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Universities, Inventors, and the Bayh-Dole Act

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Like a poorly written *DaVinci Code*, every few years someone miraculously “discovers” new meanings in the Bayh-Dole Act hitherto undetected. The latest revelation is that university inventors should be “free agents,” owning their federally funded discoveries rather than assigning them to the school that actu-

ally received the federal grant for possible commercial development. Some claim that such a chaotic commercialization system was what Congress envisioned when enacting the Bayh-Dole Act of 1980.

Nonsense!

Luckily, those of us involved in creating Bayh-Dole are still alive and well. It is important to set the record straight on this point in light of the well-organized campaign to promote an alternative gospel. The premise of Bayh-Dole is as viable now as it was after its implementation in 1980 and can help restore our economy today—unless policy makers listen to the siren call to dismantle it.

The Bayh-Dole Act unleashed the previously untapped potential of university inventions, allowing them to be turned from disclosures in scientific papers into products benefiting the taxpaying public. The law also allowed for the effective licensing of inventions made by government inventors, such as those at the National Institutes of Health. Injecting this previously untapped “secret weapon”—the billions of dollars spent on federally funded R&D, by far the largest such investment in the world—into the U.S. economy had much to do with the miraculous restoration of U.S. competitiveness in the 1980s. This occurred at a time when many “experts” were writing off the future of American innovation.

The Bayh-Dole Act works because it aligns the interests of the taxpaying public, the federal government, research universities, their departments, inventors, and private sector developers transforming government supported research into useable products. Breaking this alignment of interests would have truly disastrous consequences. Yet, this is exactly what a small clique of vocal critics recommend.

Nothing has done more to benefit and motivate university inventors than passage of the Bayh-Dole Act. It requires universities to share royalties resulting from

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the commercial development of their federally funded inventions with those making the discovery. Before the law, any rights to these discoveries were considered to be federal property and owned by the government. Consequently, researchers were never accorded a share of any proceeds generated if the government itself patented and licensed them. However, it was never part of the premise of Bayh-Dole that university inventors would automatically own federally funded inventions.

Those now promoting this view seek to use the decision in the recent patent infringement suit brought by Stanford University against Roche to overturn the university technology transfer system (*Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc.*, Fed. Cir., No. 2008-1509, 9/30/09). The ruling against Stanford turned on the wording of the various agreements whereby scientists assign rights to inventions to the universities employing them. In the ruling the court found certain ambiguities in the Stanford contract which in the court's opinion, defeated the intent of the contract. Under constitutionally based U.S. law, individuals own their own inventions. However, it is a normal and accepted practice for them to assign these rights in whole or in part to their employers if they are made on the job utilizing the employer's time, materials, and facilities, particularly if they are hired to invent. Most employers, whether in the private or academic sectors, utilize signed employment contracts specifying such ownership. The Bayh-Dole Act is based on the expectation and assurance that such agreements are in place in the university sector to safeguard the interests of the taxpaying public.

Notwithstanding, the court's ruling gave rise to a series of articles, such as the Oct. 27, 2009, story in *USA Today* titled "Lucrative inventions pit scientists against universities" alleging that: "The federal government is here saying that Bayh-Dole does not give away inventors' rights to universities."¹ As the theory went around the world, the claims became even more breathless.

In South Africa, the headline became "US: Academics, not universities, own their inventions."² That story quoted the same critic as saying: "The court's ruling confirms that faculty inventors own the rights to their ideas and creations, and that universities can no longer use the Bayh-Dole Act as a bulldozer to claim ownership away from inventors themselves." Later the same source added that with the 30th anniversary of the Bayh-Dole Act "just around the corner" it was time to "correct the misuse of the law to take IP ownership away from academic inventors."

In a Nov. 6, 2009, opinion piece by the leaders of the Kaufmann Foundation in *The Wall Street Journal*, it is claimed that allowing university professors to choose how to manage their federally funded inventions would "lead to a much more rapid commercialization of government-funded research at universities" than the current policy of working through the university technology transfer office.³

Of course, there is no evidence given to explain how that would be the case—since none exists.

