Responding to the Critics: Why the Revisionist Attacks on the Bayh-Dole Act Are Wrong—and Dangerous to Our Future

Summary

It's no secret that the U.S. economy faces serious challenges. However, the U.S. has tremendous advantages for succeeding in the technology markets creating wealth in the 21st Century, if we chose to deploy them.

And this is a choice. In many respects, it depends on policy makers recognizing the inherent strengths of the U.S. innovation system. This paper focuses on a key component of the system: the combination of our unparalleled research universities and entrepreneurial private sector under the Bayh-Dole Act of 1980. This alliance turns publicly funded science into products, jobs and companies benefiting U.S. taxpayers.

While this linkage is generally believed to have been very successful, a persistent school of critics have charged that this was not the case. These advocates have become more prominent in recent years, urging policy makers to make changes in the Bayh-Dole Act correcting what they view as its shortcomings. And many appear to be accepting their arguments at face value.

Because the recommended changes would have profound impacts on the ability of the U.S. to respond to unprecedented international economic competition in the 21st Century, any potential changes to the Bayh-Dole Act must be carefully considered.

Therefore, it is our purpose to examine the charges against Bayh-Dole against the factual record. And, thus examined, the revisionist arguments against Bayh-Dole are shown to be unfounded, based on anecdotes or incorrect interpretations of data that should have been readily apparent to those skilled in the field.

It is also shown that reams of objective data exists indicating that the Bayh-Dole Act greatly improved the commercialization of federally-funded research, that the system is working very well, and that resulting public sector-private sector partnerships are essential to our well being.

That these conclusions are correct is further demonstrated by our most serious economic rivals who are now adopting their own versions of Bayh-Dole to better compete with us. Such imitation really is the most sincere form of economic flattery. It would be ironic, indeed, if our own policy makers chose this critical moment to weaken our system. We may need it more than ever to maintain a prosperous economy in an increasingly high technology world. The choice is ours to make.

Background

The U.S., Europe and Asia are gearing up for a new round of competition to create wealth from high technology industries driving the international economy. In many ways, this is a replay of the 1970's and 80's when it appeared that Japan and Germany were riding the wave of the future—and many predicted that America's best days were behind it.

At that time, the U.S. had lost its lead in traditional fields like automotives, electronics, steel, etc. Many experts confidently predicted that Japan and Germany would soon eclipse the U.S. in the few remaining markets where we led.

However, these predictions did not come true. Instead, the U.S. enjoyed a tremendous burst of entrepreneurial activity that restored our competitive advantage, laying the groundwork for decades of economic growth. This turnaround came through adopting many new policies that were hotly debated at the time. One was the passage of the Bayh-Dole Act of 1980. Here's how the Economist Technology Quarterly summarized its impact:

Remember the technological malaise that befell America in the late 1970's? Japan was busy snuffing out Pittsburgh's steel mills, driving Detroit off the road, and beginning the assault on Silicon Valley. Only a decade later, things were very different. Japanese industry was in retreat. An exhausted Soviet Empire threw in the towel. Europe sat up and started investing heavily in America. Why the sudden reversal of fortunes? Across America, there had been a flowering of innovation unlike anything seen before.

Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980. Together with amendments in 1984 and augmentations in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money.

More than anything, this single policy helped to reverse America's precipitious slide into industrial irrelavance.

Further on the article summarized the law:

The Bayh Dole Act did two big things at a stroke. It transferred ownership of an invention or discovery from the government agency that had helped to pay for it to the academic institution that had carried out the actual research. And it ensured that the researchers involved got a piece of the action.

Overnight, universities across America became hotbeds of innovation, as entrepreneurial professors took their inventions (and graduate students) off campus to set up companies of their own. Since 1980, American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2,200 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute $40 billion annually to the U.S. economy. America's trading partners have been quick to follow suit. Odd, then, that the Bayh-Dole act (sic) should now be under such attack in America.

The Economist Technology Quarterly, Dec. 14, 2002

Before examining the specific charges used to attack the law, it is helpful to examine why Congress enacted it and what it does.

Prior to 1980, inventions made with federal funding were rarely developed. Because most government funded inventions are very early stage, it requires considerable time and investment by the private sector to turn them into useful products. Federal policies at the time mandated that any invention made with federal funding—whether made by employees, contractors or grantees—would be taken by the government. They were then generally made available to all applicants through non-exclusive licenses. It became clear that such practices rarely turned public research into commercially available goods. Thus, a series of presidential policy memoranda dating back to the Kennedy Administration allowed contractors or grantees to petition funding agencies on a case by case basis asking to retain patent ownership. Such actions could take 18 months or more to decide. The answer was not necessarily positive.

