Enacting Bayh-Dole

By Joseph P. Allen

There is a tide in the affairs of men
Which taken at the flood, leads on to fortune;
Omitted, all the voyage of their life
Is bound in shallows and in miseries.

Julius Caesar by William Shakespeare

We caught the tide-- but just barely. That the Bayh-Dole Act passed was amazing. That it passed in a lame duck session of Congress with its principal author defeated, the US Senate changing hands, and a sitting president thrown out, was a miracle. Even then success was not assured. The bureaucracy was waiting to undermine the implementing regulations. Yet the new law survived, strengthening the economy while improving public health and well-being.

Success depended on slipping through a narrow window of opportunity. In **Julius Caesar,** Brutus hesitates and is swept away. Fortunately, we launched and caught the tide. This is my "staff's eye view" of how it happened.

In 1978 I was on Senator Birch Bayh's (D-IN) staff when Purdue University asked for a meeting. Our general counsel invited me to sit in. Purdue had several promising government funded inventions taken away under existing federal patent policies. They explained that taking early stage inventions from their creators, making them widely available through non-exclusive licenses doomed the technology's development. Confirming Purdue's observation was Howard Bremer of the Wisconsin Alumni Research Foundation and Norman Latker, the National Institutes of Health (NIH) patent counsel. They added that NIH had a very successful policy granting patent ownership to inventing universities, but it was being abolished by the Carter Administration. Would Senator Bayh look into this matter and consider introducing legislation allowing universities and small companies to own inventions made with government support?

The economy was then in a tailspin. Combining double digit inflation with double digit unemployment created the "Misery Index". The federal government funded 50% of U.S. research, but few inventions made it to the marketplace. The Department of Defense routinely granted patent ownership to major contractors, but not to universities or small companies. Yet these very entities are the most likely to make breakthrough discoveries. Instead, universities

and small companies had to petition to own their discoveries. The procedure was slow and cumbersome. The answer was frequently "No."

We learned that Senator Robert Dole was also looking at the problem. This raised an interesting possibility. Senator Bayh was a liberal Democrat and Senator Dole a conservative Republican. Both served on the Senate Judiciary Committee. Both reached the same conclusion: patent incentives must be restored to the federal R&D system. They were happy to work together to make that happen. The political combination of Birch Bayh and Bob Dole was formidable. Together they bridged the partisan divide.

A draft bill was introduced in late 1978 to get comments from interested parties before the bill was re-introduced the next Congress. We asked the Comptroller General of the United States, Elmer B. Staats, to conduct a study of the federal patent policies then in place. Staats knew the subject well. He had the clout to get data from reluctant agencies how effectively taxpayer-supported R&D was being commercialized.

As Congress reconvened, we held a press conference showcasing university inventions at risk. The inventors explained that medical discoveries would not alleviate human suffering unless they were turned into products. This would not happen when government destroyed the incentives of patent protection. The event got great press coverage.

The next day the **National Inquirer** called. "Is it possible the cure for cancer is being delayed?" I replied that anything is possible, but that was hardly likely. For weeks I glanced nervously at the checkout counter to see if a headline screamed *"Government Hides Cure for Cancer."* Luckily, the story didn't run.

Our hearings that spring went very well. The Comptroller General confirmed that the government's patent policies were not working. He showed that petitions for patent ownership took up to 18 months to process. Approximately 28,000 inventions had piled up, and less than 5% were ever licensed.

University and small business witnesses told how detrimental the current policies were to American innovation. The Carter Administration had not taken a position on the bill so they did not testify. However, Admiral Hyman Rickover ("The Father of the Nuclear Navy") appeared under full steam.

Rickover was a staunch believer that whatever the government funded should be freely available. Experience in the nuclear industry showed that patents were not critical to development, he said. Rickover and Sen. Bayh had a lively debate on the merits of the patent system. The Admiral deeply believed in his view. He also had a close ally in Congress—Senator Long of Louisiana.

Russell Long was the son of the legendary Huey ("The Kingfish") Long. Sen. Long chaired the powerful Senate Finance Committee overseeing tax policy. He reportedly replied when asked about a pending tax reform provision: "If I have to explain it, we'll be here all day. Just vote Yes."

Sen. Long greatly admired Admiral Rickover, sharing his views on government patent policy. Long was not someone you crossed lightly. We hoped that limiting our bill to universities and small companies would avoid his wrath if we got to a full Senate vote. Universities and small companies were the crux of the problem anyway. But first we had to get out of the Senate Judiciary Committee.

The next step was the Committee "marked up." This is when the Judiciary Committee reviews the bill, makes any amendments, and then votes it up or down. If approved, the bill proceeds to Senate consideration.

The Committee had the most liberal Democrats and conservative Republicans in Congress. But the political alliance of Bayh and Dole, with support from the universities and small businesses was our secret weapon.

One day Chairman Ted Kennedy (D-MA) and Ranking Minority Member Strom Thurmond (R-SC) independently called to be co-sponsors. I made a bee line to the Senate chamber to give Senator Bayh the good news. Mischievously looking up from his reading glasses he said: "Are you sure this bill is ok?'

Shortly before the Committee vote in December 1979, we were visited by the Carter Administration. They had sat on the bill for a year. I was astounded when they asked that we stop while they developed an alternative approach. I replied we had waited long enough as Congress was already half over. The Administration would make their presence felt -- to our dismay.

The Judiciary Committee unanimously approved Bayh-Dole, reporting it to the full Senate.

We were now at a point of great peril. We continued to hear from Admiral Rickover. He was also prodding Senator Long to get involved. We would soon know if Rickover had succeeded or not.

The actual hit came from an unexpected direction. Giving up on dissuading us, the Administration moved to the Senate Commerce Committee. They developed a rival bill geared toward large contractors, arguing that these companies performed the majority of federal R&D. Senator Bayh met with Senators Stevenson and Cannon. He argued that universities and small companies were those suffering most from the current policies, that they were the ones most

likely to make breakthrough discoveries with federal funding, and the alternative approach was not politically feasible. Bayh's views were rejected.

Before debate on Bayh-Dole began in February 1980, all Senate offices received a "Dear Colleague" letter from Commerce Committee. They intended to amend our bill to include big business. Senator Bayh and Dole replied with a rebuttal letter. Both sides worked the phones hard lining up support.

The next day showed who had the votes. After a lively debate, we handily beat back the amendment. However, just as the vote concluded, Senator Long emerged. He was not a happy man. As Stevenson and Cannon fled, Senator Bayh whispered "Great, they're leaving me to clean up their mess."

I had a good relationship with Wiley Jones on Senator Long's staff. Senators Long and Bayh also got along very well. Wiley and I agreed not to sandbag each other. Long feared that Bayh-Dole was a "Trojan horse" limited at first, but later expanding to include big business. Sen. Bayh pledged to fight such efforts. But the Commerce Committee had waved a red flag before a very powerful bull. When he charged, you knew it.

Senator Long's seat was directly behind Sen. Bayh. As a staffer, I was sitting beside my boss. Senator Long soon brought further consideration of Bayh-Dole to a screeching halt, muttering to us: "This is the worst bill I've seen in my life."