However, evidence does exist comparing the system the critics advocate with the Bayh-Dole model. And the lessons could not be more clear as to which works best. A prominent study compared the underperforming Swedish technology transfer system with what Bayh-Dole established in the United States. Here's what the authors found:

Surprisingly, we find suggestive evidence that the American university system, whereby intellectual property is commonly awarded to universities, is more effective in facilitating the commercialization than the Swedish system in which rights are awarded directly to the inventors.⁴

The authors explain their findings this way:

It might be surprising that we are arguing that awarding property rights to the university, as opposed to the inventor, has successfully increased the incentives of inventors to commercialize their activities. However, rewards are tied to project value as universities have found it best policy to reward inventors, along with departments and schools with shares of proceeds from an invention. Generally, universities also deduct funds to recover expenses associated with licensing patents. Hence, awarding property rights to the university accomplished two goals. First, it encouraged the establishment of hundreds of offices of technology transfer at universities. These offices relieve inventors from a need to develop expertise in the legal and business sides of invention commercialization. Second, since the offices typically cover expenses associated with marketing, patenting, and licensing, inventors avoid the risk associated with covering such costs. Not only are such activities expensive, but they are also time consuming. This implies that inventors would incur substantial opportunity costs if they were to engage in such activities. When these costs overwhelm the (additional) expected returns the inventor would have earned had he had 100 percent of the intellectual property rights, commercialization become more likely when rights are assigned to the university.⁵

The study continues:

However, not only does awarding property rights to an individual inventor create disincentives for the university, when property rights rest solely with the individual researcher, there is no "profit sharing" with his/her department. This has probably given rise to anti-entrepreneurial peer pressure at Swedish universities. Informal interviews as well as an in-depth government report on the collaboration between university and industry point to the existence of such pressure. US TLOs (technology licensing offices) have mitigated this problem by awarding proceeds to the inventor's department.⁶

It concludes:

Interestingly, putting property rights in the hands of the inventor does not automatically create the best

¹ "Lucrative inventions pit scientists against universities," *USA Today*, Oct. 27, 2009.

² "US: Academics, not universities, own their inventions," *University World News*, Nov. 1, 2009.

³ "New Business, Not Small Business, Is What Creates Jobs," *The Wall Street Journal*, Nov. 6, 2009

⁴ Brent Goldfarb and Magnus Henrekson, *Bottom-Up vs. Top-Down Policies towards the Commercialization of University Intellectual Property*, SSE/EFI WORKING PAPER SERIES IN ECONOMICS AND FINANCE No. 463, Feb. 25, 2002, p. 2.

⁵ *Ibid*, pp. 11-12.

⁶ *Ibid*, p. 15.

incentives for commercialization. To facilitate involvement in commercialization activities, not only must an academic inventor face strong incentives in the market for technology, but she must also not face strong disincentives in her university environment. The system works better when incentives are aligned.⁷

Thus, there is strong evidence that undermining the alignment of interests of the Bayh-Dole technology transfer system would be a disaster for the U.S. economy—and the interests of the American taxpayer.

University inventors are neither trained to be, nor inclined to become, experts in patent licensing or technology commercialization. That is not at all a simple process. Furthermore, one of the most important contributions of the Bayh-Dole Act was providing assurance to industry developers that there was certainty of title to inventions, which were candidates for development, and that there would be uniform, predictable systems in place to justify their high risk investments. This is a highly significant factor in commercializing university-based inventions.

Experience shows that because most university inventions tend to be embryonic in nature it takes from five to seven years to turn a “good” university invention into a commercial product. Consequently, the costs of moving from the research lab into the marketplace can easily exceed investment in the initial research by a factor of 10 or more. In the life sciences arena (where most technology transfer successes under Bayh-Dole have occurred), private sector development can cost between \$800 million to \$1.3 billion per new drug delivered to the market, while requiring more than 10 years for development and product approval. Even then, there are absolutely no guarantees of success in the marketplace.

Asking companies taking such risks to run all over campus tracking down each inventor attempting to strike a deal is unthinkable, as well as impractical. Such a system puts an enormous burden on the shoulders of already overloaded academic bench scientists. They joined the public sector to advance the frontiers of knowledge, not to negotiate patent licensing agreements, or to have to pay for the preparation and prosecution of patent applications and employ counsel to handle the legalities out of their own pockets. Being unversed in the complexities of technology transfer, they easily could be taken advantage of at the negotiating table or in their efforts to assert such patent rights as they may have acquired.

