No. 09-1159

IN THE

Supreme Court of the United States

BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,
Petitioner,

v.

ROCHE MOLECULAR SYSTEMS, INC., *et al.*,
Respondents.

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

BRIEF *AMICUS CURIAE* OF BIRCH BAYH IN SUPPORT OF PETITIONER

WILLIAM D. COSTON
Counsel of Record
JOHN F. COONEY
MICHAEL A. GOLLIN
DAVID D. CONWAY
VENABLE LLP
575 7th Street, N.W.
Washington, D.C. 20004
(202) 344-4000
wdcoston@venable.com

Counsel for Amicus Curiae

December 23, 2010

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES—Continued

OTHER AUTHORITIES

TABLE OF AUTHORITIES—Continued

IN THE

Supreme Court of the United States

No. 09-1159

BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,
Petitioner,

v.

ROCHE MOLECULAR SYSTEMS, INC., *et al.*,
Respondents.

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

BRIEF *AMICUS CURIAE* OF BIRCH BAYH IN SUPPORT OF PETITIONER

This Brief *Amicus Curiae* in support of Petitioner is filed by former United States Senator Birch Bayh.

INTEREST OF *AMICUS CURIAE* [1]

Amicus Curiae Birch Bayh served as United States Senator for the State of Indiana from 1963 to 1981.

[1] Pursuant to Supreme Court Rule 37.3, *Amicus Curiae* states that all parties have consented to the filing of this brief, and letters evidencing such consent have been filed with the Court. Pursuant to Supreme Court Rule 37.6, *Amicus Curiae* further states that no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *Amicus Curiae* or his counsel made a monetary contribution to its preparation or submission.

In that capacity, he was the co-principal Senate sponsor of the legislation ultimately enacted as the University and Small Business Patent Procedures Act, commonly known as the Bayh–Dole Act, 35 U.S.C. §§ 200–212 (2006). Senator Bayh has a long-standing commitment to scientific and technical innovation as a means of stimulating American economic growth. As a principal proponent of this statute, Senator Bayh retains an enduring interest in its proper construction and application.

Senator Bayh has previously submitted Briefs *Amicus Curiae* to this Court in 1981 and 2004.[2]

SUMMARY OF ARGUMENT

In 1980, Congress faced three vexing problems: (1) a national recession caused, in part, by a reduction in the country's competitiveness in international markets; (2) the insufficient commercialization of patents owned by the government and developed through federally-funded research by universities, small businesses, and nonprofit organizations; and (3) a hodge-podge of ineffective, inconsistent, and incoherent patent transfer policies. As a result of these problems, the creative genius of American inventors was not reaching the marketplace. Great American ideas were not leading to great American commercial successes.

Congress enacted legislation to address these problems. The Bayh–Dole Act determined that federally-funded patents should not and would not be warehoused in government bureaucracies. Rather, specified government contractors—universities, small

---

[2] *See North Haven Bd. of Educ. v. Bell*, 456 U.S. 512, 526-527 (1982); *Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167 (2005).

businesses, and nonprofit organizations—were given the right and the responsibility to explore the development of these federally-funded innovations. The statute established clear and unequivocal rules on institutional ownership of patents for inventions developed by contractor organizations with federal research funding.

In the Bayh–Dole hierarchy, the ownership rights of contractors come first, followed by the government, with inventors last:

(1) Contractors "retain title" to all "subject inventions"—inventions "conceived or first actually reduced to practice in the performance of work done under a [federal] funding agreement." 35 U.S.C. §§ 201(e), 202(a).

(2) If a contractor fails to retain the invention, or chooses not to, the government can claim title, *see id.* § 202(c)(1)-(3), or "march-in" to develop the invention itself, *see id.* § 203.

(3) The inventor has no direct ownership interest in inventions developed with federal research funding, but only a provisional, subordinated ability to obtain title if the contractor and the government choose not to exercise their superior rights. Under the statute, neither the contractor nor the government requires an inventor's permission to develop their respective statutory rights. Rather, the nonprofit contractor has a responsibility to negotiate a share of royalties with an inventor. *See id.* § 202(c)(7)(B). In very limited circumstances, an inventor can request title if the contractor and government eschew their rights. *See id.* § 202(d).

