

No. 09-1159

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In The  
**Supreme Court of the United States**

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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 OF *AMICUS CURIAE* BAYHDOLE25, INC.  
IN SUPPORT OF PETITIONER**

—◆—  
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**INTEREST OF *AMICUS CURIAE***<sup>1</sup>

BayhDole25, Inc. (“BayhDole25”) is a non-profit, non-governmental organization named for the Bayh-Dole Act of 1980 (“Bayh-Dole”) and related legislation, and founded on the twenty-fifth anniversary of passage of the Act. BayhDole25 does not receive federal funding, nor has it received financial support from research institutions, universities, or individual biotechnology companies. BayhDole25’s mission is to increase awareness of the importance of Bayh-Dole for creating and commercializing new technologies for economic and social benefit. Since incorporation in 2006, BayhDole25 and its Board have made important contributions to the understanding of public policy priorities relating to technology transfer and the key role of Bayh-Dole in continued United States global competitiveness, particularly in the area of the life sciences.<sup>2</sup>

BayhDole25’s educational materials, capacity building programs and web site have become “go-to” resources for policy makers domestically and around

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<sup>1</sup> Pursuant to this Court’s Rule 37.3(a), BayhDole25 understands that letters of blanket consent from all parties to the filing of this brief have been submitted to the Clerk. Pursuant to this Court’s Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus* or its counsel made a monetary contribution to fund the preparation or submission of this brief.

<sup>2</sup> BayhDole25 publications and related presentations are available online at: <http://www.bayhdole25.org/resources> (last visited December 21, 2010).

the world.<sup>3</sup> Since 2006, BayhDole25 has participated in numerous science and technology programs in the United States, as well as in Brazil, China, Chile, France, India and Italy, where the benefits of a Bayh-Dole-type approach have been showcased as the way to commercialize public investment in scientific research. The technology transfer scheme of Bayh-Dole, in which ownership of government funded inventions are maintained by the research entities, has been emulated around the world with great success. See THE BAYH-DOLE ACT AT 25, at 37-44 (Apr. 17, 2006) (hereinafter “BAYHDOLE25 WHITEPAPER”) (citing both Organization for Economic Co-operation and Development (“OECD”) members and advanced developing countries that have benefited from adoption of technology transfer statutes or related mechanisms.)<sup>4</sup>

The Parties and other *amici curiae* represent the interests of federally funded contractors, research

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<sup>3</sup> For example, BayhDole25 publications already have been cited in this appeal by *amicus curiae* Massachusetts Institute of Technology in its Brief in Support of Petitioner for Writ of Certiorari, at 6, 8. Internationally, BayhDole25 publications have been cited by policy makers in South Africa and India. Closer to home, the Levin Institute of the State University of New York recommends the use of BayhDole25’s IP Toolkit for an understanding of intellectual property globalization. See [http://www.globalization101.org/issue\\_sub/technology/suggestReadings/](http://www.globalization101.org/issue_sub/technology/suggestReadings/) (last visited on December 21, 2010).

<sup>4</sup> Available online at: <http://www.bayhdole25.org/whitepaper> (last visited on December 21, 2010).

institutions and universities, private sector businesses and, of course, the Government. All of these are important stakeholders in the Bayh-Dole statutory framework, in which research institutions and universities receive critical research funds as contractors to the Government, private industry transforms the resulting science and technological advances into commercially successful products and services, and the Government furthers its objective of promoting the commercialization and public availability of inventions made as a result of federally funded research projects. Although BayhDole25 is not an economic stakeholder, it has the broader mission of advocating for the powerful social and economic benefits that have flowed from Bayh-Dole. As such, BayhDole25 is uniquely situated to provide an additional perspective that may be useful to the Court.