Most importantly, the “solution” proposed by the critics does not protect the vital interests of those funding the initial research—the hard-pressed U.S. taxpayer. Bayh-Dole was not established to enrich universities or their inventors. While royalties resulting from successful commercialization are re-invested in campus research, paying associated technology transfer costs, and in rewarding inventors, those are not the primary goals of Bayh-Dole. Bringing new products into the marketplace where they benefit the public through providing enhanced health, safety, and the realization of better living standards—as well as promotion of economic growth—is the real objective.

Thus, the university is entrusted as a steward of the public interest. Universities are expected to reasonably

represent these interests, reaching “win-win” deals with private sector developers. As the law clearly envisions, that end is best accomplished when those skilled in patent licensing and working in a supporting organization are making the deals. This can be done either by the university technology transfer office itself or contracted out, but is clearly not an appropriate role for individual academic researchers with neither the time nor the expertise to do so.

So how is the current system working? There has now been almost 30 years of experience to judge Bayh-Dole’s effect. What the critics always gloss over is that as imperfect as they make out that law to be, *Bayh-Dole is the most successful system in history for turning university research into useable products.*

And, unlike the critics’ claims, there is real data to back up that conclusion. For example, in its 2006 licensing survey, the Association of University Technology Managers found:

- more than 6,000 new U.S. companies formed from university inventions—such formation is a key ingredient in virtually every state economic development plan;
- two new companies formed every working day of the year;
- 4,350 new products came on the market as a result of university patent licensing; and
- 5,000 active university-industry licenses are in effect, mostly with small companies.⁸

Another study found that 153 new drugs, vaccines, or in vitro devices had been commercialized from federally funded research since enactment of Bayh-Dole.⁹

A study supported by the Biotechnology Industry Organization (BIO) on the impact of university patent licensing on the U.S. economy between 1996 and 2007 has just been released. Even using very conservative methodologies, that study reports:

- a \$187 billion impact on the U.S. gross domestic product;
- a \$457 billion impact on U.S. gross industrial output; and
- 279,000 new jobs created in the United States from university inventions.¹⁰

A 2009 survey of BIO member companies reveals how dependent that industry is on patent licensing, largely from universities, finding that:

- 50 percent of those reporting said their companies were based on in-licensed technologies; and
- 76 percent have licensing agreements with U.S. universities in place.¹¹

That the existence of the U.S. biotechnology industry is largely attributed to university research is under-

⁸ Association of University Technology Managers (AUTM): U.S. Licensing Activity Survey, 2006.

⁹ Jonathan J. Jensen, Kathrine Wyller, Eric R. London, Sabami K. Chatterjee, Fiona E. Murray, Mark L. Rohrbach, and Ashley J. Stevens, “The Contribution of Public Sector Research to the Discovery of New Drugs,” presented at BIO Technology Transfer Symposium, San Francisco, Oct. 28, 2009.

¹⁰ David Roessner, Jennifer Bond, Sumiye Okubo, and Mark Planting, “The Economic Impact of Licensed Commercialized Inventions Originating in University Research, 1996-2007,” Sept. 3, 2009.

¹¹ “BIO’s 2009 Member Survey: Technology Transfer & the Biotech Industry,” presented at BIO Technology Transfer Summit, San Francisco, Oct. 28, 2009.

⁷ Ibid. pp. 30-31.

scored by BIO's citation of the Bayh-Dole Act as an essential foundation for the creation and growth of the industry:

It is only fair to note that these accomplishments were attained through the currently much maligned university technology transfer system, and that nothing even approximating such impacts existed before the Bayh-Dole Act.

Perhaps before considering claims that the Bayh-Dole system should be turned on its head (with devastating consequences to a struggling U.S. economy), it might be worth reflecting on the context of how and why the Bayh-Dole Act was developed.

Bayh-Dole was enacted in 1980 to allow universities and small businesses contracting with the federal government to own and manage patentable inventions made with government support. Before that time, federal agencies normally took title to inventions away from the creating organizations and inventors, thus destroying the very incentives intended to be provided by the U.S. patent system. The result was that few such inventions were commercialized. That is common knowledge. What is not commonly known is the foundation of the Bayh-Dole approach. This had much to do with its success while competing bills fell by the wayside.

In the 1960s the National Institutes of Health (NIH) realized the futility of taking federally funded inventions away from universities if such discoveries were to result in products helping to alleviate human suffering. As a consequence, NIH established the Institutional Patent Agreement (IPA) program, *allowing universities with technology transfer offices* to own and manage such inventions. It was correctly believed that skilled university technology transfer professionals are the best means for insuring that the public benefits from the billions of dollars annually invested in university-based research.