Congress believed that this regime of explicitly-defined ownership rights would remove obstacles and enable American innovators to roar back into the market. This statutory scheme has now worked effectively for 30 years, resulting in thousands of commercialized inventions that might have otherwise lain fallow in government filing cabinets. Indeed, the Bayh–Dole Act has been called "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century."[3]

The decision of the Federal Circuit improperly alters this regime by recognizing inventor rights (and inventor assignee rights) inconsistent with the Bayh–Dole Act hierarchy. The Bayh–Dole Act carefully balances the interests of all parties with interests in the discovery and commercialization of new technologies, but grants initial ownership rights to the research institution only, not the inventor it employed. The court below failed to recognize the provisional, subordinated nature of the innovator's interest, and its decision threatens to disrupt the careful balance of interests that Congress adopted.

The Court should answer the Question Presented by concluding that a federal contractor's ownership rights to inventions covered by the Bayh–Dole Act *cannot* be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor's rights to a third party.

---

[3] *Innovation's Golden Goose*, The Economist Technology Quarterly, Dec. 12, 2002, at 3, *available at* http://www.economist.com/node/1476653?story_id=1476653.

ARGUMENT

I. CONGRESS ENACTED THE BAYH–DOLE ACT TO ADDRESS A FRAGMENTED FEDERAL TECHNOLOGY POLICY THAT COMPOUNDED AN AMERICAN PRODUCTIVITY SLUMP AND CAUSED THOUSANDS OF GOVERNMENT-FUNDED INVENTIONS TO GO UNUSED.

The Bayh–Dole Act was passed in 1980 to address a specific problem facing the United States. In the midst of a national recession, the federal government was spending huge sums of money to sponsor research and development at universities and small businesses, but very few of the patentable technologies resulting from this investment were reaching the marketplace. *See* S. Rep. No. 480, 96th Cong., 1st Sess., at 2 (1979) (*Senate Report*).

What made the recession so alarming was that, of its many causes, "an important factor [was] likely a slowdown in technological innovation in the United States" in the face of enhanced competition from overseas competitors in Europe and Asia.[4] *Id.* In the 1970s, for the first time since World War II, the United States' global leadership in productivity and innovation began to decline. The United States imported more foreign manufactured goods than ever before, resulting in a trade deficit in 1978 of $5.8 billion in those products. *Id.* at 1. At the same time, American businesses were spending less private

[4] In 1980, the House Judiciary Committee warned that "the roots of the current recession lie in a longer term economic malaise which arises out of a failure of American industry to keep pace with the increased productivity of foreign competitors." H.R. Rep. No. 1307, 96th Cong., 2d Sess. Pt. 1, at 1 (1980).

money on research and development. *Id.* Moreover, small businesses—the traditional incubators of U.S. innovation and engines of job growth—were receiving a "distressingly low" percentage of federal research funding. *Id.*

Against this backdrop, as Congress began exploring new ways to stimulate the American technology sector, the troubled federal patent transfer system came to the fore of the debate.

A. Federal Agencies Employed a Host of Discordant Patent Transfer Policies.

Prior to the passage of the Bayh–Dole Act, federal agencies employed at least 24 different patent transfer policies, most of which were complex and occasionally contradictory. *See id.* at 2; H.R. Rep. No. 1307, 96th Cong., 2d Sess. Pt. 1, at 5 (1980) (*House Report*).

Most federal agencies required universities and small businesses to agree, as a precondition of federal funding, that ownership of all patentable inventions arising from federally-funded research would be retained by the sponsoring agency. *Senate Report* 2. In some instances, these agencies even required universities and small businesses to relinquish title to "background" inventions—*i.e.*, inventions created and owned independent of federal financial support—when those technologies were necessary to practice federally-funded inventions. Unfortunately, after obtaining title to the inventions they funded, these agencies would "follow the passive approach of making them available to private businesses," at no cost, for development and commercialization under non-exclusive licenses. *Id.*; *see* 126 Cong. Rec. 8742 (1980) (statement of Sen. Nelson).

Other agencies, such as the National Aeronautics and Space Administration, allowed grantees to retain title to federally-funded inventions only after they successfully completed lengthy waiver processes, in which the applicants were required to justify to the funding agency why they deserved to retain title. *See Senate Report* 2. These waiver processes were so cumbersome and time consuming that grantees often did not bother pursuing them to obtain ownership of their inventions.

