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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

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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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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.

Pharmaceuticals

Pfizer Takes Cancer By Storm

Matthew Herper, 05.16.05, 12:00 PM ET

ORLANDO, FLA. - In the battle against breast cancer, Indiana University oncologist **Kathy Miller** has taken the lead. She stood by **Genentech**'s Avastin even when, in a clinical trial she led, the drug failed against the disease. Years later, she proved that it could extend patients' lives. To hear Miller tell it, she didn't have a choice.

"It's a little implausible to have so much data that something is important to the disease, and then to find that it wouldn't have an effect," said Miller.

Now, she is working on another drug for breast cancer, which could be the next step. The drug, Sutent, comes not from a small biotech but from **Pfizer** (nyse: PFE - news - people), the biggest of big pharmaceutical firms. Pfizer says it is just the beginning, and it is pouring 12% of its $8 billion annual research budget into developing new cancer medicines--making oncology second only to heart disease as a priority.

Today, Miller is presenting early data for the first time here at the annual meeting of the American Society for Clinical Oncology (ASCO). It shows Sutent shrank tumors by a third or more in 14% of 51 patients who were available for evaluation. All the patients had failed with the two main classes of medicines used in breast cancer and were extremely sick. In a similar trial, years ago, Avastin had shrunk tumors in 9% of patients. Previous trials have shown Sutent extends life in patients with stomach cancer and shrinks kidney tumors--results that could put it on the market next year.

Pfizer says that Sutent is only the beginning. It is developing 13 experimental cancer drugs. "We hope that Pfizer will, in time, grow into one of the larger cancer companies," says **William**

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This Year's Cancer Debutantes

Slichenmyer, Pfizer's head of oncology.

To do that, the $50 billion drug giant may have to learn from the creative flexibility of tiny biotech firms. "I keep telling them that they need to think more like a biotech," says **George Demetri**, an oncologist at the Dana-Farber Cancer Institute. "I think they've listened."

One piece of evidence is in the trials Demetri conducted of Sutent for gastrointestinal stromal tumors (GIST), a deadly disease but a tiny market. Three years after the first patient got Sutent, the drug has been shown to help patients live longer.

Just a decade ago, GIST patients lived for only a year and a half, and there was little doctors could do. Then came Gleevec, from **Novartis** (nyse: NVS - news - people). The drug worked on the single protein that went defective in GIST cancer cells, and the cancer stabilized. But eventually, doctors found, the cancer always became virulent again. Sutent made sense as a follow-up drug because it hit several defective proteins involved in cancer and, it was hoped, would get around the tumor cells' resistance.

Robert P. Keefe, 72, was one of the first patients dosed with Sutent for GIST in April 2002. Demetri was his doctor. He called Keefe a week and a half after the treatment began and said his tumors were shrinking. "He said, 'You're making waves around the world!' " Keefe recalls. Now, the former marathon runner and football player is running six days a week, and spending time with his wife of 43 years. Without Sutent, he says, he might have missed his two grandsons. One child is 3, and the other is only a month old. One of his sons helps run the Web site www.gistsupport.org.

In kidney cancer, Sutent shrank tumors by 40% in two midstage clinical trials. It took a median of 8.7 months for their tumors to start growing again in one of the trials; the other is too recent to get a reading. It is possible Pfizer could file with the U.S. Food and Drug Administration based on those results, in addition to the GIST results, but the idea is controversial because the studies had no placebo controls. **Bayer** and **Onyx Pharmaceuticals** presented data on their own cancer drug, sorafenib, and found that the drugs extended life, compared with a placebo.

However, some think Pfizer might have an edge because Bayer's drug shrank tumors by only 2%. Tumor shrinkage doesn't always mean better survival, but doctors are used to thinking of it as important. **Nicholas Vogelzang**, director of the Nevada Cancer Institute, says that if Pfizer slows the progression of disease, Bayer's marketers could face an "uphill battle."

Pfizer already has a second kidney cancer drug on the way. Here at the cancer meeting, data were presented on AG-13736, another pill that hits

two of the five cancer proteins Sutent targets. Early results are promising, and the second compound may lack Sutent's side effects, which include fatigue, an incredibly sensitive tongue and yellowed skin.

Even more medicines are on the way. An injectible antibody for a target protein called CTLA4 has shown promise in melanoma. **Bristol-Myers** (nyse: BMY - news - people) and **Mederax** (nyse: MEDX - news - people) are racing to develop a similar drug. A second antibody, licensed from privately held **Coley Pharmaceuticals** and code-named PF-0351676, is also under development. Nine more drugs are in the first stages of clinical testing.

It remains an open question whether Pfizer can turn its expertise to cancer. **Amgen** (nasdaq: AMGN - news - people) and **GlaxoSmithKline** (nyse: GSK - news - people) are also moving into the cancer field. Skeptics might note that Pfizer's cancer pills come from separate acquisitions of big biotech companies, although the melanoma drug was developed in-house. But Pfizer has managed to become a big presence at this year's ASCO meeting. Says Leonard Saltz, of Memorial Sloan-Kettering Cancer Center, "I hope they become a player."

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Yes, America Has a 'New Economy': Technology

Global View

By George Melloan

Federal Reserve Chairman Alan Greenspan gave unexpected support to "New Economy" theorists in a speech at the Gerald R. Ford Foundation in Grand Rapids 13 days ago. Information technology, he said, "has begun to alter, fundamentally, the manner in which we do business and create economic value." By enabling businesses to remove "large swaths of unnecessary inventory," real-time information is accelerating productivity growth and raising living standards. This has contributed to the "greatest prosperity the world has ever witnessed."

That is bullish talk for a man better known for chiding Wall Street for its "irrational exuberance," long before the Dow soared above 11,000. There can be little doubt, however, that there is a new, technology-based economy roaring toward the year 2000 and that Americans are its primary driving force. So it is fascinating to contemplate what new technological marvels we're likely to see in the 21st century. Just as engaging is reflection on why it is that the U.S. has become the fountainhead of creativity in science and engineering. A lot of other nations would like to find the secret and bottle it.

But first a look at some of the hot technologies, some gleaned from a bibliography prepared by the Organization for Economic Cooperation and Development in Paris. OECD researchers expect further dramatic advances in information technology, with desktop computers heading onward and upward in memory and speed. Gene-replacement therapy could be widespread by 2025, as the Human Genome Project unlocks further mysteries of the human body.