### **SUMMARY OF ARGUMENT**

Before the Bayh-Dole Act was enacted in 1980, federally funded scientific research resulted in little commercial development. A fundamental problem was that the Government retained ownership of the intellectual property resulting from that research, and there was often no clear process for transferring invention rights to the university or private industry sectors. In particular, universities and other non-profit research organizations – the chief recipients of federal research dollars – often would not end up owning the patents for the inventions created from

their work.<sup>5</sup> Because the universities did not own the patent rights, they were hamstrung in their efforts to collaborate with the private sector to commercialize any innovations resulting from federally funded research because private industry would not invest in the development of technology it ultimately could not protect. As a result, very little federally funded research was ever commercialized. This problem prompted Senator Birch Bayh's famous comment: "What sense does it make to spend billions of dollars each year on government sponsored research and then prevent the new developments from benefitting the American people because of dumb bureaucratic red tape." *A Special Status Report from Birch Bayh*, NEWS FROM BIRCH BAYH (Apr. 23, 1980).

By passing Bayh-Dole and related technology transfer legislation, Congress created a strong federal policy encouraging private development of publicly funded research. Bayh-Dole created the needed economic incentives for commercialization, largely through its clear ownership scheme in which "contractors" (universities, other non-profit research organizations and small businesses receiving federal research funding) can "elect to retain title to any subject invention" (*i.e.*, any invention of the contractor conceived or first reduced to practice in the performance

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<sup>5</sup> One study indicated that before 1980, fewer than 250 patents were issued to United States universities each year. *See* BAYHDOLE25 WHITEPAPER, at 23. In contrast, in 2003, 3,933 patents were issued to United States universities. *Id.*

of work under a funding agreement) by following the steps set out in the statute. 35 U.S.C. §§ 201, 202.

The economic results from this clarity have been dramatic. One survey of university licensing activity noted that between 1993 and 2003 alone, over 32,000 patents were issued from federally funded research, and over 4,000 companies were created as a result of federally funded university research between 1980 and 2003. *See* AUTM Licensing Survey: FY 2003 Survey Summary, at 3-4, 28 (Ashley J. Stevens & Frances Toneguzzo, eds., Assoc. of Univ. Tech. Mgrs., Northbrook, Illinois 2004). A similar recent survey reported that in 2009, 658 new commercial products were introduced, 5,328 licenses and options were executed, 596 new companies were formed, 3,423 startup companies were still operating, and there had been \$53.9 billion in total sponsored research expenditures. *See* AUTM U.S. Licensing Activity Survey: FY 2009 (Survey Summary).<sup>6</sup>

As the National Institutes of Health (“NIH”) has reported to Congress:

It is impossible to overstate the achievements of the global macroeconomic impact

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<sup>6</sup> Available online at [http://www.autm.net/AM/Template.cfm?Section=Licensing\\_Surveys\\_AUTM&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=5239](http://www.autm.net/AM/Template.cfm?Section=Licensing_Surveys_AUTM&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=5239) (last visited December 21, 2010).

of U.S. taxpayer-supported biomedical research. Federally funded biomedical research, aided by the economic incentives of Bayh-Dole, has created the scientific capital of knowledge that fuels medical and biotechnology development. American taxpayers, whose lives have been improved and extended, have been the beneficiaries of the remarkable medical advances that have come from this enterprise.

National Institutes of Health: *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected* (July 2001).<sup>7</sup>

BayhDole25 believes that the Federal Circuit's holding, if not reversed, threatens a return to the pre-Bayh-Dole "bad old days" when uncertainty about the ownership of inventions from federally funded projects thwarted university and industry collaboration – collaboration that, when allowed to flourish, has created remarkable medical and scientific advances leading to numerous new companies and jobs for our economy.



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<sup>7</sup> Available online at <http://www.nih.gov/news/070101wyden.htm> (last visited December 21, 2010).

## ARGUMENT

### I. THE FEDERAL CIRCUIT'S INTERPRETATION OF BAYH-DOLE WILL FRUSTRATE TRILATERAL GOVERNMENT / RESEARCH INSTITUTION / PRIVATE SECTOR COOPERATION TO THE DETRIMENT OF THE UNITED STATES ECONOMY

The Federal Circuit's opinion creates new, destructive uncertainties regarding title to federally funded inventions. These new uncertainties are different than those which existed in the pre-Bayh-Dole regime, but they will be every bit as frustrating and counterproductive to the commercialization of federally funded inventions. Before Bayh-Dole, the uncertainty lay in whether the Government, on the one hand, or the federally funded contractor, on the other hand, would ultimately obtain title to the invention. The answer to that question had been determined by a complex patchwork of regulations, which varied in terms and scope with each federal agency involved. *See* H.R. Rep. No. 96-1307, Pt. 1 at 3 (1980).