A few innovative agencies, including the Department of Health, Education, and Welfare and the National Science Foundation, employed Institutional Patent Agreements ("IPAs"), which allowed prequalified universities and nonprofit organizations having technology transfer offices to retain title to inventions arising from federally-funded research. *See id.* at 21. The IPA programs proved extremely successful and led to the development and commercialization of numerous new drugs through the collaboration of universities and private industry. *See id.*

To replace these conflicting policies, the Bayh–Dole legislation was introduced to establish, by statutory mandate, a uniform patent transfer system across all federal agencies.

B. Federal Patent Ownership Policies Blocked Development of Government-Funded Inventions.

Although the federal patent policies preceding the Bayh–Dole Act led to the creation of thousands of patentable inventions, the vast majority of those inventions remained on government shelves, unlicensed, undeveloped, and unable to benefit the public. Of more than 28,000 patents owned by the

federal government, only four percent were licensed for development. *See id.* at 2. This depressing fact inspired the proponents of the Bayh–Dole Act to take action. *See id.* Existing patent policies had made federally-funded inventions freely available to all competitors—inconsistent with the core incentive of limited exclusivity afforded by the patent system. Congress concluded that this scheme, while well-intentioned, was misguided because none of the parties involved in the federal research and development process had sufficient incentives to commercialize new inventions.

In particular, universities, small businesses, and nonprofit organizations were unwilling to risk the effort and resources necessary to develop and commercialize federally-funded inventions. *See id.* The cost of marketing new products was at least 10 times the cost of the basic research that led to their conception. *See id.* at 19. Potential investors faced the risk that new technologies might ultimately prove unsuccessful in the marketplace or might not survive the regulatory approval process. *See id.* The adverse consequences of government ownership added further burdens to the considerable marketplace risks faced by innovators. *See id.*

Congress also concluded that the existing system ignored the economic reality that the funding agencies were poorly positioned to develop and commercialize new inventions arising from federally-supported research. The tasks of reviewing new inventions for commercial potential, advertising their availability, promoting their utilization, and negotiating their license were all formidable and beyond the experience of federal workers. *See, e.g., id.* at 30.

Congress also found that individual inventors had little incentive to remain involved with their discoveries given that, in most cases, title was completely claimed by the funding agency. This policy stifled commercialization. Separating inventors from their inventions was often catastrophic to the development of fledgling technologies. *See id.* at 22. The Senate Judiciary Committee noted that "[v]irtually all experts in the innovation process stress very strongly that such involvement by the inventor is absolutely essential, especially when the invention was made under basic research where it is invariably in the embryonic stage of development." *Id.*

As a result of these policies, nearly all of the patents developed by universities and small businesses with federal funding were "sitting unused under Government control," sometimes needlessly condemning people to suffer "because of the refusal of agencies to allow universities and small businesses sufficient rights to bring new drugs and medical instrumentation to the marketplace." *Id.* at 2; 126 Cong. Rec. 1796 (1980) (statement of Sen. Bayh). Mindful of its authority under the Spending Clause[5]

[5] Under the Spending Clause of the Constitution, art. I, § 8, cl. 1, Congress has "wide latitude" to appropriate public funds, and to place conditions on the appropriation of public funds, in furtherance of the general welfare. *United States v. Am. Library Ass'n*, 539 U.S. 194, 203 (2003); *Nat'l Endowment for the Arts v. Finley*, 524 U.S. 569, 588 (1998). Courts defer to Congress' discretion when determining whether a particular expenditure, or a condition placed thereon, serves the general welfare. *See Mathews v. Castro*, 429 U.S. 181, 185 (1976) ("The discretion belongs to Congress, unless the choice is clearly wrong, a display of arbitrary power, not an exercise of judgment").

and the Patent and Copyright Clause[6] of the United States Constitution, Congress took action to facilitate the commercialization of technologies developed with federal research funding.