Not surprisingly, such uncertainty discouraged innovative small businesses from accepting federal research contracts as the loss of resulting inventions would undercut their ability to compete in commercial markets. Additionally, federal agencies and their employees could not receive royalties if their discoveries were commercialized.

President Lincoln, himself a patent owner, envisioned the patent system as "adding the fuel of interest to the fires of genius." With regard to federally funded research, it was evident that those fires were extinguished. And this was no small loss as the federal government was funding the majority of basic research – precisely where breakthrough inventions were most likely to occur- and approximately 50% of all the R&D in the country at the time.

That this general policy was not effective in promoting technology transfer was recognized in by the National Institutes of Health. It was apparent that few, if any, NIH funded discoveries were every commercialized. In the 1970's NIH adopted an administrative policy allowing universities with the proven capability to manage their inventions to own resulting discoveries. Termed the Institutional Patent Agreement (IPA), this was the precursor for a revolution in federal patent policies. The program proved so successful that is was later adopted by the National Science Foundation.

However, reversals of the IPA program under the Carter Administration promoted universities to approach Senators Birch Bayh (D-IN) and Robert Dole (R-KS) requesting that the IPA program statutory be made statutory for all agencies, and that it be extended to small business contractors.

After examining the dismal record at commercializing federally funded inventions and the pending loss of competitive markets to Japan and Germany, in 1980 Congress adopted this approach. One important piece of data examined by the Senate Judiciary Committee was that the government was successfully licensing less than 5% of the 28,000 inventions it had amassed. Universities and small companies presented compelling evidence that potentially important discoveries would never be developed as long as inventor ownership was denied. Senators Bayh and Dole stated that such inefficiencies denied U.S. taxpayers the full benefits of their investment in publicly funded research.

Congress agreed and overwhelmingly passed the University and Small Business Patent Procedures Act-- commonly known at the Bayh-Dole Act. The Bayh-Dole Act encourages the development of inventions by non-profit organizations and small companies through the use of Federal funds by:

- Allowing patent ownership by non-profit organizations and small companies;
- Providing universities the discretion to license their discoveries under terms that encourage prompt commercialization and university-industry partnerships;
- Stipulating that a percentage of royalties generated through successful commercialization efforts be shared with inventors. Royalties can also be used to pay for administrative costs associated with technology transfer with the balance remaining designated to fund additional research, or for education;
- Providing that preferences be given to licensing small businesses and a requirement for substantial U.S. manufacturing where an exclusive license is granted for the United States;
- Allowing the government to practice the invention royalty free for governmental and treaty purposes; and
- Allowing the government to "march in" to require additional licensing if legitimate efforts are not being made to develop the invention (an action that has not been necessary in practice).

Congress subsequently created the Court of Appeals for the Federal Circuit, which restored faith in the reliability of U.S. patents and the Small Business Innovation Research Act (SBIR) to bring more cutting edge companies into government research.

Suddenly, several important resources were brought into play that other nations simply could not match:

1. The U.S. government funds far more R&D than our competitors, much in basic research where breakthrough technologies are likely to occur.
2. This research is largely conducted at universities and other non-profit institutions that remain world leaders in their fields

3. The Bayh-Dole Act translated this investment in science into practical applications to meet important health, safety, environmental, food production, and other important needs.
4. Small, high technology companies take the lead in driving new markets. The U.S. is the leader in forming these companies. Many of these companies spin out of universities.
5. A key asset of these small companies in attracting venture funding and remaining competitive against larger competitors is reliance on a few key patents. Thus, the U.S. patent system greatly helped create this revival.

Even though the impact of the Bayh-Dole Act seemed evident as the U.S. enjoyed a reversal of fortune as described earlier in the Economist Technology Quarterly, a small group of academics grounded in the social sciences began questioning it. Their arguments can be summarized as follows:

- Bayh-Dole really wasn't that important. Universities were commercializing inventions anyway;
- Key data Congress used to pass the Bayh-Dole Act-- the small number of 28,000 government owned inventions was misleading;
- Bayh-Dole had an "anti commons" effect, harming the publication and sharing of new academic science

The next section reviews each charge in greater detail.

Charge Number I:

Bayh-Dole really wasn't that important. Universities were commercializing inventions anyway

Howard: here's where we would insert your points. Could you also find an actual quote from Mowry summarizing his charge?