Bayh-Dole's simple yet robust framework replaced the regulatory patchwork, and calmed uncertainty over ownership of federally funded inventions. In the thirty years since Bayh-Dole's enactment, the United States has enjoyed the benefits of unprecedented scientific advancement from federally funded research, resulting in billions of dollars of economic activity, countless technology transfers, and the creation of an impressive array of innovative products

and services and millions of jobs. See BAYHDOLE25 WHITEPAPER, at 22-25. This scientific and economic prosperity was fostered in large part by the certainty of title created by Bayh-Dole, which carefully balances the potentially competing interests of the Government, research institutions, and the private sector. For its part, the Government has an interest in receiving a tangible return on taxpayer dollars invested in federally funded research projects. Non-profit federal contractors – universities and other research institutions – have an interest in obtaining a stream of royalty payments from the inventions created from federally funded research, which they then can reinvest in additional research and education, and also use to fulfill the important mandate of promoting local or regional economic development.<sup>8</sup> See, e.g., 35 U.S.C. § 202(c)(7). The private sector has an interest in developing and marketing commercially successful products from their collaboration with federal contractors, such as research institutions like Stanford.

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<sup>8</sup> “The data reported by universities reveal that academic technology commercialization continued to thrive even in the midst of the global financial crisis, providing a steady stimulus to the economy’ says Ashley J. Stevens, DPhil. (Oxon), CLP, AUTM president. ‘The majority of the startups formed are located in the licensing institution’s home state, which demonstrates that the Bayh-Dole Act continues to have a major impact on local economies across the nation,’ adds Stevens.” Gene Quinn, *AUTM Survey: University Licensing Strong Despite Economy* (Dec. 17, 2010) available online at: <http://ipwatchdog.com/2010/12/17/autm-survey-university-licensing-strong-despite-economy/id=13845/> (last visited December 22, 2010).

The certainty of title created by Bayh-Dole has resulted in unparalleled trilateral cooperation between the Government, research institutions, and the private sector the likes of which had not been seen before. Put simply, Bayh-Dole's framework of clearly defined rights to title in federally funded inventions, coupled with clearly defined statutory responsibilities of each party, made cooperation between the Government, research institutions and the private sector possible. The resulting commercialization of scientific research has enabled unprecedented social and economic value through the creation of new lifesaving and life enhancing medical and other technologies.

In sharp contrast, the Federal Circuit's opinion has brought turmoil into this well-established and understood trilateral relationship. The opinion below has rolled back the clock and replaced the pre-Act uncertainty about title with a new, equally destructive one: namely, whether an inventor with the stroke of a pen can divest the Government, research institution, and private industry from the fruits of their multi-million dollar investments. Under the Federal Circuit's interpretation of Bayh-Dole, none of these three key stakeholders can be sure of title to any federally funded invention. The uncertain answer to this question now rests not with a patchwork of multiple federal regulations (as in the past), but with the whims of individual inventors who, according to the Federal Circuit opinion, have the unfettered right to assign their federally funded inventions without regard to Bayh-Dole's statutory provisions.

The immediate effect of the Federal Circuit's opinion will be to disrupt thirty years of cooperation

between the Government, research institutions, and the private sector. The ultimate effect, however, will be to diminish the advancement of practical scientific research in the United States, and roll it back to pre-Bayh-Dole levels. At a time when we face new economic challenges and uncertainties, as well as increasing competitive pressures from nations such as Brazil, Russia, India and China – the so-called BRICs – the United States can ill-afford to sabotage its own investment in technological advancement.<sup>9</sup>

If the Federal Circuit’s opinion is affirmed, a private business collaborating with a federal contractor will not know whether the contractor will have full (or indeed any) rights to any resulting invention. For example, if, as the Federal Circuit holds, an individual inventor working under a federal funding agreement retains the right to assign her invention to anyone, the inventor would have the right to assign it to a non-collaborating third-party. Indeed, under the