II. CONGRESS ENACTED THE BAYH–DOLE ACT TO STIMULATE COMMERCIALIZATION OF NEW TECHNOLOGIES BY PATENT OWNERSHIP REFORM.

The authors of the Bayh–Dole Act intended to design a new federal patent transfer policy that would tap the unrealized potential of federally-funded inventions. This goal would be achieved by assigning title to the entities best situated to ensure the commercialization of new technologies—namely, the universities, small businesses, and nonprofit organizations that participated in their discovery. The statute also replaced the numerous federal patent transfer policies with one uniform system that balanced the interests of all entities that participated in the development and commercialization process.

While the drafters anticipated the Bayh–Dole Act to be, at the least, "an important first step in turning around [America's] undesirable productivity and innovation slumps," *Senate Report* 29, in practice it became the "economic shot in the arm" that America

---

[6] Under the Patent and Copyright Clause of the Constitution, art. I, § 8, cl. 8, "[t]he powers of Congress to legislate upon the subject of patents is plenary by the terms of the Constitution." *McClurg v. Kingsland*, 42 U.S. 202, 206 (1843); *see also Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 648 (1999) (Stevens, J. dissenting). Courts "defer substantially to Congress" when determining whether a law is a rational exercise of legislative power under the Patent and Copyright Clause. *Eldred v. Ashcroft*, 537 U.S. 186, 204–05 (2003) (copyright case).

sorely needed to help restore its technological vitality. 126 Cong. Rec. 1798 (1980) (statement of Sen. Thurmond).

A. Congress Empowered Universities, Small Businesses, and Nonprofit Organizations to Commercialize Federally-Funded Technologies by Providing Them a Priority Right to Patent Ownership.

The Bayh–Dole Act, by operation of law, presumptively and automatically vests ownership rights in inventions arising from federally-funded research in the universities, small businesses, and nonprofit organizations responsible for their creation. *See House Report* 5. Congress did not provide for individual inventors to have transferable ownership interests in patentable inventions created with federal funding. Rather, Congress rewarded individual inventors by requiring their employers to provide them with a share of royalties to be negotiated with the universities or nonprofit organizations. *See* 35 U.S.C. 202(c)(7)(B); *Senate Report* 22. Congress concluded that this allocation of rights would promote commercialization, while providing an adequate incentive for inventors to remain involved in the early-stage development of their inventions. *See Senate Report* 22.

Congress elected to give universities, small businesses, and nonprofit organizations "preferential treatment" in the new federal patent transfer system in order to provide a more "attractive business opportunity" to private sector developers that were "unwilling to take a non-exclusive license under a Government-owned patent." *House Report* 5; *Senate Report* 18. Congress decided that these preferred

entities were in the best position to ensure "that inventions and processes arising from [federally-funded research would] be delivered to the marketplace as efficiently as possible." *Senate Report* 29.

Congress chose to give universities and nonprofit organizations the lead role because they received a large portion of federal research funding and "are much more efficient in delivering these important discoveries to the marketplace than are the agencies." *Id.* at 29. For example, in 1977, the federal government provided $3.35 billion in research support to universities, hospitals, and other nonprofit organizations. *See id.* at 19. As a result, these institutions conducted 68 percent of the country's basic research—"by far the biggest percentage" in the United States. *Patent Policy*: *Joint Hearing Before the S. Comm. on Commerce, Sci., and Transp. and the S. Comm. on the Judiciary*, 96th Cong., 2d Sess. 459 (1980) (statement of Sen. Bayh). Because so many patentable inventions arose from the basic research conducted by universities and nonprofit organizations, Congress concluded that these institutions—not federal agencies and not inventors—were best situated to manage and commercialize the resulting discoveries in collaboration with private industry.

Congress selected small businesses for their "impressive record as one of the leading sources of technological breakthroughs since World War II," and for their demonstrated "willingness to take risks that many larger companies [were] not willing to take in the pursuit of new technologies and products." *Senate Report* 29. Moreover, the drafters believed that small businesses would receive the greatest benefit from retaining title to patents invented by their employees because "a small business has fewer private resources

to develop and market raw products than their big business competitors." 126 Cong. Rec. 2004 (1980) (statement of Sen. Bayh).

B. Congress Adopted a Uniform and Balanced Patent Ownership Policy to Induce More Efficient and Predictable Technology Transfer.