Charge Number II:

The Bayh-Dole Act was passed in the throes of the "competitiveness crisis" of the 1970's and 1980's, ***in response to the belief that IPA's and other arrangements for university patenting of publicly funded research results impeded technology transfer and commercialization of these results, thereby weakening U.S. competitiveness.*** (emphasis added) *In particular, the framers of Bayh-Dole argued that if universities could not be granted clear title to patents and allowed to license them exclusively, firms would lack that incentive to develop and commercialize university inventions.* ***This argument was based on***

the "evidence" that government owned patents had lower utilization rates than those held by contractors, evidence that Eisenberg (1996) has shown to be faulty. (emphasis added)

Numbers, Quality, and Entry: How Has the Bayh-Dole Act Affected U.S. Patenting and Licensing, by David C. Mowry and Arvids A. Ziedonis, P. 3

The second emphasized assertion is based on the article by Rebecca Eisenberg "Public Research and Private Developments: Patents and Technology Transfer in Government-Sponsored Research", Vol. 82:1663 Virginia Law Review.

Ms. Eisenberg maintained that "the primary argument against government ownership was a statistical one", based on the "testimony of numerous witnesses" that "only a small percentage of its estimated 28,000 - 30,000 patents had been successfully licensed and exploited commercially".

The author thereafter submits that "...the statistical evidence presented was inadequate to document this claim" because it "reflected a huge selection bias; as it consisted largely of inventions made by contractors whose research was sponsored by DOD... that could have retained title to the patents if they had wanted to do so."

On the basis of this analysis, Ms. Eisenberg concludes that, "It is hardly surprising that few firms were interested in taking licenses from the Government to patents that had already been rejected by contractors that could have been owned by them outright if they had found them at all commercially interesting."

Ms. Eisenberg alleged that 17,632 of the 28,021 inventions in the government patent portfolio were made by Department of Defense (DOD) contractors, falling into the category described above.

Response:

Contrary to the first emphasized statement, the Bayh-Dole Act built on the Institutional Patent Agreements (IPA's) because it had been so effective. It was felt that an effective patent policy needed to be statutory rather than administrative so it could not be weakened as happened to the IPA during the Carter Administration.

The fact that the authors misunderstand this clear history is quite puzzling.

The second fallacy is that Ms. Eisenberg disproved the contention that the poor licensing rate of the 28,000 government owned inventions before passage of the Bayh-Dole Act was because they represented inventions passed over by contractors, because they had little commercial potential. Ms. Eisenberg's conclusion has been widely quoted.

However, review of the data she cites indicates that, in fact, her conclusion is simply wrong.

The evidence that fewer than 5% of government owned inventions were being successfully licensed came from the 1976 FCST combined report[12] **(NORM: what does FCST stand for? Do you have a footnote for this, don't see it below)**
(here after the "76 report").

Ms. Eisenberg alleges that the 17,632 patents created through Department of Defense funding were "patents that had already been rejected by contractors." This contention is simply not supported by the 1976 report, and is clearly incorrect.

In pursuing her research, Ms. Eisenberg failed to note that the 1976 report clearly establishes that the 17,672 DOD patents includes:

(1) 6,026 U.S. patents granted during the 1970-1976 reporting period to ***DOD employees*** obligated to assign their rights to DOD; and
(2) 2,594 U.S. patents based on reported inventions during the 1970-76 reporting period from contractors.

The second group comes not only from companies contracting with the agency. Because of policies in place, some portion of the 2,594 inventions were taken from ***universities and other non-profits*** who had no choice but to assign their inventions to the government before passage of the Bayh-Dole Act.

It should be noted that the total 8,621 patents accrued to the DOD patent portfolio during the 1970-76 reporting period in the two categories above is less than the 17,632 DOD patents identified in the report.

The remaining 9,022 patents (17,632 - 8,621) are unexpired patents granted and assigned to DOD prior to 1970 that remained open for licensing within the 1970-76 reporting period. Since there is no data in the '76 report indicating the source of the patents granted before 1970, let's assume that the ratio of these patents is approximately equal to that of the 1970-76 reporting period. That is they were 70% government employee generated, and 30% contractor generated (including universities and non-profit organizations).

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[1] See footnote 57 of 1 above.
[2] Norman J. Latker - served as DHEW representative when Patent Counsel, DHEW.