Meanwhile, Rand Corp's Critical Technologies Institute, surveying corporate executives, forecasts that over the next 20 years "molecular medicine" will lead to powerful medications and therapies that treat diseases at the genetic level. Therapy will be applied at earlier stages of disease and will be adapted to individual patients. These more precise treatments will further advance life expectancies.

"The same deeper understanding of genetics that is poised to revolutionize health care and its attendant industries also offers the potential for more precisely breeding plants and animals," says the Rand survey. "Depending on consumer acceptance, by the early part of the next century, much of the world's produce may be genetically engineered in some way."

Materials technology is a wide-open field, with possibilities for flexible glass or ceramics and, most fascinating, the marriage of biology and engineering to produce combinations of organic and inorganic materials that are, in effect, self-assembling. Tiny sensors will someday eliminate the need for highway toll booths and regulate automobile engines, in both cases saving enormous amounts of fuel. Imaging technology is progressing toward identifying tinier objects, advancing molecular medicine and genetic engineering.

In transportation, look for the "hybrid car" early in the 21st century, using fuel cells, an advanced electrical battery. "Over the longer term, fuel cells, combined with super-strong, ultra-light polymers or ceramics, could provide true energy savings for the transportation sector," the Rand study says.

The reason the U.S. is leading the technological revolution is partly its great wealth. Its corporations, universities and national laboratories are the world's leading spenders on research and development, with outlays double the nearest rival, Japan. But there is a lot more to this great burst of creativity than just the amount of money spent. Far more important is the environment that Americans have created—or perhaps preserved is a better description—that fosters and rewards creative effort.

The Bayh-Dole Act of 1980 allows recipients of government grants to retain title to their inventions. Says a study on basic research by the Committee for Economic Development: "This law has stimulated intense growth in university patenting and a subsequent technology transfer from basic research institutions to industry. As a result, industry is increasingly involved in collaboration with, and sponsorship of, university-based researchers." For example, the CED report notes that there are 1,000 companies in Massachusetts with relationships with the Massachusetts Institute of Technology. Their worldwide sales are $53 billion. "Similar developments have taken place in California's Silicon Valley and the Research Triangle of North Carolina."

Genetics research will revolutionize health care.

But many places elsewhere in the world are lacking one or more of the magic ingredients that have made the U.S. the great dynamo of the technological revolution. No country, for example, can match America's vast network of colleges and universities, teaching hospitals and private-research institutions, not to mention the labs of its multinational corporations. These centers of research attract aspiring scientists and engineers from all over the world and many find the intellectual climate so much to their liking that they settle permanently in the U.S.

U.S. national laboratories, though suffering from the usual inefficiencies of tax-supported institutions, nonetheless direct grants to thousands of individuals who are pursuing promising lines of research. And the ease with which individuals can start businesses in the U.S., in sharp contrast to Europe and Asia, means that good ideas spawn new firms, which often grow large and provide shelter and stimulation for new generations bent on making their marks in research and development.

But there is more to it than that. The U.S. would never have arrived at this stage without the changes in the public-policy environment that have transpired over the last 20 years. Ronald Reagan set in motion a deregulatory and tax reform process that has survived to this day. Efforts by the Clintons to nationalize the health industry, which surely would have stultified medical research, failed. So did the effort of Vice President Al Gore to whip up "environmental" hysteria and thus expand the regulatory burden, which is a particular curse for small start-up firms, at a faster rate.

Another Rand study comparing the U.S. with the European Union, Japan, China and South Korea shows that the U.S. leads in providing a climate of openness to foreign trade and investment. This helps make the U.S. economy highly competitive. Competition stimulates innovation. That is reflected in Rand statistics showing that American industry sharply expanded its employment of Ph.D. scientists and engineers between the years 1973 and 1991, increasing its share, relative to other employers, to 36% from 24%.

There are lessons in all this. All this new science didn't just happen. It had to be incubated. If the U.S. can preserve the environment that hatches inventions, it can look forward with optimism to the 21st century. Present evidence suggests that the 21st may even outstrip the 20th as a century of science.

Remarks of Rebecca S. Eisenberg Esq., Robert and Barbara Luciano Professor of Law , The University of Michigan Law School
At a symposium entitled:
THE NEW BIOLOGY: CELEBRATING THE PAST; IMAGINING THE FUTURE
Presented by
The Center for Strategic and International Studies and
The National Academy of Sciences
On the Occasion of the Annual Meeting of the National Academy of Sciences
April 28, 2003 ~ 2:30 to 5:30pm

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ARTICLE

Public vs. Proprietary Science: A Fruitful Tension?

Rebecca S. Eisenberg, JD, and Richard R. Nelson, PhD

ABSTRACT

The authors examine the presumption that basic scientific research is most effectively utilized when the findings of that research are openly disseminated without significant restriction, while research with more practical application should be the prerogative of private enterprise.

However, many fields, including molecular biology generally and genomics in particular, lie in the intersection between basic research and application. Moreover, institutional boundaries that once reasonably sharply demarcated basic research from technological development have grown porous, with more academic research finding application in industry. The authors consider the Human Genome Project and rival industry sequencing efforts as a case in point of the new political economy of scientific research. Since the inception of the Human Genome Project, there has been general agreement among researchers that the project would be most advantageous to science if the sequence data were made publicly available, quickly and without restriction. Many of these arrangements required federal agencies and some universities to "maneuver around" the Bayh–Dole Act. In several cases, most notably genomic sequences and the SNPs (i.e., single nucleotide polymorphisms) consortium, it was the pharmaceutical industry that initiated or helped enable the project to ensure open and unencumbered access to information, the type of access that has historically been the provenance of academia and the raison d'eˆtre of academic research. The authors conclude by reasserting the value of public science as a broadly valuable and enabling social commitment, not limited simply to the products or technologies it spawns.

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What should be public and what should be private in scientific research?

The competitive sprint of public and private laboratories to complete the sequence of the human genome has brought this question to the fore. The same question frames the developing struggle over terms of access to human embryonic stem cell lines and the conflict between Microsoft and the open-source movement over how best to promote software development.

We expect such conflicts to become more widespread as the role of for-profit research expands in a broader range of scientific fields. Will science progress more swiftly and fruitfully if its findings are in the public domain, or if they may be captured as intellectual property? What kinds of research should be funded publicly and what kinds left for private financing? Is competition between public and private science stimulating and constructive, or is it wasteful and counterproductive?