In adopting the Bayh–Dole Act, Congress replaced the existing assortment of "at least 24 different patent policies in effect in the Federal agencies" with a single, uniform national policy for vesting patent rights in government-funded research. *Senate Report* 2.

Congress found that the federal patent policies in existence prior to the Bayh–Dole Act served as "artificial barrier[s], discouraging the commercialization" of federally-funded inventions. *Id.* at 29. They frequently presented costly roadblocks to universities and small business that lacked the legal expertise to navigate the labyrinthine maze of regulation standing between their inventions and the market. *See id.* at 3. Even agencies that permitted grantee institutions to retain patent rights to their inventions did so only after a lengthy decision-making process that served "to seriously jeopardize the ability of new inventions to be commercialized." *Id.* at 21.

In 1978, Senators Bayh and Dole compiled a list of 30 medical discoveries that had been delayed from nine months to more than a year while the funding agency determined whether to retain patent rights for itself. *See id.* at 21; 126 Cong. Rec. 8740 (1980) (statement of Sen. Bayh). To correct this problem, the legislation installed a streamlined patent transfer system to prevent "these promising inventions from

being suffocated under reams of unnecessary bureaucratic red tape." *Senate Report* 21. The statute was intended to ensure that new discoveries would be "commercialized as quickly as possible without the artificial restraints caused by the unnecessary delays and uncertainties . . . which only serve to make an already risky attempt to develop new products more of a burden on interested companies." *Id.* at 19.

By enacting the Bayh–Dole Act, Congress reduced the costs and risks of commercializing new ideas by making it easier for universities and small businesses to determine the nature and scope of their intellectual property rights. In particular, the statute presumptively permitted contractors to "elect to retain title" to federally-funded inventions rather than requiring them to petition the government for a waiver. 35 U.S.C. § 202(a). The statute also eliminated the risk to contractors that the government would force them to license their preexisting "background" inventions. *See id.* § 202(f). Along with predictability came reliability: universities and small businesses could rely on the statutory guarantee of clear title to their inventions, which, in turn, allows them to attract potential licensees and negotiate exclusive licenses, thereby hastening the commercialization of new technologies.

III. THE BAYH–DOLE ACT ESTABLISHES A CAREFUL BALANCE OF INTERESTS AMONG THE PUBLIC, THE GOVERNMENT, THE CONTRACTOR, THE PRIVATE DEVELOPER, AND THE INVENTOR.

The Bayh–Dole Act allocates ownership rights in patents for federally-funded inventions in a deliberate, hierarchical fashion, designed to balance the interests of each party participating in the patent

transfer process. Under the statute, universities, small businesses, and nonprofit organizations receive presumptive priority of title. The lowest rung of the hierarchy is reserved for individual inventors, who were intended to have only a provisional, and subordinated, opportunity to own technologies developed with federal funds.

The success of the Bayh–Dole Act is attributable to its deliberate and balanced distribution of rights and benefits among the stakeholders in federally-funded research and commercial development. The Federal Circuit's decision, allowing inventors to assign title to federally-funded inventions outside of the Bayh–Dole Act's carefully drawn parameters, would disturb this careful balance and undermine the statute's effectiveness.

A. The Statute Gives Universities, Small Businesses, and Nonprofit Organizations Presumptive Ownership Rights to Patents, and an Inventor May Obtain an Ownership Interest Only if the Contractor Surrenders its Rights and the Funding Agency Approves.

The Bayh–Dole Act created a structural hierarchy for the American technology transfer system that has operated successfully for 30 years. In adopting the statute, Congress never intended that ownership of federally-funded inventions would be contingent in the first instance upon assignment agreements between inventors and their employers. Rather, Congress allocated priority of title, in descending order, first to grantee research institutions, second to fund-

ing agencies, and lastly to individual inventors.[7] The Federal Circuit decision below stands the statutory system on its head by giving the inventor first priority to ownership.

Congress intended for universities, small businesses, and nonprofit organizations to have the preeminent and presumptive right to "elect to retain title" to federally-funded inventions. *Id.* § 202(a).[8] Although the statute grants these contractors the primary opportunity to retain title, it also allows them to forego ownership by waiving title or by failing to comply with the statutory requirements for retaining title. In those instances, the statute expressly provides that ownership reverts to the agency responsible for funding the research giving rise to the subject invention. *See id.* §§ 202(a), 202(c)(1)-(3). Thus, the contractor and the funding agency, respectively, occupy the top two rungs of the Bayh–Dole Act's three-tier hierarchy.

