation, research suggests that newer companies add jobs faster than older established companies. In this respect then, fostering start-ups generates more value to workers and the economy than for example, giving tax credits or other government support to older companies. These are the outcomes that deserve attention, recognition and support.

To best effectuate the goals of the BDA this means generating the most return and public benefit and there needs more clarity throughout the entire contracting process. For this to occur title to inventions must be more carefully defined and the disposition of rights must be more transparent, possibly through creating a system for recording assignments so as to avoid the problem of multiple inconsistent assignments. Further, other provisions should address: when

Cases, Vol. 236, No. 61, N.Y.L.J. Sept. 26, 2006, available at http://www.bakerbotts.com/files/Publication/42e73ea4-2eb0-4be6-be9f-c130d3817012/Presentation/PublicationAttachment/9113f414-c44b-4131-98c6-c436546dc3b0/Scheinfeild%20NYLJ%20Article,%209-27-06.pdf (last visited June 21, 2011) (the Court has shown a "willingness to tackle sophisticated patent cases which promise to exert a long-lasting effect..."); see also Brian T. Yeh, Cong. Research Serv., No. 7-5700, An Overview of Recent U.S. Supreme Court Jurisprudence in Patent Law (Sept. 17, 2010) ("nine cases that have been decided since 2005: Merck KGaA v. Integra Lifesciences I, Unitherm Food Systems v. Swift-Eckrich, Illinois Tool Works v. Independent Ink, eBay v. MercExchange, Laboratory Corporation of America Holdings v. Metabolite Labs., MedImmune v. Genentech, KSR International Co. v. Teleflex Inc., Microsoft v. AT&T, Quanta Computer, Inc. v. LG Electronics, Inc., and Bilski v. Kappos."). Furthermore, three patent cases were considered during the 2010-2011 Term: the Board of Trustees case herein, Microsoft v. idl L.P. 598 F.3d 831 (Fed. Cir.), cert. granted, 2010 U.S. LEXIS 9311 (U.S. Nov. 29, 2010) (No. 10-290) (Microsoft is challenging long-standing precedent requiring clear and convincing evidence to prove invalidity of a patent. Microsoft is arguing that this standard is too high a threshold), and Global-Tech Appliances, Inc. v. SEB S.A., 594 F.3d 1360 (Fed. Cir.) cert. granted, 2010 U.S. LEXIS 8068 (U.S. Oct. 12, 2010) (No. 10-6) (the Court is considering the level of intent required for a finding of inducing infringement).

See Yeh, supra.

employee's rights vest and terminate, what rights survive or extinguish upon assignment, and so forth. This could be most easily accomplished by the Secretary of Commerce who is vested with power to enact regulations for the BDA. If the conditions are ideal for a coherent and transparent system for the transfer of technology and rights, this will encourage more collaboration for the purpose of research and development and subsequent commercialization. It is critical to ensure that the government retains access to the technology, that contractors and their employees are recognized for their role, and that business partners may pursue access to this technology and know-how so that the technology develops and the public can reap the benefits of these contributions.