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***Dr. Eisenberg** is the Robert and Barbara Luciano Professor of Law, University of Michigan Law School, Ann Arbor, Michigan. **Dr. Nelson** is the George Blumenthal Professor of International and Public Affairs, Business and Law, Columbia University, New York, New York.*
Correspondence should be sent c/o Stephen Heinig, AAMC, 2450 N Street, NW, Washington, DC 20037.

Our aim in this essay is to bring these issues into clearer view. They have been kept in the analytic shadows until recently by the presumption that science and technology are largely distinct enterprises. In fact, the problems arise in areas where science and technology overlap.

We thus begin our discussion by reviewing the conventional distinction between science and technology. We then consider different perspectives on the appropriate public and private spheres in fields where science and technology are intertwined, first in general, and then in the context of the Human Genome Project. We conclude with a brief analysis of policy options.

It is often assumed that science and technology are—or ought to be—independent enterprises. In a classic series of essays, collected in his 1973 book *The Sociology of Science*, Robert Merton described science as a public enterprise generating public knowledge. This has become the standard view, accepted by many working scientists.

According to this theory, the goal of scientific research is to advance fundamental knowledge about the world. This effort need not be directly useful, much less profitable, at least in the near term, although sponsors and practitioners of science generally expect that advances in scientific understanding will foster later useful advances in applied technology.

The principal venues for science are universities and

government laboratories, and the principal reward for success is recognition and acclaim from the scientific community. Open disclosure of research results, through timely publication and other mechanisms permitting free access, is the norm. Since researchers do not earn financial returns from this work, they rely on philanthropic or public funding.

Most social theorists, including Merton, have drawn a sharp contrast between basic science and applied technology. While basic science is a public enterprise pursuing fundamental knowledge, applied technology is a private enterprise pursuing proprietary solutions to practical problems. The goal of the individuals and firms doing such applied research is to solve practical problems in the hope of earning profits. Such research draws freely on the pool of public scientific knowledge, but does not contribute to that pool. Intellectual property rights protect the profits of those who invest in successful technology research, preserving incentives to provide additional funding.

There is considerable truth in this conventional account and the distinction between science and technology on which it rests. Basic science and applied technology often differ in important ways and flourish under different institutional regimes. Horace Freeland Judson's fine history of molecular biology, *The Eighth Day of Creation*, illustrates the power of a research regime in which all scientists can draw freely upon the prior work of others, each pursuing their particular interests and bets regarding the most promising lines of inquiry, checking, correcting, and building upon each other's results. At the same time, the history of technological progress in such fields as pharmaceuticals shows the power of profit incentives to promote the development of products that meet human needs.

What the conventional account leaves out, however, is the often complex ways in which basic science and applied technology frequently overlap. Such cases of overlap raise difficult questions about where, and how, to draw lines between the public and private spheres. Moreover, in cases where science and technology do overlap, public and private interests may conflict—which only makes more pressing the question of where, and how, to distinguish between what ought to be public and what ought to be private.

From the start of modern science, many scientists have been interested in practical problems, and the challenge of solving those problems has driven their search for fundamental knowledge. Universities long have dedicated a considerable portion of their research efforts to understanding and solving practical problems, particularly in the United States, where, until World War II, agriculture occupied a large share of academic research. In the postwar era, medical schools have accounted for a large and growing share of research at U.S. universities, currently amounting to roughly half of the total. Much of this work is motivated by the practical goal of improving human health.

More generally, much academic science lies in what the late Donald Stokes called "Pasteur's Quadrant."[1] Standard taxonomies place the pursuit of fundamental knowledge and

the solution of practical problems at opposite ends of a onedimensional spectrum from "basic" to "applied" research; Stokes's taxonomy recognizes that the work of many scientists combines both objectives simultaneously. Like Niels Bohr, Louis Pasteur sought fundamental understanding, and like Thomas Edison, he sought solutions to practical problems. For scientists conducting research within "Pasteur's Quadrant," the objective is to achieve the fundamental understanding necessary to solve practical problems.

This hybrid motivation characterizes most research in the biomedical sciences as well as in material science, computer science, and theoretical work in engineering. These fields are not exceptional: they are in the mainstream of contemporary academic research, posing a serious challenge to a taxonomy that draws a sharp distinction between basic science and applied technology. In recent years private industry has been a growing source of funds for academic research in these areas, and universities have been increasingly inclined to patent their discoveries.

The other side of the coin is that corporate research and development (R&D) often involves the pursuit of fundamental knowledge. Many technologies depend on scientific knowledge, and focused scientific research is often essential in order to advance these technologies. Some private firms perform basic research, and many of their researchers publish scientific papers, although for-profit firms are less inclined than universities to place their findings in the public domain without restrictions.

In fields where scientific advances have conspicuous commercial potential (such as pharmaceutical research), the pursuit of profit and the pursuit of knowledge often converge, creating substantial overlap in research pursued in academic and industrial settings. Research results are at once part of a growing corpus of scientific knowledge for use in further research and an important step toward a promising commercial product. Within this zone of overlap, Mertonian public science and market-driven proprietary research coexist, setting the stage for conflict over what should be public and what should be private. The challenge for public

policy is to devise arrangements that preserve the great advantages of an open system for basic science while still preserving profit incentives for the creation of valuable new products.

In our view, a common way of thinking about how to draw the line between public and private science is seriously misleading. It is often said that public science ought to focus only on research that private firms will not conduct. If certain areas of research appear to have high social value yet promise relatively low returns, then public financing may be necessary to correct for the failure of markets to get the job done. Private sponsors might not expect to capture enough value to justify R&D costs if anticipated research results are far removed from practical applications, if they are unlikely to be patentable, or, more generally, if profits are highly uncertain.

On the other hand, if the research offers a reasonable prospect of yielding practical benefits, if intellectual property law permits the sponsor to appropriate a sufficient share of the value of those benefits, and if private firms are therefore willing to undertake the research, so much the better. In this case, it is commonly argued, public funds are not needed and should be spent for other purposes (or left in the pockets of taxpayers).

This analysis assumes that the only argument for public support of science is that important research would not occur without it. Although this is an excellent reason for public support of research, it is not the only reason. Even if expected practical benefits make patentable outcomes likely and motivate private firms to pay for the research, public funding might still be justified in order to increase the open domain of commonly owned knowledge upon which scientists may draw freely in future research.