In contrast, the individual inventor does not receive any ownership interest in inventions discovered by federally-funded research. Congress instead gave the inventor an opportunity to receive reasonable compensation for any successful commercialization resulting from his inventions through negotiation

---

[7] Congress did not include large private corporations that develop and commercialize federally-funded inventions in this hierarchy. Instead, these entities were expected to take exclusive licenses from the contractor institution under the statute. *See generally* 35 U.S.C. § 202.

[8] The House Judiciary Committee explicitly stated that Congress intended to "establish[] a *presumption* that ownership of all patent rights in government-funded research will vest in any contractor who is a nonprofit research institution or a small business." *House Report* 5 (emphasis added).

with the university or nonprofit organization. *See id.* § 202(c)(7)(B) (instituting "a requirement that the contractor share royalties with the inventor").

Only in exceptional and clearly defined circumstances may the inventor receive title under the statute. First, the contractor must decline title. *See id.* § 202(a). Second, the funding agency must take title. Third, the individual inventor must then petition the funding agency for title. *See id.* § 202(d). Indeed, the inventor may not even petition the funding agency for title unless and until the contracting entity declines title and the funding agency takes ownership. *See id.* § 202(d). If the inventor files such a petition, the funding agency must consult with the university, small business, or nonprofit organization before issuing an explicit decision granting or denying the inventor's request for ownership. *See id.* § 202(d).

Thus, Congress subordinated the inventor's ability to obtain title to the invention in the interest of greater development and commercial use of patents developed with federal funding. This deliberate decision is shown by the explicit language of the Act, requiring both an explicit surrender of title by the contractor and the agency's express approval before the individual inventor can take title to a federally-funded invention. *See* 35 U.S.C. § 202(d).

B. The Bayh–Dole Act's Success Lies in Its Precise Balance of the Rights and Interests of the Entities That Participate in the Patent Transfer Process.

For three decades, the public has benefitted from the positive effects of the Bayh–Dole Act. The Association of University Technology Managers recently

reported that more than 6,000 new domestic companies have arisen from university inventions, and nearly 5,000 new products have come onto the market, as a result of university patent licensing of federally-funded inventions in every significant field of technology.[9] A separate study has shown that 153 new pharmaceuticals resulting from federally-funded research have been brought to market since the law was passed.[10] The biotechnology industry has calculated that the Bayh–Dole Act has increased the United States gross domestic product by $187 billion, producing 279,000 new jobs between 1996 and 2007 alone.[11]

An essential feature of the Bayh–Dole Act is its precise balancing of the divergent interests of all the parties involved in the discovery and commercialization of new technologies. The statute has gone largely unchallenged in the courts until now, due to Congress' success in accommodating the divergent

---

[9] *See* Association of University Technology Managers, Inc., *AUTM U.S. Licensing Activity Survey, FY2006: A Survey Summary of Technology Licensing (and Related) Performance for U.S. Academic and Nonprofit Institutions, and Patent Management and Investment Firms* (2006), *available at http://www.autm.net/AM/Template.cfm?Section=Home&CONTENTID=3954&TEMPLATE=/CM/ContentDisplay.cfm*

[10] *See* Ashley J. Stevens *et al.*, *The Contribution of Public Sector Research to the Discovery of New Drugs and Vaccines* presented at PraxisUnico Annual Meeting, Nottingham, United Kingdom (June 16, 2010), *available at* http://www.praxisunico.org.uk/uploads/Ashley%20Stevens.pdf.

[11] David Roessner, Jennifer Bond, Sumiye Okubo, & Mark Planting, *The Economic Impact of Licensed Commercialized Inventions Originating in University Research, 1996-2007*, 7–8 (Sept. 3, 2009), *available at* http://www.bio.org/ip/techtransfer/BIO_final_report _9_3_09_rev_2.pdf.

interests of its beneficiaries—namely, the public, the government, the contractor, the private sector developer, and the inventor.

1. The Bayh–Dole Act benefits the general public, in their capacities as both consumers and taxpayers, by ensuring that tax dollars invested in federal research and development return social and economic dividends.