Long told the presiding officer that he had several amendments to the bill. It became obvious that the debate would take much longer than the Senate leadership had allocated. We had to pull Bayh-Dole from the floor.

Under the rules, one Senator can greatly complicate consideration of a bill. They can object to it being scheduled. They can drag out debate offering endless amendments, or use parliamentary maneuvers like the filibuster.

As the 96th Congress got closer and closer to election day, non-essential bills were severely limited on the time allotted for debate. Three precious months were spent working behind the scenes with Senator Long's office to re-schedule Bayh-Dole. In late April 1980 we succeeded--again pledging to oppose any attempts to broaden it.

The bill passed the Senate 91-4. Sen. Long voted no.

Meanwhile, the House was also looking at federal patent policies. Consideration began in the House Science and Technology Committee, then onto the House Judiciary Committee. The end of the Congress was rapidly approaching. The Carter Administration gained support for their approach. The House bill included big business.

The reaction was predictable. On September 24, 1980 Senator Bayh received a public letter from Sen. Long: "I am adamantly opposed to the House bill. I urge you to join with me in taking whatever steps are necessary to prevent this monopolistic provision from being included in the final form of any patent policy legislation."

Two days later, Bayh replied: "I will offer an amendment to bring any House passed patent policy into conformity with that already passed by the Senate, which as you know is strictly limited to universities and small businesses."

And there things stood on Election Day, 1980.

The election of 1980 was similar to 2010. Jimmy Carter was initially viewed as a political outsider who would change Washington. Political missteps, an economy spiraling downward, and the Iran hostage crisis ate away his support. Americans felt that it was time to clean house. Carter lost to Reagan. Birch Bayh lost. The Senate went to Republican control for the first time in decades.

However, Congress had recessed without enacting a budget so a lame duck session was necessary. This provided a glimmer of hope for Bayh-Dole. But Senate policies for bringing up non-budgetary bills were strict: they must pass unanimously.

The House combined several patent related provisions into one bill, including their version of patent policy. The bill manager was Rep. Robert Kastenmeier of Wisconsin. Through informal negotiations, we made it clear that we could not accept this approach as evidenced by Senator Long's letter. The House would not back down. We stopped talking. However, the University of Wisconsin was a large part of Kastenmeier's district. And they backed Bayh-Dole.

One afternoon I received a call from Bruce Lehman (later PTO Commissioner). Bruce was Representative Kastenmeier's staffer on their bill. Bruce offered a deal. They would include our patent policy if we would accept the rest of their omnibus bill. I ran it by Senator Bayh. He gave the green light. The House would pass the bill with Bayh-Dole included. We would then pass their revised bill without any changes. However, if even one Senator objected, we were sunk.

I contacted the Senate Majority Leader's office to schedule a vote as soon as the House acted. The Majority and Minority leaders then alert their respective members to see if anyone objected. Congress was adjourning any moment when the final parts of the budget were completed.

I received a call. We would not be scheduled because a Democratic hold had been placed on our bill. Under the procedures, any Senator can anomalously "hold" legislation blocking consideration. I checked with Wiley Jones. He said Long had not placed the hold.

There was another likely candidate: Senator Stevenson. He had developed rival legislation that would become the Stevenson-Wydler Act. Stevenson, like Bayh, was leaving Congress. I went looking for his staffer, Steve Merrill.

Finding Steve in the Senate cafeteria, we had a direct conversation. I said that two could play this game. If the hold wasn't lifted on Bayh-Dole anything with Sen. Stevenson's name would have a similar hold —and they would not even have to guess who had done it.

Shortly the hold was removed. However, the Majority Leader's staff said because of Senator Long's interest; they had to call his office as well.

Minutes later my phone rang. It was Wiley Jones. "I have two questions for you. One is from Senator Long and one is from me." He asked if Senator Bayh really wanted the bill. I said that he did. Wiley then asked if it would be better for me not to pass the bill so I could find a new boss and have a job next year. Moved by his thoughtfulness, I replied it was now or never for passing Bayh-Dole. He said "OK," and hung up.

Senator Long immediately called Senator Bayh. "Birch, you can pass your damn patent bill-- and I'm really going to miss working with you."

I ran to the Senate chamber. It was in chaos. Staff fought to get bills scheduled while there was still time. In the confusion, I found the Majority Leader's staffer. We would be up in 10 minutes, but if we weren't ready, too bad.

I called for Senator Bayh. He was at a press conference and would take 20 minutes to return. My heart sank. I looked around the Senate cloakroom. There stood Senator Dole!

Running over I explained our dilemma. Senator Dole said "Follow me," and went out on the Senate floor. I handed him the statement I had written for Senator Bayh, he read it, and asked for the vote. On November 21, 1980 Congress passed H.R. 6933 including the Bayh-Dole Act. We had done it-- or so we thought.

As Bayh-Dole was moving through Congress, agency opposition centered in the Department of Energy (DOE). DOE is a large funder of nuclear weapons research and very sensitive on how their technology is developed. Over the years DOE amassed a large staff reviewing patent petitions. They rightly saw Bayh-Dole as a threat to their job security.

After Congressional passage, legislation moves to the President's desk for signature. The Constitution says:

> *If any Bill shall not be returned by the President within ten Days (Sundays excepted) after it shall have been presented to him, the Same shall be a Law, in like manner as if he had signed it,* ***unless the Congress by their adjournment prevents its Return, in which case it shall not be a law.*** (Article I, Section I, emphasis added)

Congress had adjourned so the President could "pocket veto" Bayh-Dole by simply ignoring it. We heard that DOE was working the White House against the bill. As days ticked by without the President's signature we became increasingly alarmed.

Our ally in the fight was the Office of Advocacy in the Small Business Administration. Headed by Milton Stewart (later founder of INC magazine), they supported Bayh-Dole over the Carter Administration proposal. Milt had worked with Stuart Eizenstat, Carter's chief of staff, organizing a very successful small business conference before the election. Deftly countering DOE, Stewart cleared the roadblocks.

On the very last day President Carter signed Bayh-Dole into law.

But it was still in jeopardy. Any law is only as effective as its implementing regulations. With Sen. Bayh gone and the new Reagan Administration not in place, DOE had a golden chance to torpedo the regulations.

While Bayh-Dole held the general principle that universities and small companies making inventions with federal support could own them, we stipulated that in "exceptional circumstances" the agency could provide otherwise. Congress envisioned situations where government agencies were actually developing the technology, or where national security concerns prevailed. The Department of Energy launched their assault using this provision. They tried to exempt broad categories of research from the law.

Luckily, we had a capable person in place guiding the regulations. Norman Latker as NIH patent counsel realized that unless universities were allowed to own and manage federally funded discoveries, inventions were unlikely to ever be developed. Norm developed a highly successful administrative policy that worked for years until the Carter Administration decided to roll it back—and fire Latker.

Instead, Bayh and Dole got Norm relocated and placed oversight of the new law under him. His boss was Dr. Bruce Merrifield, Assistant Secretary of Commerce in the new Reagan Administration-- a great stroke of luck.