From an economic standpoint, patents are not an unmixed blessing. Patent rights motivate private firms to invest in research, but they also introduce significant inefficiencies that may inhibit future research. Patents permit innovators to restrict access to, and thus raise prices for, their inventions. Although sometimes necessary to allow firms to recover R&D costs and thus profit from innovation, such pricing is inefficient, because it excludes users who would be willing to pay enough to cover marginal production costs but not the additional patent premium. The resulting losses could be considerable if the excluded users are not merely private consumers, but publicly funded researchers performing a socially valuable activity.

While the effect of patents on prices has been a central concern of economists, we think another inefficient aspect of patents is especially important in the context of scientific research: patents on essential materials and processes may require researchers to seek licenses before they proceed, which can impose significant transaction costs. In biomedical research today, exchanges of proprietary research materials, techniques, and data are increasingly governed by material transfer agreements, patent license agreements, and database access agreements.

At a minimum these agreements need to be reviewed and approved before research proceeds; often they must be renegotiated, leading to further delays and sometimes to bargaining breakdown with the potential for future litigation.[2]

Having the relevant knowledge and materials freely available in the public domain minimizes transaction costs by relieving users of the need to identify and bargain with intellectual property owners.

A third problem patents present for research activity is that they may give patent holders broad control over future research paths, allowing them to block research by rivals. Patents on fundamental discoveries that open up new research areas are typically broader than patents on incremental technological advances in established fields, because the principal constraint on the scope of patent claims is the prior state of knowledge in the relevant field.[3] Broad claims on

early discoveries that are fundamental to emerging fields of knowledge are particularly worrisome in light of the great value, demonstrated time and again in the history of science and technology, of having many independent minds at work trying to advance a field. Public science has flourished by permitting scientists to challenge and build upon the work of rivals. Intellectual property rights to fundamental discoveries threaten to limit the number of players in the system at an early stage, thereby diminishing its power.

On the other hand, private enterprise has been an extraordinarily powerful engine for the generation of new products and processes, and in some fields (notably pharmaceuticals) strong patent protection has been a vital part of the system. Businesses, driven by the hope of profit and the fear of competition, have a far better feel than government agencies for the kinds of new products the market wants and can respond more quickly to emerging demand and technological opportunities.

For the most part, the inefficiencies associated with patents do not generate strong pressures to substitute public R&D for proprietary R&D, even for products such as pharmaceuticals that meet important public needs. Although we might lament the high cost of patented drugs, the advantages of promoting private investment in new product development generally outweigh the inefficiencies of patents. Rather than displacing private R&D, the government can subsidize access to patented inventions for needy users (such as AIDS patients in sub-Saharan Africa or Medicare patients in the United States).

The problem that concerns us arises when the domain of public science becomes entangled with the domain of proprietary product development. This zone of overlap has been growing steadily since the late 1970s. An important factor

has been the development of molecular biology, a science squarely in Pasteur's Quadrant, as a field of both public and private research. Partly because of a series of laws often referred to collectively as "the Bayh–Dole Act," by which businesses and universities can claim property rights to technology created under publicly funded programs, universities have become active participants in the patent system.[4] A large share of university patents are in molecular biology. Many of these patents cover basic discoveries: as the Patent and Trademark Office (PTO) and courts have allowed such "upstream" patents, a significant private industry has grown up around pre-product development research in molecular biology, seeking to profit by patenting and licensing discoveries to other firms that use them to develop commercial products. The result has been a considerable blurring of the public-private divide, with universities and other one-time champions of open science claiming their own intellectual property, while private firms extend proprietary research further upstream, sometimes in collaboration with academic scientists and sometimes in competition with them.

Although the convergence of public and private resources

for biomedical research has accelerated progress, we believe that current policy and practice may have gone too far in promoting patenting of fundamental research discoveries. Patents on inventions with clear practical applications may well facilitate product development, but patents on discoveries that may spur future basic research impose serious costs on the scientific enterprise and are much harder to justify. The Bayh–Dole Act ignores this distinction, although it is becoming increasingly important to federal agencies that support fundamental research and to private firms that draw on emerging knowledge to develop new products. The Human Genome Project provides a useful focus for exploring these issues.

Public and private efforts to complete the DNA sequence of the human genome vividly illustrate the interests at stake in mediating the public-private divide in Pasteur's Quadrant. Although the Human Genome Project began in the late 1980s as a government funded "Big Science" project, from the outset it promised both new fundamental knowledge and practical payoffs with the potential for commercial profit.[6] By the late 1980s private firms already had a substantial presence in genetics and molecular biology and had developed proprietary tools that would greatly accelerate the Human Genome Project, including automated DNA-sequencing machines and the polymerase chain reaction. The mass-production character of sequencing three billion base pairs of DNA, and the "top-down" organization such a task seemed to entail, set it apart from the investigator-initiated proposals for creative, small-scale, academic investigations that had been typical of NIH-funded research. Yet talk of private initiatives to sequence the genome repeatedly provoked concerns about ensuring access to the data for use in future research, renewing enthusiasm for public funding. Private investors have repeatedly funded targeted projects within the broad scope of the Human Genome Project that seemed likely to yield commercially significant results, sometimes taking advantage of the reluctance of the public project to focus on "cream-skimming" projects that could jeopardize later support for the more costly job of completing a definitive reference sequence of the human genome.[7] In the early 1990s private firms focused on sequencing the estimated 3% of the genome that cells use to make proteins, using an approach called "CDNA sequencing." One such firm, Human Genome Sciences, was founded to exploit a research strategy pioneered by Dr. J. Craig Venter, then at the NIH, of using automated DNA-sequencing machines to obtain partial sequences (called expressed sequence tags, or ESTs) for genes expressed in human tissue samples. While academic researchers debated the wisdom of pursuing this strategy given available technology, resources, and priorities, private investors seized the opportunity to bypass skeptical government sponsors and peer reviewers and created a nonprofit research institution to support Venter's work, reserving commercial rights for Human Genome Sciences. This and similar efforts created valuable private databases of information, but academic institutions soon complained

about the restrictive terms of access offered by the database owners.

In the mid-1990s, when new technology made it feasible to detect and identify single base-pair differences in the DNA of different individuals (single nucleotide polymorphisms, or SNPs), private firms invested in SNP identification. Like gene fragments, SNPs promised to be a valuable information resource for both academic research and product development. Recent experience with proprietary databases of gene fragments led some scientists to worry that proprietary SNP collections might not be accessible to them on reasonable terms, prompting the public Human Genome Project to compete with the private sector by allocating some of its own funds to SNP identification.