The public benefits because new products and technologies have been brought to market, instead of having the underlying inventions sit undeveloped on government shelves. The drafters of the statute knew that an idea that is "frustrated and never gets out on the marketplace is, for all intents and purposes, worthless so far as helping the American people are concerned." 126 Cong. Rec. 1797 (1980) (statement of Sen. Bayh). In addition, because the law requires universities and nonprofit organizations to use the net proceeds of their licensing efforts to fund further "scientific research and education," the public continues to benefit from the further advancement of science and the self-reinforcing creation of additional technologies. 35 U.S.C. § 202(c)(7)(C).

The public also enjoys the economic stimulus and enhanced tax revenues that result when new technologies enter domestic and global markets. Moreover, the Bayh–Dole Act creates jobs by requiring that universities, small businesses, or nonprofit organizations that grant "exclusive right[s] to use or sell any subject invention" ensure that their licensees will manufacture the licensed products "substantially in the United States." *Id.* § 204.

2. The Bayh–Dole Act reserves key rights to the federal government as sponsor of this scientific

research, thus further protecting the public interest. When a contractor elects to retain title, the funding agency is entitled to a "nonexclusive, nontransferable, irrevocable, paid-up" license in the federally-funded invention. *Id.* § 202(c)(4). The funding agency also is empowered to monitor the commercialization efforts of the contractors by obtaining occasional reports on the development of federally-funded inventions. *See id.* § 202(c)(5). Furthermore, the Bayh–Dole Act permits federal agencies to "march-in" and license federally-funded inventions, even if the contractor has retained title, when the agency determines that the entity has not taken reasonable steps toward achieving practical application of the invention. *See id.* § 203. Finally, the Act allows the funding agency to take title to inventions arising from federally-supported research that implicate sensitive government interests, or when the government intends to develop the research to the point of utilization. *See id.* § 202(a).

3. Universities, small businesses, and nonprofit organizations are entrusted, as stewards of the public interest, to commercialize new technologies arising from federally-funded research. The Bayh–Dole Act gives these contractors a priority right to "elect to retain title" to inventions arising from federal grants, subject to mandatory procedural requirements. *See id.* § 202(a). Moreover, the Act permits these entities to obtain royalties by granting exclusive licenses to private corporate developers interested in commercializing new technologies. *See id.* § 202(c)(7). The statute also protects their "background" inventions by strictly limiting the government's ability to force contractors to license these inventions to only the rarest of circumstances. *See id.* § 202(f).

4. Private sector entities that seek to develop and commercialize new technologies also benefit from the predictability afforded by the Bayh–Dole Act. Rather than permitting such businesses to obtain title to patent rights in federally-funded inventions, the Bayh–Dole Act provides several other paths by which they may reliably acquire exclusive rights to develop and market promising new technologies. First, the Act enables universities, small businesses, and nonprofit organizations to grant exclusive licenses to private sector entities interested in incurring the risk and expense of developing federally-funded inventions for commercial sale. *See id.* § 202(c)(7). This allows the parties to conduct license negotiations with the assurance that the contracting party possesses clear title and can convey it. This reduces substantially the expense of due diligence as to title and the risk of patent litigation.

Second, if the contractor fails to retain or maintain title to a federally-funded invention, the Bayh–Dole Act allows the government to "march-in" and grant private sector entities exclusive licenses. *See id.* § 203. This ensures that a contractor will not unreasonably deny private developers the right to commercialize federally-funded inventions. Finally, the statute allows private sector developers to engage in negotiations with universities, small businesses, and nonprofit organizations, rather than legally unsophisticated inventors or cumbersome bureaucratic agencies.

5. The Bayh–Dole Act does not give individual inventors a direct right to any ownership interest in federally-funded inventions covered by the statute. Rather, Congress concluded that new advances would move more quickly from the laboratory to the medi-

cine cabinet if the Bayh–Dole Act recognized and rewarded the contributions of inventors in a different manner. To that end, the statute provides that universities and nonprofit organizations should enter into discussions with their inventors to determine a fair allocation of royalties arising from successful inventions. *See id.* § 202(c)(7)(B); *see also Senate Report* 22. By giving "special recognition" to inventors, Congress sought, successfully, to keep inventors involved with their discoveries through the commercial development process in order to bring new technologies to the market more rapidly. *Senate Report* 22, 33. In addition, by reducing the obstacles to successful commercialization of federally-funded inventions, Congress sought to expand the pool of royalties from which inventors would be compensated.