As an entrepreneur, Merrifield immediately understood the importance of Bayh-Dole. He strongly backed Latker in his fight with DOE, alerting the White House of the importance of the new law to an ailing economy. Eventually, President Reagan issued an Executive Order giving his support to Bayh-Dole.

In 1982, I began working in Dr. Merrifield's office overseeing Bayh-Dole's implementation.

We stopped a State Department agreement with Japan giving visiting scientists rights to inventions made in US universities and federal labs. When State protested, the issue was taken to the President's Economic Policy Council, where we prevailed. The agreement was renegotiated bringing it into line with Bayh-Dole. We developed a standard intellectual property rights clause for agreements with other countries. We also protected Bayh-Dole in free trade agreements. We worked closely with Congress protecting the law and extending its provisions. The Federal Technology Transfer Act allowing federal laboratories to develop "cooperative R&D agreements" (aka CRADAS) was one result.

Steve Merrill, formerly of Senator Stevenson's staff, is now with the National Academy of Sciences. Their new report **Managing University Intellectual Property in the Public Interest** addresses the Bayh-Dole Act. While supportive of the law and its benefits, the report concludes that Bayh-Dole failed to establish an effective oversight function. This is not accurate.

As shown above, when the oversight function was staffed by those knowledgeable and supportive of the law, it was highly effective. Deborah Wince-Smith, who succeeded Bruce Merrifield as Assistant Secretary of Commerce, was an untiring defender of Bayh-Dole.

Unfortunately, support for overseeing Bayh-Dole waned in the Clinton Administration. The Department's Advanced Technology Program was exempted from Bayh-Dole. The oversight function was downgraded until it landed at the National Institute of Standards and Technology. As a laboratory, NIST cannot insure interagency compliance with Bayh-Dole, or halt international agreements.

Bayh-Dole was enacted and thrived because a small band recognized its potential benefits for the United States. Its future depends on having new hands willing to pick up that banner.

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Perspective

Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience

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Recently, countries from China and Brazil to Malaysia and South Africa have passed laws promoting the patenting of publicly funded research [1,2], and a similar proposal is under legislative consideration in India [3]. These initiatives are modeled in part on the United States Bayh-Dole Act of 1980 [4]. Bayh-Dole (BD) encouraged American universities to acquire patents on inventions resulting from government-funded research and to issue exclusive licenses to private firms [5,6], on the assumption that exclusive licensing creates incentives to commercialize these inventions. A broader hope of BD, and the initiatives emulating it, was that patenting and licensing of public sector research would spur science-based economic growth as well as national competitiveness [6,7]. And while it was not an explicit goal of BD, some of the emulation initiatives also aim to generate revenues for public sector research institutions [8].

We believe government-supported research should be managed in the public interest. We also believe that some of the claims favoring BD-type initiatives overstate the Act's contributions to growth in US innovation. Important concerns and safeguards—learned from nearly 30 years of experience in the US—have been largely overlooked. Furthermore, both patent law and science have changed considerably since BD was adopted in 1980 [9,10]. Other countries seeking to emulate that legislation need to consider this new context.

Overstating Claims

On a positive note, the BD Act required different agencies that funded US research and development to adopt more consistent policies about ownership of patents arising from federal funding [5]. One of BD's intended virtues involved transferring default patent ownership from government to parties with stronger incentives to license inventions. BD assigned ownership to institutions, such as universities, nonprofits, and small businesses, although it could just as easily have opted for individual grant and contract recipients.

Nevertheless, many advocates of adopting similar initiatives in other countries overstate the impact of BD in the US. Proponents note *The Economist's* 2002 claim that the Act was "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century" [11]. They also cite data (originally used by US proponents of the Act) on the low licensing rates for the 28,000 patents owned by the US government before BD to imply that the pre-BD legal regime was not conducive to commercialization [12]. But as Eisenberg [5] has argued, that figure is misleading because the sample largely comprised patents (funded by the Department of Defense) to which firms had already declined the option of acquiring exclusive title. Moreover, these figures are of questionable relevance to debates about public sector research institutions, because most of the patents in question were based on government-funded research conducted by firms, not universities or government labs [13]. Finally, and most importantly, the narrow focus on licensing of patented inventions ignores the fact that most of the economic contributions of public sector research institutions have historically occurred without patents—through dissemination of knowledge, discoveries, and technologies by means of journal publications, presentations at conferences, and training of students [6,14,15].

Throughout the 20th century, American universities were the nation's most powerful vehicles for the diffusion of basic and applied research results [16], which were generally made available in the public domain, where industry and other public sector researchers could use them. These activities were central to the rise of American technological success broadly and to the growth of knowledge-based industries, such as biotechnology and information technology, in particular.

Public sector research institutions also relied on generous public funding for academic research—from a highly diverse group of federal funding agencies—which grew dramatically after the Second World War, and on the availability of venture capital to

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Abbreviations: BD, Bayh-Dole; NIH, National Institutes of Health; R&D, research and development

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foster the development of early-stage ideas [6]. These and other unique features of the US research and development system explain much more about innovation in the US after BD than the rules about patenting that BD addressed.

In the pre-BD era, discoveries emanating from public research were often commercialized without patents, although academic institutions occasionally patented and licensed some of their publicly funded inventions well before BD, and these practices became increasingly common in the 1970s [17]. Since the passage of the Act in 1980, US academic patenting, licensing, and associated revenues have steadily increased. BD accelerated this growth by clarifying ownership rules, by making these activities bureaucratically easier to administer, and by changing norms toward patenting and licensing at universities [6]. As a result, researchers vested with key patents sometimes took advantage of exclusive licenses to start spin-off biotechnology companies. These trends, together with anecdotal accounts of "successful" commercialization, constitute the primary evidence used to support emulating BD in other countries. However, it is a mistake to interpret evidence that patents and licenses have increased as evidence that technology transfer or commercialization of university technology has increased because of BD.

Although universities can and do patent much more in the post-BD era than they did previously, neither overall trends in post-BD patenting and licensing nor individual case studies of commercialized technologies show that BD facilitated technology transfer and commercialization. Empirical research suggests that among the few academic patents and licenses that resulted in commercial products, a significant share (including some of the most prominent revenue generators) could have been effectively transferred by being placed in the public domain or licensed nonexclusively [6,18].

Another motivation for BD-type legislation is to generate licensing revenues for public sector research institutions. In the US, patents are indeed a source of revenues for some universities, but aggregate revenues are small. In 2006, US universities, hospitals, and research institutions derived US$1.85 billion from technology licensing compared to US$43.58 billion from federal, state, and industry funders that same year [19], which accounts for less than 5% of total academic research dollars. Moreover, revenues were highly concentrated at a few successful universities that patented "blockbuster" inventions [20].

A recent econometric analysis using data on academic licensing revenues from 1998 to 2002 suggests that, after subtracting the costs of patent management, net revenues earned by US universities from patent licensing were "on average, quite modest" nearly three decades after BD took effect. This study concludes that "universities should form a more realistic perspective of the possible economic returns from patenting and licensing activities" [21]. Similarly, the head of the technology licensing office at MIT (and former President of the Association of University Technology Managers) notes that "the direct economic impact of technology licensing on the universities themselves has been relatively small (a surprise to many who believed that royalties could compensate for declining federal support of research)... [M]ost university licensing offices barely break even" [22].