In May of 1998, just as the public Human Genome Project had completed its initial mapping goals and was entering the phase of large-scale sequencing of the genome, a new private company came on the scene with the goal of completing the sequence several years ahead of the public project—under the scientific direction of Craig Venter, who by then had left the NIH. The new company, to be called "Celera" after the Latin word for speed, would use a new generation of DNA sequencing machines and pursue a "whole-genome shotgun sequencing" strategy that Venter had used successfully to sequence microbial genomes.[8] Like cDNA sequencing, whole genome shotgun sequencing was a strategy that the academic community had so far passed up for the human genome,[9]

leaving an opportunity on the table that private investors seized. But this was a more surprising plan from a business perspective. By this time cDNA sequencing had revealed many of the commercially promising genes (and generated patent applications on them). Although more genes were expected to surface in the course of completing the genome, most of the remaining sequence was presumed to be "junk DNA" of greater interest to scientists than to investors. Nonetheless, investors were sufficiently optimistic to drive the market capitalization of Celera up to over two billion dollars by the end of 1999.

The sponsors of the Human Genome Project responded by accelerating and increasing their financial commitments to complete the public version of the sequence more rapidly. At first, they criticized Celera's proposed sequencing strategy, charging that it would leave significant gaps in coverage that would be difficult and costly to finish. Soon, however, the public project changed its own course in order to provide an unfinished "rough draft" of the genome as quickly as possible. The two groups claimed substantial completion of their respective efforts in simultaneous publications in *Science* and *Nature* in February of 2001.[10]

The brief history of public and private involvement in sequencing the human genome shows conflicting views from the two estates regarding the importance of making knowledge freely available in the public domain. Free access to the genome has been a mantra within the public genome community,

repeatedly invoked as a motivation for accelerated disclosure policies and justification for accelerated funding to complete the sequence before private competitors capture it as a proprietary resource. Although it is a common ploy to invoke public-spirited justifications in support of requests for public funding, it is harder to dismiss the many concurring views emanating from the private sector, sometimes backed by private funds to generate information in the public domain.

From the beginning, scientists worried that it would be difficult to enforce norms of public disclosure and access for sequences generated by different scientists in different institutions. The usual trigger for disclosure in academic research —publication of results—would not serve as a timely enforcer for release of accumulating data that might not be ripe for journal publication until long after it was generated. The presence of commercial interests and the looming prospect of intellectual property claims heightened these concerns.

Controversy over the public or private character of the genome erupted more urgently in 1991 when the NIH filed patent applications on the first few hundred gene fragments (or ESTs) sequenced by Craig Venter. This was a provocative act on many levels. The patent filings, although consistent with U.S. laws encouraging government agencies to patent discoveries and license them for commercial development,[11] were in tension with rhetorical justifications for public funding of the Human Genome Project to ensure public access to the sequence. Foreign governments viewed the patent filings by a U.S. government agency as inconsistent with efforts to promote the Human Genome Project as an international collaboration to reveal the universal heritage of humanity. Patent claims for the discovery of mere fragments of genes struck many scientists as a premature reservation of commercial rewards for incomplete research results that were not yet meaningful and required further research to identify useful applications. Industry trade groups feared that patents on gene fragments would inhibit research to understand the role of genes in disease and would add to the costs of drug development.

Databases of ESTs quickly proved to be a valuable information resource for both private and academic scientists. But the two groups faced different constraints on their ability to gain access to the proprietary databases. As pharmaceutical firms signed database access agreements with price tags ranging from under $10 million to over $100 million, academic institutions balked at signing agreements that would commit them in advance to share future intellectual property rights with the database owners. Finally, in a dramatic inversion of traditional public and private roles, the Merck pharmaceutical firm agreed to sponsor a competing CDNA sequencing effort at Washington University, with newly identified sequences to be promptly disclosed in a public database.[12] Paradoxically, a controversy that began with patent filings from a government agency ultimately gave way to an extraordinary private-sector endorsement of the value of the public domain.

Another variation on traditional public and private roles occurred a few years later when ten pharmaceutical firms joined the Wellcome Trust Foundation to form the SNP Consortium, a private venture to identify common points of variation in the human genome for disclosure in the public domain. SNP identification had begun as proprietary research in the private sector, provoking the public Human Genome Project to call for a consortium of federal agencies to fund SNP discovery and to place the results in unrestricted public databases.[13] The candid justification for public funding was to prevent private appropriation of SNPs as intellectual property. But this strategy was constrained by the Bayh–Dole Act, which allows grant recipients to retain title to inventions unless the funding agreement specifies otherwise based upon an appealable finding of "exceptional circumstances."[14] Loath to invoke this rarely used and cumbersome provision, the NIH took a different approach. In its request for grant applications, the NIH stressed the importance of making SNP information readily available to the research community, advised grant applicants that their plans for sharing results would be considered by NIH staff as

one of the criteria for an award, and warned that the NIH would monitor grantee patenting activity.[15] This approach was arguably in tension with the spirit, if not the letter, of the Bayh–Dole Act. Ultimately, the private sector again came to the rescue of the public domain with the formation of the SNP Consortium, which unabashedly proclaims a strategy of identifying and disclosing SNPs in order to prevent other firms from patenting them. Once again, in the Bayh–Dole era it appeared to be simpler for private firms to endow the public domain than it was for the federal government to do the same.

The importance of public access to the human genome figured prominently in the case for continued funding of the public Human Genome Project following Celera's entry into the field. Celera's founders acknowledged the importance of free access by promising initially to release Celera's raw sequence data to the public on a quarterly basis,[16] although the timing and details of this commitment wavered thereafter. The public sponsors of the Human Genome Project stressed the importance of prompt and unrestricted access to the sequence, which they ensured by requiring grantees to deposit new sequence data in the publicly accessible Genbank database within 24 hours.[17] Celera's business model, which involves selling access to proprietary data and bioinformatics capabilities that subscribers would not pay for if they could get them for free, constrains its disclosure policies. Although Celera's promised quarterly data releases never occurred, Celera agreed to provide limited access to its data free of charge on its own Web site as a condition of publication in *Science*, subject to restrictions that preserved the market for its proprietary products.

Celera has had more success than prior owners of proprietary genomics databases in marketing database access agreements

to academic and government subscribers. It has made agreements on undisclosed financial terms with a number of major research universities and academic hospitals, as well as with the National Cancer Institute. Evidently Celera has something to sell over and above the information and tools that are freely available from Genbank, and evidently Celera's terms of access are not prohibitive for publicly funded investigators. Celera's database should be at least as good as the public database, given that Celera itself has free access to Genbank. At the same time, the existence of a public database with much of the same information presumably limits what subscribers are willing to pay (and what Celera is able to demand) for access to the proprietary database. The existence of Genbank may thus constrain Celera's market power in ways that make the proprietary data more affordable for all researchers.