Thus, of the 9,022 patents granted before 1970, 6,315 would be government employee generated patents, and 2,706 would be contractor generated patents. Thus, the total DOD employee generated patents is 12, 331 (6026+6315) and the total DOD contractor generated patents is 5,300 (2594+2706)

Since DOD employee generated patents came from cutting edge federal laboratories like the Naval Medical Center at Bethesda, Maryland, or the Walter Reed Hospitals in Washington D.C. , they most certainly do not fit Ms. Eisenberg's characterization as "rejected" inventions without commercial interest. Nor do they fall within her definition of " contractor" inventions.

Further, the remaining 5,330 patents generated by actual DOD contractors most certainly do not support Ms. Eisenberg's allegation that the patents available for licensing "reflected a huge selection bias; (consisting) largely of inventions made by contractors whose research was sponsored by DOD."

The DOD contractor generated portion of the government patent portfolio amounts to no more than 19% (5330/28021) rather than the 63% (17632/28021) erroneously alleged by Ms. Eisenberg.

It is further believed that there is no documented support that even the 19% of the government patent portfolio identified above are based on inventions "rejected by contractors" as not "at all commercially interesting", as alleged by Ms. Eisenberg.

First it must be noted that an unidentified number of the 5,330 patents were generated by *university and other non-profit contractors* that were simply taken by the funding agency, whether they had commercial potential or not.

It's not even possible to support Ms. Eisenberg's contention that there was little commercial value in the unknown subset of patents from for-profit contractors. Most large company contractors of the time kept their government and commercial research operations segregated because of fears that federal agencies would try to assert ownership of important discoveries. In addition, some percentage of this category of inventions was taken from *small business contractors*, who like universities, had no choice but to give up inventions to DOD. Thus, Ms. Eisenberg's theory is not proven even here.

In summary, the revisionist theory that the supporters of the Bayh-Dole Act misinterpreted the lack of commercialization of 28,000 government owned inventions does not hold water. The data speaks for itself.

Latker, Carole (NIH/NIGMS) [E]

From: Norman Latker [NJLatker@browdyneimark.com]
Sent: Tuesday, February 24, 2009 1:00 PM
To: Latker, Carole (NIH/NIGMS) [E]
Subject: FROM JOE ALLEN - Draft article
Attachments: A Response the the Critics, 2-23-09.doc

Maureen Adams
Legal Assistant
BROWDY AND NEIMARK PLLC
624 Ninth St. N.W.
Suite 300
Washington D.C. 20001
Telephone: (202) 628-5197
Facsimile: (202) 737-3528
E-mail: adamsm@browdyneimark.com

From: Joe Allen [mailto:jallen@allen-assoc.com]
Sent: Tuesday, February 24, 2009 9:42 AM
To: Norman Latker
Subject: Draft article

Haven't heard from you for a while. I just left a message on your home phone. Just in case you're back at work, here's a rough draft of our article with your section. See what you think. I sent it out yesterday to Howard and John for their comments as well.

Also sent a copy to Carole's email.

Hope you're well on the road to recovery by now!

Joseph Allen
President
Allen & Associates, Inc.

740-484-1814
304-280-2259(cell)
60704 Rt. 26 S.
Bethesda, OH 43719
www.allen-assoc.com

Latker, Carole (NIH/NIGMS) [E]

From: Maureen Adams [AdamsM@browdyneimark.com]
Sent: Tuesday, February 24, 2009 1:01 PM
To: Latker, Carole (NIH/NIGMS) [E]
Subject: FROM JOE ALLEN FOR NJL - Possible source for quotes to refute
Attachments: Is Bayh-Dole good for developing countries.pdf; BIO response to McGill U study.doc

Maureen Adams
Legal Assistant
BROWDY AND NEIMARK PLLC
624 Ninth St. N.W.
Suite 300
Washington D.C. 20001
Telephone: (202) 628-5197
Facsimile: (202) 737-3528
E-mail: adamsm@browdyneimark.com
Please consider the environment before printing this email.

From: Joe Allen [mailto:jallen@allen-assoc.com]
Sent: Tuesday, February 24, 2009 11:28 AM
To: preston@mit.edu
Cc: Howard Bremer; Norman Latker
Subject: Possible source for quotes to refute

Here's an article that summarizes pretty well the current arguments against the patent system and B-D. While ostensibly geared to warning developing countries away from the "dangers" of a Bayh-Dole approach, the recommendations for weakening Bayh-Dole are also in play here, particularly at NIH. They are mirrored in the recent McGill University study (refuted by BIO letter attached) and are incorporated in the pending HHS Secretary's Advisory Committee on genomic research.