It is thus misleading to use data about the growth of academic patents, licenses, and licensing revenues as evidence that BD facilitated commercialization in the US. And it is little more than a leap of faith to conclude that similar legislation would automatically promote commercialization and technology transfer in other, very different, socioeconomic contexts.

Sources of Concern

What have we learned from the US experience with BD? Because the Act gives recipients of government research funds almost complete discretion to choose what research to patent, universities can patent not only those inventions that firms would fail to commercialize or use without exclusive rights, but also upstream research tools and platforms that do not need patent protection and exclusive licensing to be adopted by industry [6,9,10].

For example, while the patented technologies underlying recombinant DNA were fundamentally important for biotechnology and generated ample revenues for Stanford, the University of California, Columbia University, and City of Hope Medical Center [6], the patenting and licensing of these research platforms and technologies were not necessary for commercialization. Both the Cohen-Boyer patents for recombinant DNA and the Axel patents on cotransformation were rapidly adopted by industry even though neither invention came with the BD "carrot" of an exclusive right. The Cohen-Boyer patents reportedly contributed to 2,442 new products and US$35 billion in sales. Its licensing revenues to Stanford University and the University of California San Francisco were US$255 million [23]. With 34 firms licensing the technology, the Axel patents earned US$790 million in royalties for Columbia University over the patent period (Colaianni and Cook-Deegan, unpublished data). While the patenting and licensing of these inventions clearly enriched the universities involved, there is no reason to believe that nonexclusive licensing (as opposed to simple dedication to the public domain) deterred commercialization of the invention(s). In fact, Columbia University justified efforts to extend the life of its Axel patents not because such extension would improve commercialization, but rather because it protected royalty income that would be channeled back into its educational and research mission.

While BD gave those conducting publicly funded research the discretion to patent fundamental technologies, changes in US patent law since 1980 provided the means, by expanding eligibility standards to include basic research and research tools. These trends have been notable in the biotechnology and information technology sectors [24,25]. A widely watched, recent consequence of this shift involves the suite of University of Wisconsin patents on embryonic stem cell lines [26–28]. Biotechnology firms eager to do research on stem cells have complained about the excessive licensing fees that Wisconsin charges (as well as about "reach through" provisions that call for royalties on any product developed from research on embryonic stem cells, and impose restrictions on use) [29]. Rather than promote

commercialization, these patents on basic research platforms constitute a veritable tax on commercialization [30]. Nor were these efforts to tax future innovation unprecedented, as the example of recombinant DNA shows. The Wisconsin Alumni Research Foundation's extension of licensing terms to academic research institutions [31] and its imposition of restrictions on use became especially controversial because these measures went beyond the Cohen-Boyer precedent. The manager of recombinant DNA licensing at Stanford quipped, "[W]hether we licensed it or not, commercialization of recombinant DNA was going forward...a nonexclusive licensing program, at its heart, is really a tax...But it's always nice to say 'technology transfer'" [32].

The broad discretion given to publicly funded research institutions to patent upstream research raises concern about patent thickets, where numerous patents on a product lead to bargaining breakdowns and can blunt incentives for downstream research and development (R&D) [33,34]. Barriers to bundling intellectual property necessary for R&D become higher in frontier interdisciplinary research areas, such as synthetic biology, microarrays, and nanobiotechnology, because they draw upon multiple fields, some of which may be likelier than others to form thickets over time [9,10,32,35]. Although there is some evidence that biotechnology and pharmaceutical firms may be able to avoid thickets through secret infringement or by "off-shoring" research to countries with fewer patent restrictions [36], secret infringement and the transfer of R&D to other countries are hardly tactics that government policy should encourage.

The problems that BD has raised for the biopharmaceutical industry are dwarfed by the problems it has raised for information technology. Universities may too often take a "one size fits all" approach to patenting research results, notwithstanding the evidence that patents and exclusive licensing play a much more limited role in the development of information technology than they do in the pharmaceutical sector [37]. In testimony to the US Congress, a prominent information technology firm complained that aggressive university patenting impeded both product development and university–industry collaboration, which encouraged companies to find other university partners, often outside the US [38]. Expressing similar concerns in a proposal to explore alternatives to the BD model, officials from the Ewing Marion Kauffman Foundation (the leading US foundation supporting entrepreneurship research) recently argued that "Technology Transfer Offices (TTOs) were envisioned as gateways to facilitate the flow of innovation but have instead become gatekeepers that in many cases constrain the flow of inventions and frustrate faculty, entrepreneurs, and industry" [39].

These problems have not escaped the attention of funding agencies, most notably the US National Institutes of Health (NIH), which has issued guidelines stating that patents should be sought, and exclusive licenses should be restricted, only when they are necessary for purposes of commercialization [40,41]. Beyond such hortatory guidelines, however, US funding agencies retain very limited authority to guide the patenting and licensing practices of publicly funded research institutions. Under BD, agencies can declare particular areas off-limits to patenting only when they find "exceptional circumstances." Moreover, they must present this decision to the Department of Commerce, the primary administrator of BD. The "exceptional circumstances" authority has only rarely been used [30]. However, when exclusive licensing demonstrably impeded commercialization, the funding agencies did not intervene by exercising their authority to mandate additional licensing. Their reluctance to take such action stems in part from the realization that, under the BD regime as enacted, any mandate could immediately be challenged (and its effect stayed) pending the outcome of protracted litigation [30].

Some of the top US universities have themselves begun to recognize the difficulties that overly aggressive proprietary behavior can engender, as demonstrated by their March 2007 declaration highlighting "Nine Points to Consider in Licensing University Technology" [42]. How this declaration will affect university behavior is difficult to predict. Moreover, the "Nine Points" declaration focuses almost entirely on licensing and fails to address how universities should determine whether patents are necessary for commercialization in the first instance.

BD has also led to downstream concerns. The BD framework makes minimal reciprocal demands from licensees of government-funded technologies, and neither universities nor government agencies have sought to include requirements that products derived from these inventions be sold to consumers on reasonable terms [43]. Nor do funders require either disclosure of follow-on investments, so that prices might reflect the private contribution to development or the avoidance of abusive or anticompetitive marketing practices [43–47].

Some have raised concerns that the Act contributed to a change in academic norms regarding open, swift, and disinterested scientific exchange [48,49]. For example, in a survey to which 210 life science companies responded, a third of the companies reported disputes with their academic collaborators over intellectual property, and 30% noted that conflicts of interest had emerged when university researchers became involved with another company [50]. Nearly 60% of agreements between academic institutions and life science companies required that university investigators keep information confidential for more than six months—considerably longer than the 30 to 60 days that NIH considered reasonable—for the purpose of filing a patent [50]. Similarly, in a survey of life science faculties at universities receiving the most NIH funding, nearly a third of the respondents receiving a research-related gift (e.g., biomaterials, discretionary funds, research equipment, trips to meetings, or support for students) reported that the corporate donor wanted pre-publication review of any research articles generated from the gift; and 19% reported that the companies expected ownership of all patentable results from the funded research [51].