The story of the Human Genome Project in the public and private spheres is not yet over. Although most of the genome has now been sequenced, the hard work of figuring out what it all means has barely begun. So far, the most significant intellectual property constraint on use of the sequence in research has come from the terms of database access agreements rather than from patents. But many patent applications are pending on genes, gene fragments, SNPs, and even DNA sequences stored in computer-readable medium, and many of these patent applications were filed before the same sequences were deposited in Genbank. Although the patenting of DNA molecules that encode therapeutic proteins is a well-established practice, the patentability of DNA sequences with more speculative utility is much contested and has not yet been addressed by the courts. Depending on how these issues of patentability are resolved, scientists might soon discover that they need patent licenses to make use of sequences they thought were in the public domain.

Although it may never be known whether public or private research efforts ultimately contribute more to future biomedical research and product development, it is probably safe to say that neither of these efforts would have achieved as much as quickly without the other. Apart from providing additional and complementary capabilities and enabling technologies, the private sector has repeatedly provided funding for productive research strategies that public sponsors passed over.

In a Big Science project that allocates government research funds according to a coordinated plan, the existence of a vigorous private-sector research enterprise limits the risk that good ideas will go unfunded, at least when they offer a reasonable chance of yielding practical payoffs. The peerreview process for allocating government research funds does much to ensure the political independence and high quality of public science, but it may tend to favor conventional approaches and prevailing beliefs over bold new ideas. Competition among researchers pursuing different strategies with similar goals speeds science along and improves the likelihood of success.

At the same time, freely available data from the Human Genome Project has undoubtedly accelerated research in both the public and private sectors. In addition to providing a free resource for users of genomic information, it has improved the completeness of proprietary databases (by providing data that owners may incorporate in proprietary products and by setting a benchmark that they must exceed in order to have something to sell) and improved terms of access to proprietary databases (by providing a free alternative that limits how much owners may demand). Although proprietary databases might be more profitable if there were no Genbank, the free database plainly has neither destroyed the market for proprietary databases nor undermined incentives to create them.

Numerous public-policy choices determine the balance

between public and private research in Pasteur's Quadrant. These choices include legal rules about what may be patented and how patents are used and managed, as well as decisions about what kinds of research the government will fund and what strings are attached to public funding.

If science and technology were entirely separate estates, one might preserve an open domain for science by limiting what may be patented to technology while relying on public funding to promote science. This is arguably the intuition behind traditional legal exclusions from patent protection for natural products and laws of nature and for inventions with no demonstrated practical utility.[18] But steady pressure to provide patent protection for discoveries in Pasteur's Quadrant has eroded these restrictions. Perhaps the erosion has gone too far.

Long before the advent of commercial genomics, the courts had narrowly construed the exclusion dealing with products of nature to uphold patents on purified preparations of products isolated from nature.[19] Although intuitively appealing, excluding the stuff of nature from patent protection has no clear basis in the patent statute, and judicial opinions recognizing the exclusion have failed to articulate a consistent rationale for it. It has thus been vulnerable to the same systematic erosion of judicial limits on patentability that has recently made way for patents on computer algorithms and business methods.[20]

The utility requirement has a clear statutory basis,[21] and academic scientists have urged the PTO to use this requirement to reject patent claims on DNA sequences until their biological function is understood. But an appellate court sharply rebuked the PTO just a few years ago for applying a strict utility standard to biotechnology products; the court reminded the PTO that "usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development."[22] At least as presently understood, the utility requirement does not seem to preclude patenting fundamental discoveries with practical implications that remain unproven. These time-honored limitations on the reach of the patent

system have arguably been degraded without explicit attention from Congress and may now need to be fortified to preserve the freedom of scientists to study the natural world.

A necessary first step would be a careful analysis of the purposes these rules serve in mediating the public-private divide in science and technology. On one hand, withholding patent protection could prove costly if it undermines private R&D incentives. On the other hand, the benefits to future research and product development of preserving the scope and vigor of public science might outweigh these costs.

Another option would be to carve out an exemption from infringement liability for researchers. Ideally, this approach would retain effective protection against competition in the commercial marketplace while minimizing the impact of patents on the research community.

But it is difficult to define the proper scope of such an exemption when there is no clear line between the commercial and research spheres. Should researchers in academic and commercial laboratories be treated similarly? Should patents on research tools that have no significant market outside the research community be subject to a research exemption that effectively eviscerates their commercial value?

The Human Genome Project offers numerous examples of patented research tools that were marketed to both academic and commercial researchers to the great benefit of the research community. Such tools might never have been developed without patents, making the ultimate impact on research of such a change in the law difficult to predict. On the other hand, many important research tools have come out of government-funded university research, and their invention arguably did not require patent protection.

Yet another option, which would not require changing the patent rights of private firms, would be to provide public funding to generate research results in the public domain, even if the private sector is already performing similar research on a proprietary basis.

This was ultimately the strategy pursued by the public sponsors of the Human Genome Project, although they had to maneuver around the Bayh–Dole Act to do it. The extraordinary commitment in the scientific community to making the human genome sequence freely available offered the sponsors protective cover for a policy that grantees might otherwise have challenged as contrary to the law. But if the Bayh–Dole Act impedes the ability of public research sponsors to enrich the public domain of science, perhaps it needs revision.

The flourishing of a robust private genomics industry alongside the public Human Genome Project calls into question the strong presumption under the Bayh–Dole Act that the results of government-sponsored research must be patented in order to preserve incentives for follow-on research in the private sector. That the pharmaceutical industry has repeatedly conspired with public sponsors to get genomic information into the public domain at its own expense is compelling evidence that proprietary control of information can impose significant costs on subsequent research and

thereby obstruct, rather than promote, product development. But public science is more than a prelude to product development. At its best, it is a social commitment to disinterested investigation of the world by credible experts operating under the critical scrutiny of their peers. It is a shared archive of an expanding knowledge base, a training ground for future researchers, and the germ from which future advances in human understanding will grow. Its social value

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does not depend on the ultimate profitability of the advances it spawns. If we need profit-seeking firms to tell us that the public domain has value, something important is missing from our understanding of science.

