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# It Ain't Necessarily So

## *Just Saying That Bayh-Dole Gives Patent Ownership to University Inventors Doesn't Make It True*

BY JOSEPH P. ALLEN AND HOWARD W. BREMER

As the saying goes, everyone is entitled to their own opinions—but not entitled to their own facts. Therefore, we feel compelled to respond to Gerald Barnett's *Point of View* article ''Ownership or Stewardship: Universities Need to Reconsider Patent Policies in Light of *Stanford v. Roche* Ruling,'' which was published in *Genetic Engineering News* Feb. 1, 2012, Vol. 32, No. 3.

Mr. Barnett claims that the University and Small Business Patent Procedures Act of 1980, commonly called Bayh-Dole, ''does not require that the university own federally supported inventions, nor grant the university title in such inventions.''

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He summarizes the Supreme Court ruling in the *Stanford v. Roche* case, claiming: ''The ruling of the Supreme Court was clear: inventions made at a university using federal funds are the property of the inventors. The Bayh-Dole Act does not require that the university own federally supported inventions, nor grant the university title to such inventions. Quite the opposite; the Act anticipates a diversity of approaches to the private development of research inventions. Only when the university happens to be the owner of the federally supported inventions do most of the requirements of the Act apply.''

He is wrong about the Bayh-Dole Act, and greatly misinterprets the Supreme Court ruling. And this is not a dispute over semantics.

We were involved in crafting and implementing the Bayh-Dole Act, and actively weighed in on *Stanford v. Roche*. It is imperative that the record be set straight.

With its passage, the Bayh-Dole Act ushered in an unprecedented era of university-industry commercialization partnerships that are vital to U.S. competitiveness and prosperity. Under Bayh-Dole, more than 6,000 new companies have been created around university technologies and more than 5,000 new products are available to the public, with at least 279,000 good-paying jobs created in the United States between 1996 and 2007 alone.

It is no exaggeration to say that university-industry alliances are the linchpin of the U.S. life sciences industry, an area where our leadership is under tremendous international pressure. Losing this dominance will affect the quality of life and the economic well-being of our citizens. Thus, it is important that the public accurately understands why Bayh-Dole was passed and how it works.

Bayh-Dole replaced a morass of federal polices based on the premise that the government should own any inventions made in whole or in part with agency support, believing that this approach would make them readily available to all. While perhaps a noble goal, the policy undermined the intended incentives of the U.S. Constitution-based patent system—with predictable results. Only rarely were these discoveries commercialized.

Thus, the public was denied the full benefits of the research it was supporting through its hard-earned tax

dollars. For example, not a single new drug was developed from National Institutes of Health (NIH) research under this policy.

Reacting to this failure, NIH launched an administrative program allowing universities with technology transfer offices to own and manage their federally supported inventions. Immediately, universities had significant success turning their patentable discoveries into products benefiting the public health and well-being.

When the Carter administration threatened to end the NIH program, then-Senators Birch Bayh (D-Ind.) and Robert J. Dole (R-Kan.) introduced legislation giving it statutory authority, while expanding it to all federal agencies.

Subsequent hearings found 28,000 inventions gathering dust on agency shelves under the government's failed patent policy. Realizing that billions of dollars invested in federally supported research were being squandered as promising discoveries were not turned into useful products, Congress overwhelmingly passed Bayh-Dole.

Contrary to Mr. Barnett's assertion, Bayh-Dole created a uniform federal patent policy guaranteeing universities, other nonprofit organizations, and small businesses title to inventions they made with government support—not to their employed researchers.

The statutory language on this point is unambiguous. Section 202(a) states: ''Each **nonprofit organization or small business firm** [emphasis added] may within a reasonable time after disclosure (of the invention to the funding agency) . . . elect to retain title to any subject invention.''

Subject inventions are defined as ''any invention **of the contractor** [emphasis added] conceived or first actually reduced to practice in the performance of work under a funding agreement.''

However, Bayh-Dole does require universities to share royalties with their inventors, recognizing the vital role academic researchers play in the commercial development of the technology.

Interestingly, Mr. Barnett fails to cite the language in Bayh-Dole that specifically addresses the possibility that patent rights can be assigned to university inventors. This is unfortunate, as reading the statute disproves his theory.

Bayh-Dole stipulates that before academic researchers can own federally funded inventions, the university must first decline to take ownership of the patent. Next, the university must notify the federal agency funding the research, which has the option to take patent ownership. *Only if both the university and the agency decline ownership can the invention be assigned to the researcher.*

Clearly, Congress was not putting employed inventor ownership on a par with the university that received the federal funding.

Finally, a word about *Stanford v. Roche*. U.S. patent law is based on the premise that inventors are owners of their inventions. It is well established that organizations can require their employees to assign patent rights for inventions made during the course of employment to them. Bayh-Dole is based on this premise.

As *Stanford v. Roche* wound its way through the courts, the theory arose that invention assignment agreements with faculty were not necessary under Bayh-Dole because the law automatically ''vested'' ownership in the university. We pointed out that this theory was erroneous, having no basis in the law, its implementing regulations, or in actual practice.

In its ruling, the Supreme Court agreed with our assertion. The court held that universities must have their researchers assign patent rights to them to trigger the provisions of Bayh-Dole granting contractor's ownership of their inventions. That is precisely how the law had always worked. So rather than throwing open the question of who owns federally funded inventions as Mr. Barnett alleges, the court simply affirmed the common practice under Bayh-Dole.

Thus, the law keeps on working and benefiting the nation as it has since 1980. And this is a very good thing, indeed.

It's no accident that *The Economist's Technology Quarterly* called Bayh-Dole ''Possibly the most inspired piece of legislation to be enacted in America over the past half-century.'' It was mentioned previously that before Bayh-Dole, not one drug had been commercialized when the government owned the patent. A recent study shows there are now more than 153 new drugs, vaccines, or medical devices protecting public health worldwide because of Bayh-Dole.

Critics are certainly free to float alternative theories, but they face a heavy burden of proof when seeking to turn a system as successful as the Bayh-Dole Act on its head. To claim that everyone has been misinterpreting the law for 30 years while offering no supporting facts must be weighed accordingly.

The Bayh-Dole system of university and small business ownership of inventions made with federal support clearly works. It is a recognized best practice that our competitors are adopting to challenge our lead in the technologies that will define the 21st century.

As baseball great Satchel Paige said: ''Never look back, they might be gaining on you.'' India, China, Japan, and others have adopted Bayh-Dole systems so they can run faster to overtake us. For the United States to undermine the law would be very foolish. It would not take long before we are the ones running behind.

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