Although the surveys discussed above were conducted in the mid to early 1990s, their findings appear robust over time. In a more recent

Box 1: Safeguards Serving the Public Interest

Governments adopting laws styled after the US BD Act should be vigilant to ensure that the public's interests are served. In commercializing publicly funded research, a number of safeguards on patenting and licensing practices should be built into any law or its regulatory implementation.

No Exclusive Licensing Unless Necessary for Commercialization

Any BD-style legislation should be founded on the principle that publicly funded research should not be exclusively licensed unless it is clear that doing so is necessary to promote the commercialization of that research. Public sector institutions should not, for example, exclusively license research tools that were developed with public funding if those tools can instead be used off the shelf by others. Where exclusive licenses are not required for commercialization, one may ask whether universities and public sector labs should be patenting research at all. Will encouragement of patenting and nonexclusive licensing, as in the Cohen-Boyer model discussed above, help or hurt researchers, firms, and the public in developing countries? Even nonexclusive licenses will tax downstream users, although presumably with lower rents and transaction costs and more procompetitive effects. As suggested above, revenues from licensing academic inventions are likely to be minuscule for most institutions, and aggressive university patenting can have other deleterious effects. A robust research exemption can ward off some of the problems potentially associated with restrictive licensing of upstream inventions [62].

Transparency

The legislation should ensure transparency in the patenting and licensing of publicly funded research. Public accountability should follow public funding. Institutions that engage in patenting and licensing should be required to report or make public all information that is necessary to determine whether they are reasonably serving the public interest. Such information may include the number of patents and licenses obtained, the funds expended on patenting and licensing activities, licensing revenues, and the key terms (e.g., exclusive or nonexclusive, humanitarian access, research exemption, definition of market segmentation or field of use, performance milestones, and march-in rights) of licenses. The lack of a transparency mandate is a key flaw of the BD Act that should not be replicated.

Government Authority To Issue Additional Licenses

Where licensing arrangements for publicly funded research do not achieve public interest objectives, governmental authorities must have power to override such licenses and to grant licenses to additional or alternative parties [9,10,43]. In the US, this authority is formally embodied in the government's "march-in" rights under BD, but this power has never been exercised. Petitions to invoke it have been made a few times [46,47,63,64], but they have never been granted, and because of the administrative disincentives built into BD, this power is unlikely ever to be used [30]. To avoid this result, legislatures must develop standards to ensure that march-in rights or comparable authority will be exercised when public interest objectives are not otherwise attained.

In evaluating licensing options, those receiving government research funding could also be required to consider the option of licensing patented inventions to a "technology trust," that is, a commons that would ensure designated inventions remained available to all interested parties on predetermined terms. Such a commons could enable the pooling of socially useful bundles of technology, particularly research tools and health technologies for neglected or rare diseases. Governments might also consider reducing or waiving patent application and maintenance fees for such inventions when they are made broadly available for research and humanitarian application, without royalty, for a specific geographical area or field of use.

Government Use Rights

The government should retain an automatic right to use any invention arising from its funding. Under BD, the US government has an automatic "nonexclusive, nontransferable, irrevocable, paid-up license" [65] to use any invention developed with government funds. Typically, however, it does not invoke such a license and often pays monopoly prices for products that it funded. The US experience shows the importance both of establishing that the government should be provided with an automatic license in products resulting from its funding and of elaborating standards to ensure such licenses are actually exercised in appropriate circumstances.

From a broader perspective, governments retain the right to use any invention, whether or not it arises from public funding, under international law [66]. Governments may choose to use patented inventions to promote public health [67], national security [66], or comparable objectives, while public-interest compulsory licenses may sometimes be granted to avoid abusive licensing practices or to ensure access to patented research products on reasonable terms and conditions [43,66]. Where publicly funded grantees fail to commercialize a technology appropriately or to foster its availability, the trigger for government use—under any enabling provision adopted in domestic law—must work better than the march-in right has under BD.

Access to End Products

Besides promoting commercialization, the government must ensure consumer access to end products. The public is entitled to expect that the inventions it paid for will be priced fairly. The US experience shows that a BD system that lacks mandatory rules concerning the affordability of end products will not deliver on this reasonable expectation [43–47]. As a condition of receiving a license to a government-funded invention, parties should be required to ensure that end products are made available to the public on reasonable terms and conditions. What constitutes "reasonable" will vary by national context, but it is important to ensure that the term is defined with enough precision to be enforceable.

Licenses to government-funded inventions should presumptively include access-oriented licensing provisions that address humanitarian needs in other countries [68]. One such provision is an open license for production and sale of end products in (or to) developing countries in exchange for a fair royalty [69]. At the very least, when inventions have foreseeable applications in resource-poor regions, a plan for access in those regions should be explicitly incorporated into technology licensing.

survey of university geneticists and life scientists, one in four reported the need to honor the requirements of an industrial sponsor as one of the reasons for denying requests for post-publication information, data, or materials [52]. This finding is also corroborated by a survey of US medical school faculty. In these settings, researchers most likely to report being denied research results or biomaterials by others were "those who have withheld research results from others" or who had patented or licensed their own inventions [53]. So the practices of patenting and licensing clearly encumber the openness of scientific exchange in universities.

Instituting Safeguards

Countries seeking to enhance the contributions of universities and public sector laboratories to social and economic development have numerous policy options. Many of these policies do not involve intellectual property rights at all, but rather look to provide funds for basic and applied research, subsidize scientific and engineering education, strengthen firms' ability to assimilate university research, and invest in extension, experimentation, and diffusion activities [39,54,55]. But even policies focused on intellectual property management need not presume that patenting and exclusive licensing are the best options. For example, they may instead focus on placing by default or by strategy government-funded inventions into the public domain, creating a scientific commons, enabling collective management of intellectual property, or fostering open-source innovation [56–60]. Where greater commercial incentives seem necessary, the benefits of nonexclusive licensing should always be weighed against the social cost of exclusive licenses.

The appropriate array of policies will vary from country to country: there is no "one size fits all" solution. Based on our review above, we believe it is doubtful that the benefits of legislation closely modeled on BD would outweigh their costs in developing counties. For those countries that nonetheless decide to implement similar laws, the US experience suggests the crucial importance, at a minimum, of considering a variety of safeguards (see Box 1).

Conclusion

While policies supporting technological innovation and diffusion contribute to economic growth and development, the appropriate sets of policies to harness public sector R&D are highly context-specific. Much depends on factors such as the level of publicly funded research, the focus of such research on basic versus applied science, the capabilities of industry partners, and the nature of university–industry linkages [54,55].

Recognizing these difficulties, reasonable minds may disagree about the likely impact of BD-type legislation elsewhere. Nevertheless, the present impetus for BD-type legislation in developing countries is fueled by overstated and misleading claims about the economic impact of the Act in the US, which may lead developing countries to expect far more than they are likely to receive. Moreover, political capital expended on rules of patent ownership may detract from more important policies to support science and technology, especially the need for public funding of research. Given the low level of public funding for research in many developing countries, for example, the focus on royalty returns at the expense of public goods may be misplaced [61]. Furthermore, it is unclear whether any of the positive impacts of BD in the US would arise in developing countries following similar legislation, absent the multiagency federal pluralism, the practically oriented universities, and other features of the US research system discussed above.