ENDNOTES

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[19]E.g., *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F2d 156 (4th Cir 1958) (upholding patentability of purified vitamin B12).

[20]See *State St. Bank & Trust v. Signature Financial Group*, 149 F3d 1368 (Fed. Cir 1998), cert. denied, 515 US 1093 (1999); *AT&T Corp. v. Excel Communications, Inc.*, 172 F3d 1352 (1999).

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WASH. POST 11/7/04

Milton Stewart Dies; Small-Business Expert

By PATRICIA SULLIVAN
Washington Post Staff Writer

Milton D. Stewart, 82, a well-known advocate for small businesses in Washington who was known as "Mr. Small Business," died of pneumonia Nov. 5 at St. Luke's Hospital in Phoenix.

Mr. Stewart was appointed in 1978 by President Jimmy Carter as the government's first chief advocate for small business. He organized three White House confe[rences] on small business, in 1980, [1986] and 1995. His career took him [from] Wall Street to the editorship of [a] magazine, to academic posts an[d] to the White House and the hal[l of] Congress.

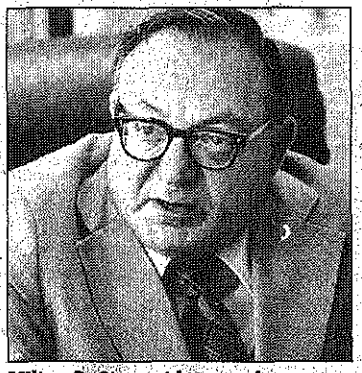
As the Small Business Asso[ciation]'s chief counsel for advocacy, [he] championed small solar firms, [gas] dependent gas stations and pate[nt] seeking inventors and argu[ed] against government regulation.

In 1980, when a study found th[at] time-consuming, duplicative but l[egally] gally required government form[s] cost the nation's 10 million sma[ll] businesses $12.7 billion a year, M[r.] Stewart appeared at a Senate hea[ring] ing to urge congressional action.

"Much of the sense of being over whelmed by paperwork that small business feels comes from the seeming unpredictability, aimlessness and lack of apparent control of the paperwork flood," he said. "This is where the psychological crunch on the entrepreneurial manager is greatest—the sense that he does not know what will hit him from the government in the next mail."

He held the government job until 1981, when he formed the Small Business High Technology Institute, a nonprofit agency that promoted innovation in small businesses and fostered relationships between those firms and universities, large companies and the government.

Born in Brooklyn, N.Y., Mr. Stewart received a bachelor's degree from New York University and a master's degree in journalism from Columbia University in 1945. He received a law degree from George Washington [University].



Milton D. Stewart became known as "Mr. Small Business" for his longstanding advocacy efforts.

[...]iation. In addition to ed-
[...]magazine in the early
[...]as a radio commentator
He served on Columbia
Graduate Faculty of
and was an assistant
the New School for So-
[...]rt's nomination to the
into criticism after it
[...]at in 1974 he signed a
[...]e with the Securities
Commission and was
[...]m investment activ-
[...]ys for violating SEC
[...]dent involved wheth-
[...]ly advised shareholder
involved in an affili-
[...]uilding lease. His
wever, was support-
[...]izations and individ-
[...]ll the former heads

[...] private banking division of a New York investment banking firm in the mid-1950s.

He was a partner in a Wall Street law firm from 1961 to 1965, when he became president of two venture capital companies that later would play a part in his nomination for the SBA job.

He served a year each as president of the National Association of Small Business Investment Companies and the National Small Busi-

He moved from Washington to Phoenix in 1981.

His marriage to Dorothy Stewart ended in divorce.

Survivors include his wife of 24 years, Joan Graves Stewart of Phoenix; two daughters from the first marriage, Ricky Perkins of Lancaster, Calif., and Abigail Stewart of Ann Arbor, Mich.; a son from his first marriage, David Stewart of Garrett Park; eight grandchildren; and four great-grandchildren.

TEL 304-230-3980
FAX 304-230-3989
JALLEN@WVHTF.ORG

the Dow Jones Industrial Average closed at 501, while the Nikkei Stock Average of 225 major Tokyo stocks closed at 496. That was the last time the Dow closed ahead of the Nikkei for almost 50 years. On December 29, 1989, the Nikkei peaked at 38,916, an astonishing fourteen times higher than the Dow, which closed at 2,753 that day. Not until mid 2002 would the Dow again close higher than the Nikkei.

As the 1970s came to a close therefore, the U.S. Congress was struggling to find ways to rejuvenate the U.S. economy. Three philosophies were struggling for supremacy and bore an uncanny resemblance to some of the opposing philosophies that had fought for supremacy in the newly independent America. A microcosm of this debate was reflected in the discussion over how best to manage more than $75 billion a year invested in Government sponsored R&D:

- The first philosophy was a Hamiltonian belief that the solution lay with a strong central government, which should take charge and actively manage these resources. In the 1970s, this philosophy was advocated by Senator Adlai Stevenson (D., IL) and the Carter Administration.
- The second philosophy was a Jeffersonian belief that the solution lay with the individual and that the best thing government could do to provide incentives for success was get out of the way of these individuals. This mantle was borne by Senators Birch Bayh (D., IN) and Robert Dole (R., KS).
- The third philosophy, in some ways in the middle of the first two but in some ways at the opposite apex of a triangle from them, held that government could only hurt and that it should make sure that everyone benefited financially from government's efforts; the flag bearer of this philosophy was the populist Senator Russell Long (D., LA).

The seemingly arcane issue of government patent policy became a battlefield for these competing philosophies as economic stagnation pushed this issue to the fore. Starting after World War II, the government had been taking an increasingly strident position that any inventions resulting from federally funded research belonged to the government and would only be non-exclusively licensed—the "favor everyone one" philosophy. Realizing that the policy nullified economic incentives for commercial development, Presidents Kennedy, Johnson and Nixon issued limited exceptions to this rule through Presidential policy memoranda. However, in quick succession, the federal government sued Stokely Van Camp in 1965 to force the company to abandon the patents filed on Gatorade by Dr. Robert Cade at the University of Florida and then sued the University of Wisconsin to obtain title to the anti-cancer drug, 5-fluororacil, after a secretarial coding error had attributed the purchase of $120 worth of reagents to a federal grant in a major project otherwise totally funded by a drug company.

Some people had started to realize that this idealistic approach was inhibiting the development of promising inventions simply because the government owned the rights. Norman Latker, Deputy General Counsel at the Department of Health Education and Welfare had therefore created Institutional Patent Agreements that allowed universities to take title to inventions that resulted from their work under federally funded grants. However, these agreements were totally at the government's discretion and only applied to grants from HEW.