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<sup>9</sup> “Brazil, Russia, India, and China will dominate future R&D growth, overwhelming Europe and Japan and, eventually, matching the investments in the U.S. At the current levels of spending, China alone will outspend Japan in R&D in mid-2010, match assumed aggressive spending in all of Europe combined in 2018, and match U.S. R&D spending in 2022.” Martin Grueber and Tim Studt, *2010 Global R&D Funding Forecast: An Overview*, R&D MAGAZINE (Dec. 22, 2009), available online at <http://www.rdmag.com/Featured-Articles/2009/12/Policy-and-Industry-2010-Global-R-D-Funding-Forecast-An-Overview/> (last visited December 22, 2010). See also, Gautam Naik, *China Surpasses Japan in R&D as Powers Shift*, Wall St. J., Dec. 15, 2010, at B4, available online at <http://online.wsj.com/article/SB10001424052748703734204576019713917682354.html> (last visited December 22, 2010).

rationale of the Federal Circuit's opinion, the inventor has *carte blanche* to unilaterally elect to retain the invention for herself, or to assign the rights to a third party for her own benefit without the knowledge or consent of the federal contractor. This holding is directly contrary to Bayh-Dole's statutory plan.

Without certainty of title to federally funded inventions, prudent private businesses will be reluctant to devote the time, human resources, and capital necessary to effectively collaborate with a non-profit research institution on a federally funded research project. Similarly, universities and other research institutions would be much less likely to encourage or permit their research scientists to meet with private industry experts for fear of losing future patent rights. This, in turn, will reduce the effective use of federal research dollars to promote truly innovative research.

The uncertainty created by the Federal Circuit's opinion also does violence to the Government's significant interest in ensuring that federally funded inventions are commercialized. Under Bayh-Dole, if the Government determines, for example, that the contractor or private sector licensee is not effectively commercializing the federally funded invention, the Government retains the right "to require the contractor, an assignee or exclusive licensee of a subject invention to grant" a license "to a responsible applicant or applicants" and, if the contractor, assignee, or exclusive licensee refuses, the Government may "grant such a license itself." *See* 35 U.S.C. § 203(a). But if an individual inventor retains the right to assign a federally funded invention to a third-party

(or to herself), the Government's rights to oversee and ensure the commercialization of the invention would be nullified, as would its "march-in" rights under Section 203(a) to reassign or reclaim title to the invention.

The Government therefore may be more reluctant in the future to give federal funding to any institution without first obtaining assurances from that institution that none of the researchers on the proposed research project have previously assigned any prospective rights in an invention to a third-party. Private industry will have the same concerns before investing in commercial activity arising out of Government funded research. The legal due diligence required to calm anxiety over ownership will take time and money, resulting in delays before commencement of any Government funding and any federal contractor / private sector collaboration. Even then, there would be no guarantee that a researcher would not subsequently assign "her" putative rights in any invention to a collaborating private business – as Roche contends occurred here – thereby frustrating the important interests of all Bayh-Dole participants in enjoying the fruits of federally funded research.



## CONCLUSION

We now face a United States economy eerily similar to that which existed in the "malaise" of the 1970s that immediately preceded Bayh-Dole's passage. The economy is stagnant. Businesses are fearful due to uncertainties over future economic conditions

and government regulatory pronouncements. Consumer confidence is lackluster. Unemployment (among those seeking work) hovers around 10% with little relief in sight. Foreign competition looms large.

The United States simply cannot afford to stifle innovation, scientific advancement, and economic growth. Separate and apart from the Federal Circuit's legal error in ignoring the primacy of the Bayh-Dole Act's ownership framework, the Federal Circuit's decision will frustrate the settled economic expectations of the key stakeholders in the Bayh-Dole statutory scheme. The clear economic benefits that our economy has enjoyed from Bayh-Dole for the past thirty years are now jeopardized as a result of the Federal Circuit's incorrect interpretation of Bayh-Dole.

The Federal Circuit's opinion below was wrongly decided. It should be reversed.

Respectfully submitted,

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