In any event, both the patent laws and patterns of scientific collaboration have changed substantially since BD was passed in 1980. To the extent that legislation governing the patenting and licensing of public sector research is needed in developing countries at all, it should reflect this new context rather than blindly importing a US model that is 30 years old. ■

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ADS is a Member of the Advisory Board for Universities Allied for Essential Medicines and has conducted commissioned research for the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health (2005).

BNS is a Member of the Advisory Board for the Initiative for Medicines, Access & Knowledge and has testified before the Secretary's Advisory Committee on Genetics, Health, and Society, Task Force on Impact of Patents and Licensing Practices on Clinical Access to Genetic Testing (July 10, 2007).

AKR is a Member of the Scientific Advisory Board for Science Commons and the Advisory Board for the Peer-to-Patent Project. She has testified before the Senate Committee on the Judiciary hearing on "The Role of Federally-Funded University Research in the Patent System" (October 24, 2007) and has conducted commissioned research for the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health (2005).

RC-D is a Member of the National Research Council Committee on Management of University Intellectual Property and the Task Force on Patent Reform of the Association of American Universities, Council on Government Relations, Council on Education, National Association of State Universities and Land Grant Colleges, and Association of American Medical Colleges (joint committee). He has also conducted commissioned research for the Secretary's Advisory Committee on Genetics, Health, and Society, Task Force on Impact of Patents and Licensing Practices on Clinical Access to Genetic Testing (ongoing) and for the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health (2005).

JHR is a Member of the Editorial Board for the *Journal of International Economic Law*. He has testified before the NIH Public Hearing on March-In Rights under the Bayh-Dole Act, National Institutes of Health (May 25, 2004).

RW is the Director of Essential Action. He is also Counsel to, and Member of the Board of Directors of, Essential Inventions, which has petitioned for the issuance of march-in licenses for two government-funded pharmaceutical products, ritonavir and latanoprost. He is also a Member of the Board of Directors for Health GAP (Global Access Project) and the Board of Directors for Union for the Public Domain. He has testified before the Senate Committee on the Judiciary hearing on "The Role of Federally-Funded University Research in the Patent System" (October 24, 2007).

AK is a Member of the Board of Directors for Universities Allied for Essential Medicines.

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POINT & COUNTERPOINT

THE TOP SHOTS AT BAYH-DOLE (AND WHY THEY MISS THE TARGET)

1. ***Bayh-Dole means that the public is paying twice for new discoveries, once for the research and again to buy the product. Royalties are a tax on the public.***

Counterpoint:

- The charge is based on a misunderstanding of federally funded research. The government is funding **research** on campus, not the development of commercial products.
- University research is normally early stage basic science to increase knowledge about some new or unresolved phenomenon, far removed from being a usable product.
- Commercialization under Bayh-Dole is funded by the **private sector, not the government.**
- Most university technologies with commercial potential are a minimum of 5-7 years away from becoming a marketable product.
- Companies working with universities assume enormous costs and risks to the results of university research into products. The failure rates of such efforts are extremely high. When companies do succeed in developing early stage research into useful products, they pay taxes, some of which then fund more research in a continuous cycle.
- Government does not reimburse companies for their developmental expenses. These normally greatly exceed the costs of the research (10 times or more is not unusual).
- The "trade off" for the ability to license a university invention is the payment of royalties back to the inventing organization. Such income allows the university to operate a technology transfer office, fund more research, pay patenting and other costs and reward university researchers for participating in the technology transfer process.
- Unless the private sector turns university research into a product, the public does not benefit as much as it should for participating in the technology transfer process.

Conclusion:

Tax payers are funding research, not product development, on campus. Successful technology transfer means that the public is receiving a significant additional good —access to important new products— benefiting public health, welfare and economic security.

Charging royalties for the ability to commercialize university inventions is no more a burden on taxpayers than charging fees for harvesting public forests or mining on public lands. Giving such public resources away for free to industrial developers is clearly not a good policy. Funds derived from university royalties benefit the public as the Bayh-Dole Act mandates they must be used to fund additional research, support education and reward inventors, all leading to an improvement of the human condition.

2. Technology transfer negatively affects university research priorities shifting them away from basic toward applied research to secure industry funds.

Counterpoint:

- Not so, said the National Science Foundation in its 2004 ***Science and Engineering Indicators*** report. Here's what NSF reported:

  Emphasis on exploiting the intellectual property that results from the conduct of academic research is growing... Among the criticisms raised about this development is that it can distort the nature of academic research by focusing it away from basic research and toward the pursuit of more utilitarian, problem-oriented questions.

  Did such a shift toward applied research, design and development occur during the 1990's, a period when academic patenting and licensing activities grew considerably?...

  Two indicators can be examined to determine whether any large-scale changes occurred. One indicator is the share of all academic R&D expenditures directed to basic research. ***Appendix table 5-1 shows that basic research share increased slightly between 1990 and 1996 and that there was hardly any change in this measure between 1998 and 2002.*** *The second indicator is the response to a question S&E doctorate holders in academia were asked about their primary or secondary work activities, including four R&D functions: basic research, applied research, design and development.*

  The available data, although limited, provide little evidence to date that pressures on academic institutions and faculty to change research agendas led to a shift toward more applied work. (emphasis added)

- The 2006 ***Science and Engineering Indicators*** in a section entitled **Has Academic R&D Shifted Toward Applied Work?,** said again evidence "*does not show any decline in the basic research share since the last 1980's*" , and concludes: *The available data, although limited, provide little evidence to date of a shift toward more applied work.*

- This finding was recently confirmed regarding life sciences in the new study by Barham and Foltz **Patenting, commercialization and US academic research in the 21st century: The resilience of basic, federally-funded open science.** It concludes:

> *At the most basic level, funding for life science research remains almost entirely in the public or non-market domain. Including foundation funding, more than 90% of the research funding for university life science researchers in 2005 came from non-market sources. Only 5% came from industry sources and an additional 1% from licensing revenues associated with patents. For the 8% of university life scientists with licensing revenues from patents, the median payment in support of their research labs was 2% of their 2005 budget. In contrast, on average, federal funding supported 2/3 of the research budgets of life science researchers.* ***The bottom line is that the federal government remains the primary source of research funding, and there is good reason for this. Most of the research that university life scientists pursue is basic in its orientation and made available in the public domain.*** (emphasis added)

- In fact, Internal Revenue service rules (rev. Proc. 2007-47) place strict limits on the amount of research that can be conducted by universities for private businesses in buildings financed with tax exempt bond funds.
- Technology transfer offices are not involved in setting research priorities on campus.
- Companies find universities attractive research partners largely because they are focused on fundamental research where private industry is weak. NSF reported in the 2004 ***Science and Engineering Indicators*** report:

> *Technology sources outside a company or industry, including university research, have played a key role in innovation and competitiveness from the beginnings of corporate R&D in the U.S.* ***In recent decades, however, the increased relevance of scientific research to industrial technology, coupled with the demands from a global competitive environment, has increased the importance of collaborative activities from innovation and long-term competitiveness.*** (emphasis added)

Conclusion:

The Bayh-Dole Act leverages the traditional strength of academic basic research allowing it to benefit both science and the economy with significant benefits to both.