The nice thing is that this article is co-authored by Arti Rai and Robert Cook-Deegan who are now carrying the anti B-D banner. Thought you might be able to extract a direct quote that you can refute in your part of our draft paper. There are many to choose from. As Norm did to Eisenberg, these are two we need to take head on.

By the way, despite the urgings of Cook-Deegan, South Africa enacted their Bayh-Dole Act, as did Hungary. I thought that with your international experience, this could be a fast ball headed right down the middle of the plate for you to whack!

Joseph Allen
President
Allen & Associates, Inc.

740-484-1814
304-280-2259(cell)
60704 Rt. 26 S.
Bethesda, OH 43719
www.allen-assoc.com

co-authored by Arti

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PLoS BIOLOGY

Perspective

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

Anthony D. So*, Bhaven N. Sampat, Arti K. Rai, Robert Cook-Deegan, Jerome H. Reichman, Robert Weissman, Amy Kapczynski

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

The Perspective section provides experts with a forum to comment on topical or controversial issues of broad interest.

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

Anthony D. So is with the Program on Global Health and Technology Access and the Center for Strategic Philanthropy and Civil Society, Terry Sanford Institute of Public Policy, Duke University and the Duke Global Health Institute, Durham, North Carolina, United States of America. Bhaven N. Sampat is with the Department of Health Policy and Management and the International Center for Health Outcomes and Innovation Research, Mailman School of Public Health, Columbia University, New York, New York, United States of America. Arti K. Rai and Jerome H. Reichman are with the Duke University School of Law, Durham, North Carolina, United States of America. Robert Cook-Deegan is with the Center for Genome Ethics, Law & Policy, Institute for Genome Sciences & Policy, Duke University, Durham, North Carolina, United States of America. Robert Weissman is with Essential Action, Washington, D. C., United States of America. Amy Kapczynski is with the School of Law, University of California, Berkeley, California, United States of America.

* To whom correspondence should be addressed. E-mail: anthony.so@duke.edu

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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BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

BIO RESPONSE TO McGILL/DUKE UNIVERSITIES' STUDY ON ROLE OF PATENTS IN BIOTECH INNOVATION

The proposition advanced by the study recently released by McGill and Duke universities- *Toward a new Era of Intellectual Property: From Confrontation to Negotiation* – that the protection of intellectual property rights serves as an obstacle to innovation in the life sciences and hampers further research and collaborations among scientists – has repeatedly been debunked and has no empirical basis in fact. According to a report prepared for the National Academies of Science[i], intellectual property rights do not impede research: only 1% of the random sample of 398 academic respondents reported suffering a project delay of more than a month due to patents on knowledge inputs necessary for their research, and *none* of them had stopped a research project due to the existence of patents. Further, as BIO and other experts in this area previously have found, there is an utter lack of hard evidence, except for the occasional anecdotal example, supporting the study's exaggerated conclusions[ii iii iv].

To the contrary, a robust system for protecting intellectual property rights is critical to establishing an environment in which biotechnology innovation can flourish. The presence of patents and strong IP rights in no way precludes collaborations and partnerships with companies, governments, non-governmental organizations (NGOs), or others. Rather, it is precisely *because* of patents and strong IP rights that such collaborations and partnerships can, and do, take place at an ever increasing rate.[v]

As an example, a researcher, typically in a university laboratory, discovers a novel DNA sequence that is expressed only by a particular type of cancer cell. Translating this initial discovery into a tangible product can take more than a decade and more than a billion dollars[vi]. The exclusivity and potential return on investment offered by the patenting of this early discovery is what investors rely upon to provide the further funding necessary for applied research and development of actual products. Of course, the road to a final product from this point is long and torturous, has a significant likelihood of failure, and is fraught with other commercial setbacks. However, the faith that the discovery will help improve the lives of people around the world, and the confidence that patent rights will protect products that are ultimately developed, propel the transfer of technology through licensing and collaborations, and the further research and development work that follows. Without patent rights, this efficient process simply would not be possible, and either initial discoveries would sit on laboratory shelves and never be commercialized, or

inventors would keep their discoveries as trade secrets for as long as possible – neither of which would serve the public interest or the goal of spurring innovation.