Thus, the Bayh–Dole Act struck a careful balance among the varying interests of the many stakeholders whose concerted efforts are needed to put new ideas to work in the marketplace. The balance established by the statute has provided an effective, predictable, and flexible set of incentives and restrictions that has greatly facilitated the negotiation of mutually beneficial technology transfer agreements, and the resulting transformation of federally-funded innovations into commercially successful products.

C. The Policies and Provisions of the Bayh–Dole Act Demonstrate Congress' Clear Intent That Universities, Small Businesses, and Nonprofit Organizations Should Hold Title to Federally-Funded Inventions, Not Individual Inventors.

The remarkable success of the Bayh–Dole Act would be compromised if inventors were allowed to

trump the interests of the public, the contractors, the federal government, and the private developers by independently assigning title to federally-funded inventions. The balance Congress struck in the statute would be fundamentally disrupted by an interpretation which concluded that inventors hold any ownership interest in patents obtained through federally-funded research, much less title that can be independently transferred away from the government-funded research organization.

The language of the Bayh–Dole Act clearly evidences the legislature's intention to vest patent rights in universities, small businesses, and nonprofit organizations, rather than individual inventors. The law's requirement that contractors share resulting royalties with their inventors constitutes solid evidence that the drafters intended that individual inventors themselves would not own title to patents developed with federal funds. *See* 35 U.S.C. § 202(c)(7)(B).

Congress determined that inventors would have only a provisional, subordinated ability to obtain ownership in limited circumstances. This is plain from multiple provisions of the Bayh–Dole Act, including: (1) universities, small businesses, and nonprofit organizations are entitled to "elect to retain title" to inventions, not the inventors, *see id.* § 202(a); (2) contractors, not their employee inventors, are responsible for disclosing new technologies to funding agencies, *see id.* § 202(c)(1); (3) contractors are prohibited from assigning title to *anyone* except patent management organizations, *see id.* § 202(c)(7)(A); and (4) if the contractor elects not to retain title to an invention, patent rights vest in the funding agency, not the inventor; the inventor must thereafter seek

and obtain explicit approval from the funding agency before he or she may obtain those rights, *see id.* § 202(d).

Finally, the Bayh–Dole Act establishes the fundamental basis of technology transfer relationships for research institutions by requiring contractors to negotiate exclusive licenses with private sector developers to commercialize federally-funded inventions. The Act supports this crucial relationship by establishing a system in which it is certain that the grantee research institution possesses, and can convey, clear title to the invention. Universities, small businesses, and nonprofit organizations cannot efficiently commercialize new technologies if they are unable to demonstrate such clear title.

By assuring that the contractors would have clear title, the Bayh–Dole Act also benefits private sector developers to minimize the costs of due diligence concerning ownership interests, which would otherwise create substantial disincentives to commercializing new inventions.

In sum, the language and legislative history of the Bayh–Dole Act are unequivocal. Congress intended to vest title to federally-funded inventions in the hands of those best suited to ensure their efficient commercialization—the research institutions, not their employees. Congress never envisioned that individual inventors would have any rights to assign except those subordinated rights that they might obtain from the funding agency through a multi-step statutory framework. To allow inventors to assert title and transfer it freely would destroy the carefully crafted and finely balanced mechanism that Congress established and that has served the public interest greatly for the past three decades.

CONCLUSION

For the reasons set forth above, *Amicus Curiae* respectfully submits that the Court should conclude that a university, small business, or nonprofit organization's ownership of inventions arising under the Bayh–Dole Act *cannot* be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor's rights to a third party.

Respectfully submitted,

WILLIAM D. COSTON
Counsel of Record
JOHN F. COONEY
MICHAEL A. GOLLIN
DAVID D. CONWAY
VENABLE LLP
575 7th Street, N.W.
Washington, D.C. 20004
(202) 344-4000
wdcoston@venable.com

Counsel for Amicus Curiae

December 23, 2010