3. University technology transfer offices are barriers to commercialization. It would work better if the researchers represented themselves in dealing with industry.

Counterpoint:

- A 2001 Swedish study (Goldfarb/Henrekson) comparing that country's longstanding university inventor ownership system to the US technology transfer office model found the opposite:

  > ***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 activities. 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 willing to engage in such activities.*** (emphasis added)
  >
  > Without the support of a technology transfer office, "***This leaves Swedish academic-entrepreneurs with the costly option of going it alone.***" (emphasis added)
  >
  > The study concludes by recommending that Sweden investigate new policies to increase their lackluster commercialization rate of university technologies and "***determine if, after adopting this policy, university bureaucrats would face strong enough pressure to develop offices similar to US TLO's.***"

- The Bayh-Dole Act places legal requirements in granting licenses such as preferences to small companies along with domestic manufacturing and reporting to federal agencies that would be very difficult for individual scientists to meet.
- The steadily increasing numbers of licenses, products and revenues being generated by technology transfer offices operating within the strictures of Bayh-Dole indicates that the system is working quite well—indeed it is the model many other countries are seeking to copy.

- Research is a highly collaborative enterprise often times involving multiple investigators at more than one institution. Obtaining the separate approval of each inventor would be an expensive and time consuming challenge that would discourage most investors from entering into contracts. This is even more problematic if several technologies are bundled together to form an even more attractive package for industry partners.

Conclusion:

This argument is based on anecdotes and unproven theories. Practical experience, like that documented in Sweden, indicates that having individual scientists face the burden of commercializing their discoveries in addition to conducting their research is a recipe for failure. Entrepreneurial faculty members who want to be actively involved in the commercialization of their discoveries are highly appreciated by technology transfer offices. Such researchers are great resources for identifying potential industrial partners who greatly value the worth of the original research team in subsequent product development.

Industry and investment interests require stability and predictability to justify their commitment of time and money in a research partnership. Requiring private parties to wander large public research systems looking for individual inventors would drive companies and venture capital away from collaborative arrangements with academe. Additionally, since many times there are multiple inventors of a given technology, such a system would be highly chaotic in the real world.

4. Bayh-Dole makes it harder for companies to fund sponsored research on campus by imposing unnecessary limitations on resulting rights to intellectual property by industry sponsors.

Counterpoint:

- The limitations are not a product of Bayh-Dole, but, rather arise from compliance with IRS Rev Proc 2007-47, state laws and fundamental principles of the academic environment.
- The Bayh-Dole Act only affects research sponsored or partially sponsored by the federal government. In such cases, the law requires universities to meet certain obligations (reporting of inventions to funding agencies, preferential licensing to small companies and to those who will manufacture substantially in the U.S, etc) as part of their acceptance of government funding.

- If federal funding is not present, Bayh-Dole is not a factor in industry-academic negotiations. However, there may be state laws or other restrictions that impact assignment of resulting invention rights.

- Most industry sponsored research does not lead to the creation of new intellectual property. Companies rarely sponsor research for the explicit purpose of creating new inventions. When new intellectual property is created, it more often than not arises from a faculty member whose intellectual contribution arises largely from years of (typically federally funded) research. It would be a gross neglect of that taxpayer investment to grant outright ownership of such intellectual capital to companies that pay only for the time and materials associated with conducting a specific project.

Conclusion:

The Bayh-Dole Act allows the university the flexibility to provide a preferential opportunity for a company sponsor to obtain an exclusive license when federal funds are also present. If this is not the case, Bayh-Dole is not a factor in negotiations in purely industrially sponsored university research.

5. Agencies are neglecting their responsibilities to enforce march in rights under Bayh-Dole since they are rarely, if ever, used.

Counterpoint:

- In passing the law, Congress was concerned that dominant companies in a market would license university technologies to prevent the development of technologies that compete with their own internally developed technologies.
- Because universities and non-profits operating under Bayh-Dole include requirements for actual development of the licensed technology and other incentives under their licenses, there is no evidence that companies are not making good faith efforts to develop licensed technologies.
- Most often, failure results from the steep odds against any one invention becoming a successful commercial product rather than lack of effort.
- With their ownership of inventions under the Bayh-Dole Act, universities carefully monitor the status of their licenses. In cases where development is not proceeding as planned, development criteria and goals are revised as necessary. In rare situations where good faith efforts are not being made to commercialize a technology, universities reserve the right to revoke the license so that other commercialization partners can be sought.
- Under the Bayh-Dole legislation and its regulations the ability of the government to exercise march-in rights purposefully requires adherence to strict guidelines to insure against arbitrary or politically motivated actions. The diluting of such guidelines and requirements would create great uncertainties for prospective

licensees and investors, undermining the foundation of a mutually beneficial partnership between academic institutions and the private sector.

Conclusion:

In more than 25 years of operation, no case has arisen where a federal agency made a decision to march-in under the Bayh-Dole Act because of lack of effort in commercial development. Because non-profit organizations take their stewardship of publicly funded R&D so seriously, they are effectively enforcing their own licensing agreements.

6. Patenting reduces open communication between university researchers and harms publication of important scientific papers.

Counterpoint:

- The National Science Foundation specifically looked at this charge in the July, 2007 publication **The Changing Research and Publication Environment in American Research Universities.** It said:

> *The study's findings provide little support for the idea that competing institutional demands are diverting faculty from research and publication.* ***For the most part, informants said that neither teaching nor commercial activities were absorbing time that in the past would have been devoted to research and writing.*** *Although some saw increased university concern about good teaching, and all agreed that institutional support for commercial activity was growing, faculty continue to believe that research is clearly the institutional concern that mattered most in shaping their behavior. It is possible, of course, that activities that compete with research for faculty time and attention, especially commercialization-related activities, have adverse effects on publication outputs that researchers themselves do not fully appreciate.* (Note: this last point appears to be based on latter comments about the "hidden costs" of commercial activities such as administrative infrastructure, legal arrangements, and time spent arranging material transfer agreements.)

The study later reported:

> *Very few informants, however, thought that commercially oriented activity had significantly reduced the amount of publication-oriented research.* ***Most reported that faculty colleagues who had gotten involved with***

start-up companies had continued to publish. They noted that these researchers tended to be very active and innovative, so that their commercial activity was more an addition to their academic research than a replacement for it. In addition, commercial involvements

sometimes enriched the published work of faculty researchers, involving them in new areas of research. Many people observed that awareness of the commercial potential of research sometimes prompted brief delays in publication, but they generally doubted that these delays caused an overall reduction in publication. (emphasis added)

One potential cause for the slower growth of scientific publications was cited:

It is possible that the growth in publication output has slowed as a result of a movement toward integrative collaborations. Some informants suggested that successful integrative collaborations have had disproportionate impact on their fields and that the United States has been in the forefront of movement toward this type of collaboration. ***If U.S. researchers, compared to researchers in other countries, had been more rapidly increasing their investment of time and resources in this type of collaboration, this might help explain the change in article counts.*** (emphasis added)

- The 2006 National Academy of Science report, **Rising Above the Gathering Storm** found:

  Researchers in the United States lead the world in the volume of articles published and in the frequency with which those papers are cited by others. US-based authors were listed on one-third of all scientific articles worldwide in 2001. Those publication data are significant because they reflect original scientific research productivity and because the professional reputations, job prospects, and career development of researchers depend on the ability to publish significant findings in open peer-reviewed literature.