Universities quickly showed the effectiveness of this approach. The number of university technology transfer offices quickly increased, important discoveries were licensed to U.S. industry for development, and the number of university-owned patents skyrocketed.

Unfortunately, there was a hiatus in the progress being made when the Carter administration decided to shut the program down in 1978. As the IPA program had been set up administratively, with no statutory underpinning, such arbitrary actions could be taken without congressional approval.

Then as now, Congress was rightly concerned that the government has an obligation to maximize the economic impact of the many billions of dollars invested each year in public sector research. The abolishment of the IPA program by the Carter administration consequently led to the introduction and subsequent passage of the Bayh-Dole Act.

In the report of the Senate Judiciary Committee recommending Bayh-Dole to the full Senate for consideration, it was stated:

Prior to the I.P.A. program, however, *not one drug* (emphasis in original) had been developed and marketed from HEW research because of a lack of incentives to the private sector to commit the time and money needed to commercialize these discoveries.¹²

¹² "University and Small Business Patent Procedures Act," Report of the Committee on the Judiciary, U.S. Senate, on S. 414, Dec. 12, 1979, Rep. No. 96-480, p. 21.

It was the demonstrated effectiveness of university technology transfer offices under the IPA program that persuaded Congress that universities could be entrusted with owning and managing their important discoveries. Prior to Bayh-Dole, academic inventors assigned their individual patent rights to their institutions if employment agreements were in place. These rights then were required to be conveyed to the respective federal agencies that had funded the research. *After Bayh-Dole, the relationship between inventors and their universities was not changed. What did change was that universities now owned and managed their inventions themselves.*

The fact that Bayh-Dole requires that universities must share resulting royalties with their inventors provides a pretty good clue that there was no intention that it envisioned university inventors themselves owning federally funded inventions.

Actually, "clue" is the wrong word to use. The meaning was made plain in the following provisions of the Bayh-Dole Act:

- Title to inventions initially resides in *nonprofit organizations*, since these are the entities receiving federal funding, (i.e. those organizations are the contractors with the government), not the individual inventors.
- Universities, not inventors, are made responsible for reporting inventions to the funding agencies, providing licensing preferences to small businesses and those who will manufacture in the United States plus meeting the other requirements of the law.
- Bayh-Dole specifically prohibits universities from assigning rights to *anyone* except "where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor)."
- If the university decides that it does not want to retain title to a federally funded invention *it is specifically prohibited from assigning such rights to the university inventor unless approved by the federal funding agency*—another pretty strong hint that university inventors were not intended to own such inventions outright under Bayh-Dole.

In a democracy anyone is free to float theories on how things could run in an ideal world, unconnected to everyday life. However amusing this exercise might be, the historical evidence of the necessity for a stable technology transfer system as envisioned in Bayh-Dole, along with the act's explicit wording, leaves no doubt of its intent:

Universities, not inventors, are charged with owning and managing the licensing of inventions made with federal support. Period.

Universities certainly should be making every effort to insure that they are managing their federally funded inventions as good stewards of the public trust, and always should be striving to identify and adopt best practices in this regard. With ever increasing international competition, this is no time to rest on the laurels of our past accomplishments.

Those proposing to change the current system should be held to a strict accounting, providing empirical and clearly supportable proof before any of their recommendations are seriously considered. After all, they

seek to change a law widely copied around the world as a demonstrated best practice for successful economic development, while also making available important new technologies benefiting humanity. The bar for “re-forming” or, more correctly, weakening the principles of Bayh-Dole should be set very high in light of the clear evidence of its success. The critic’s proposals, held to this standard, are “weighed and found wanting.”

The demonstrated 30-year impact of the Bayh-Dole Act—largely as implemented by university technology transfer offices—occurred in real life practice, not theory.

As the *Economist Technology Quarterly* famously stated:

Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980 . . .

More than anything, this single policy helped reverse America’s precipitous slide into industrial irrelevance. . .

Odd then, that the Bayh-Dole act (sic) should now be under such attack in America.¹³

Odd, indeed!

¹³ “Innovation’s Golden Goose,” *The Economist Technology Quarterly* (editorial), Dec. 14, 2002.