The above example is not an illustration relevant solely to the health sector. BIO members are involved in the research and development of innovative agricultural, industrial and environmental, and renewable energy biotechnology applications as well. Our members have, over time, developed more than 200 biotech drugs and vaccines, including products to treat cancer, diabetes, and HIV/AIDS, to name just a few, with hundreds of new therapies and cures in the development pipeline. Our members also have produced high-yield and insect-resistant crops to help feed a growing world. Industrial biotech applications, among other things, have led to cleaner processes that produce less waste and use less energy and water, and are at the forefront of the next generation of renewable energy sources.

Market-based incentives for transferring technology have made great progress in spurring such R&D and innovation. For example, the U.S. Bayh-Dole Act permits universities and other research entities to retain patent rights for inventions created by U.S. government-funded research programs. Experiences in the United States under the Bayh-Dole Act show that this type of simple mechanism can result in significant transfers of technology and incentives for the dramatic growth of industries such as the biotechnology sector. BIO believes that such mechanisms promote close interactions between universities and the non-profit research community and the biotechnology industry – particularly small businesses.

Strong IP rights are not the reason that so many developing countries lack access to the products and technologies enjoyed by developed economies, particularly in the public health arena. While many factors play primary roles in this access problem, such as lack of infrastructure and capacity, lack of trained personnel, and trade barriers, patents are rarely an obstacle. According to Amir Attaran, [vii] only 19 of 319 items on the World Health Organization Essential Medicines List have patent protection postdating 1 April 1982. And patents on two of these products were donated by the inventor to the WHO for the public good. [viii]

That said, BIO and its members recognize the need to continually enhance research on new biotech products and global access to them. Our members are highly supportive partners in facing the challenges of building a sustainable R&D framework to contribute to global needs. BIO is fully supportive of improving international coordination between industry, governments, and non-governmental organizations to achieve practical results to improve the lives of people all around the world. To that end, BIO has participated in the World Health Organization as a "concerned entity" and has provided constructive proposals on how industry can play a role in achieving this goal. BIO also has been actively engaged in the Convention on Biological Diversity regarding the sustainable use and benefit sharing of genetic materials.

BIO's members are committed to efforts that will enhance partnerships and collaborations with conventional and non-conventional partners as well. In March 2008,

BIO teamed up with the Bill and Melinda Gates Foundation and BIO Ventures for Global Health (BVGH) to co-sponsor the "Partnering for Global Health Forum" in Reston, Virginia, to address the pressing need for accelerating the development of medicines for neglected diseases of the developing world. Over 500 stakeholders from all over the globe attended this conference. The Forum explored the need for innovation and avenues of progress in this area by focusing on lessons learned, market incentives, innovative business models, and new potential partnerships. The Forum also highlighted what a recent BVGF study showed: that biotechnology companies are willing and have the unique expertise needed to close the innovation gap with respect to neglected diseases. The study found that expanded research funding, new product development partnerships and other market-based collaborative efforts to harness resources in the public, private, and academic sectors will help to unlock this expertise and facilitate greater participation by the biotechnology industry in this effort.

BIO and its members also understand the importance of working with others in the developing world to build their innovative capacity. One practical way that this can happen is through the sustainable development of countries' genetic resources. Strong IP protections, efficient technology transfer mechanisms, and robust research funding can entice companies to seek out developing country counterparts. In 2004, BIO adopted its "*Guidelines for BIO Members Engaging in Bioprospecting,*" which provides assistance to those BIO member companies who wish to collaborate with other countries. The guidelines, which were later supplemented with a Model Material Transfer Agreement, identify certain "best practices" and options for consideration in such agreements, including upfront benefits, research training and capacity building.

About BIO: BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the BIO International Convention, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.

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[i] Walsh et. al. Final Report to the National Academy of Sciences' Committee Intellectual Property Rights in Genomic and Protein-Related Inventions Patents, Material Transfers and Access to Research Inputs in Biomedical Research, September 20, 2005.

[ii] Ted Buckley, The Myth of the Anticommons, May 31, 2007. http://bio.org/ip/domestic/TheMythoftheAnticommons.pdf.

[iii] Claude Barfield and John Calfee, Biotechnology and the Patent System, Balancing Innovation and Property Rights, 2007.

[iv] Hansen et. al. Intellectual Property Experiences in the United States Scientific Community, AAAS, 2007.

[v] AUTM FY 2006 Licensing Survey, www.autm.net.

[vi] Tufts Center for Drug Development, Impact Report *Cost to develop new biotech products is estimated to average $1.2 billion,* Vol. 8, No. 6, November/December 2006.

[vii] Amir Attaran How do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries? Health Affairs, 23 No. 3 pp. 155-166, 2004.

[viii] *Supra.*