- NSF's 2006 **Science and Economic Indicators** report found that mature industrial nations (US, Canada, UK, France, Netherlands, and Sweden) did not recently show the same explosive growths in scientific publications as did Japan, China, Singapore, South Korea and Taiwan). However, regarding U.S. scientific publications, it found:

  The growth in the academic sector, which generates most U.S. publications (74% in 2003), mirrored the overall pattern of U.S. S&E article output... Growth trends did vary, however, among a subset of top 200 academic R&D institutions grouped on the basis of their R&D growth and 1994 Carnegie classification. ***At institutions that registered higher-***

than-average R&D growth between 1988 and 2003, the growth in article output was correspondingly greater than other institutions.

- The 2006 **Science and Economic Indicators** report also found that *"Twenty-eight percent of academic articles in 2003 were coauthored with nonacademic authors, up from 22% in 1988."* NSF also found: "*The volume and share of article production by various U.S. institutional sectors (academic, federal and state government, private for profit, and nonprofit) offer a measure of the relative role of these sectors in the U.S. S&E community. Government policies have reinforced collaboration among U.S. sectors by funding research programs that require or encourage collaborations.*"
- A newly issued study by Professors Barham and Foltz at the University of Wisconsin found no evidence that patenting and commercial partnerships have detrimental impacts on science-- even in the life sciences where critics raise the greatest concerns. The vast majority of university life scientists (80%) have no industry funding of their research and only 23% have filed for a patent in the last 3 years. Interestingly enough, the study did find:

  Life scientists with industry funding also had significantly higher numbers of articles (13.2 v. 9.7), doctorates produced (1.34 v. 0.95) and post-docs supervised (1.51 v. 1.16) over the past three years. Thus, industry funding is correlated with more research production on all fronts rather than merely commercial activities. This finding does not, however, imply a directional causality since it could be that the best researchers attract commercial interest or that the most commercial researchers are able to maintain their pre-existing research productivity differences. ***It does, however, suggest that industry funding does not detract from the production of articles, the training of doctorates, or the supervision of post-doctoral scientists.*** (emphasis added)
- These findings were confirmed in studies by Azoulay, et al (2004) "*...patenting has a positive effect on the rate of publication of journal articles, and a much smaller – though still positive – effect on NIH grant awards*" and Markiewicz and DiMinn (2004) "*...publication production by university researchers does not decrease with patent inventorship, and in fact increases significantly.*"
- U.S. universities and non-profit organizations have maintained their strong record of being world leaders in the publication of scientific papers, issuing more than 700,000 peer-reviewed papers in 2003 alone. The Milken Institute found in **Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization** that the top ten U.S. universities in biotechnology research account for 11.8 percent of world publications and that the U.S. accounts for 46% of worldwide scientific publications (European universities were next at 35%).

- The National Science Foundation cited the increase in university-industry authored papers as a positive trend in U.S. science.
- Most patent applications are themselves published after 18 months and are considered publications helping scientists achieve tenure at their institutions.

Conclusion:

Evidence indicates that technology transfer has not harmed the publication of new science. Scientists that work with companies appear to benefit from the interaction in ways that increase – not decrease -- their publications and grant awards. In fact, the increased willingness of companies to have their best and brightest work with university researchers (which they were reluctant to do before Bayh-Dole when invention rights could be taken away by the Government) makes science even stronger. Finally, patents are themselves public documents designed to further the development of science and technology.

7. Exclusive licensing should be discouraged since it's inherently unfair to exclude companies.

Counterpoint:

- Commercializing university inventions is inherently a high risk endeavor, frequently costing the company developer 10 or even 100 times as much as was invested in the research.
- Many times companies or venture investors can only justify this risk and expense through having an exclusive license.
- The majority of exclusive licenses are made to small companies.
- Prior to the passage of Bayh-Dole when only non-exclusive licenses were available, few federally funded technologies were commercialized.
- The recently issued "**Nine Points To Consider in Licensing University Technology**" provides best practice guidelines in exclusive licensing. These include insuring that the licensee is capable of developing the technology in all covered fields of use, creating well defined and regularly monitored terms including objective, time-limited milestones of performance with the possibility of termination or non-exclusivity in the rare cases they are required.

Conclusion:

The Bayh-Dole Act recognizes that the risk and expense of commercializing a federally funded invention may require exclusivity. The law also requires patent owners to consider if the company partner is a small company and whether or not the development will be conducted in the U.S. Whether or not an invention is licensed exclusively or non-exclusively is determined by which is the better path

toward prompt development. The public benefits when these discoveries are made available as commercial products. Exclusive licensing can be an important tool in turning high risk research into useful products driving our economy while protecting the public health and welfare.

8. Technology transfer offices are bottom line driven, often ignoring the public interest in commercialization of important discoveries.

Counterpoint:

- Technology transfer offices are established as important services for the research community, not as profit centers.
- The most important consideration in commercialization is finding the most likely company to develop an early stage idea into a commercial product, not which company will pay the most.
- Technology transfer offices rarely have the luxury of picking and choosing between multiple prospective licensees for a given invention.
- The vast majority of university technologies are licensed to small companies.
- Very few university technology transfer offices generate profits.
- Royalties and other income realized from technology transfer are invested in new research, educational support, paying patent and other expenses and rewarding campus inventors.

Conclusion:

While assuring that any technology transfer agreement has reasonable terms, the focus is on the likelihood of successful development by the partner company, not how much money they will pay. Because of the high risk nature of university technology commercialization, most deals are not "profitable." Realizing that development is costly and expensive, the focus of university technology transfer offices is on whether or not the potential company partner has the capability and willingness to take the invention to the marketplace, not on how much money they are willing to pay.

9. U.S. universities are so hard to deal with that many companies are now taking their basic research needs to Chinese or Indian universities.

Counterpoint:

- There is no evidence linking company decisions to take R&D off-shore to the technology transfer activities of US research institutions. Ironically, many U.S. universities report strong interest in their technologies from foreign based firms as has been the case for many years.

- Like the larger phenomena of out sourcing business operations overseas, the largest driver in moving R&D overseas is the disparity in labor costs, not technology transfer.

- However, an even larger factor in companies looking to develop new products form university research is the adequacy of intellectual property protection. While improving, both India and China have a long way to go in bringing their intellectual property laws up to international standards. Companies seeking cheaper research abroad may find these "savings" more than counter balanced by the lax enforcement of intellectual property laws in these particular countries.

Conclusion:

Many foreign countries rightly want to bolster their own universities so they become vital parts of the economy as has happened in the U.S. under the Bayh-Dole Act. While we cannot afford to be complacent, more than two decades of experience in fostering university-industry R&D partnerships under the auspices of the Bayh-Dole Act proves that the quality of U.S. university research coupled with the ability to secure necessary intellectual property protection to resulting inventions remains a winning combination.