The momentum for a fundamental legal overhaul of federal patent policy started in Bayh's home state of Indiana. Purdue had made several important discoveries under grants from the Department of Energy, which did not issue Institutional Patent Agreements. Ralph Davis, the Technology Transfer Manager at Purdue complained to Bayh, who asked Allen to investigate. Allen met with Howard Bremer, Ralph Davis and Norm Latker and confirmed the problem. Coincidently, Barry Leshowitz, who was on leave from the University of Arizona as an intern on the staff of Senator Robert Dole (R., KS) sensitized Dole to the fact that important discoveries were being bottled up at the agencies (Etzkovitz, 2002). Agreeing to collaborate, Bayh and Dole directed their staffs to develop a bill that, because of Senatorial courtesy, was called the Dole–Bayh Bill in the 95th Congress with the understanding that during re-introduction in the 96th Congress it would be the Bayh–Dole bill.

Introducing the Bill to the Senate on September 13, 1978, Birch Bayh said:

> A wealth of scientific talent at American colleges and universities—talent responsible for the development of numerous innovative scientific breakthroughs each year—is going to waste as a result of bureaucratic red tape and illogical government regulations...
>
> The problem, very simply, is the present policy followed by most government agencies of retaining patent rights to inventions.
>
> Government sponsored research is often basic rather than applied research. Therefore, many of the resulting inventions are at a very embryonic stage of development and require substantial expenditures before they actually become a product or applied system of benefit to the public.
>
> It is not government's responsibility—or indeed, the right of government—to assume the commercialization function. Unless private industry has the protection of some exclusive use under patent or license agreements, they cannot afford the risk of commercialization expenditures. As a result, many new developments resulting from government research are left idle.

The bill was circulated for support and comments so that it could be rapidly re-introduced when Congress re-convened in 1979 for the 96th Congress.

Bayh and Dole reintroduced the bill in 1979 as S. 414, the Bayh–Dole Bill, titled "The University and Small Business Patent Procedures Act". A significant change from the earlier Dole–Bayh Bill was the addition of provisions for licensing Government-owned patents.

On April 8, 1979, the *Washington Post* published an article on the bill, highlighting the shameful treatment of Norman Latker, who had been fired by Joseph Califano, Secretary of HEW, for his work on establishing Institutional Patent Agreements which the Carter administration vigorously opposed. Several of the universities that had benefited from Institutional Patent Agreements—in particular Wisconsin and Purdue—rallied to Latker's defense. They met with Allen and asked him to get Bayh and Dole to intervene on Latker's behalf, which the Senators did, publicly. Latker was reinstated.

Two days of hearings on the bill were held on May 16 and June 6, 1979, before the Senate Judiciary Committee, pitting two heavyweight witnesses on opposite sides of the argument. Arguing the case for Bayh–Dole was Elmer Staats, Comptroller of the United States. He testified to the failure of non-exclusive licensing to stimulate investment in early stage inventions. Howard Bremer talked about WARF's experiences. He said:

> Prior to the effective date of the IPA, December 1, 1968, no invention made at the University of Wisconsin with funds from DHEW (Department of Health, Education and Welfare) had been licensed to industry—one invention not falling under the IPA was licensed after that date. Since December 1, 1968, the Wisconsin Alumni Research Foundation has received a total of 69 invention disclosures under the Institutional Patent Agreements, has filed 79 applications on 55 of these disclosures and has had 55 U.S. patents issued.
>
> A total of 20 licenses were issued under one or more of these patents and patent applications, of which 14 are still extant.

Arguing the case against Bayh–Dole was Admiral Hyman B. Rickover, famous as the "Father of the Nuclear Navy" and a close ally of Senator Russell Long, who had long been a vocal critic of private use of government patent rights. Rickover argued that he had been able to develop nuclear power systems for the navy without having had to give up property rights to the contractors. He said:

> In my opinion, government contractors—including small businesses and universities— should not be given title to inventions developed at government expense. That is the gist of my testimony. These inventions are paid for by the public and therefore should be available for any citizen to use or not as he sees fit.

It should be noted that in fact the Department of Defense routinely gave waivers to its contractors, which were invariably large companies, to allow them to retain title to patents. The bill's handlers tried to balance Rickover's views by having small businesses testify, pointing out that when they get government research contracts, the

government takes the intellectual property rights away from them. No large company testified that they had any interest in working with universities. The Committee's main concern was that large companies would impede the diffusion of new technologies by restricting new developments that might threaten existing product lines. The Judiciary Committee had a long history of regarding intellectual property (as did the Department of Justice) as inherently monopolistic, which explains why Bayh and Dole limited the bill's impact to small businesses and universities.

During the hearings, Senators as politically diverse as Ted Kennedy (D., MA) and Strom Thurmond (D., SC) signed on as co-sponsors at the encouragement of the universities in their home states. By limiting the bill's scope to universities and small businesses, Senators like Gaylord Nelson (D., WI), who chaired the Senate Small Business Committee, became supportive even though that Committee had historically been very suspicious of patents, regarding them as tools that big businesses used to beat down small businesses. WARF helped educate Nelson's staff and defuse his opposition and he later became a strong proponent of the bill.

On December 12, 1979 the Senate Judiciary Committee unanimously approved and reported S. 414 to the Senate, a remarkable achievement since the membership of the committee was in general liberal and anti-business and Bayh–Dole was intended to promote the interests of business, albeit small business. A major reason for this support was that Senators Bayh and Dole were highly regarded in their respective parties and built political bridges between liberals and conservatives through their strong support of the measure. An additional reason was the dire competitive crisis facing U.S. industry, which made Congress feel that some actions must be taken to build partnerships between the public and private sectors to respond to the growing Japanese and German economic threats. The Committee Report said:

> The bill is designed to promote the utilization and commercialization of inventions made with government support ... Ultimately, it is believed that these improvements in government patent policy will lead to greater productivity in the United States, provide new jobs for our citizens, create new economic growth, foster increased competition, make government research and development contracting more competitive, and stimulate a greater return on the billions of dollars spent each year by the Government on its research and development programs.

However, trouble was brewing elsewhere in the Senate. The Carter Administration was developing its own plan to use federal research to rejuvenate American industry through a bill being developed by the Senate Commerce Committee, co-sponsored by Senators Adlai Stevenson (D., IL) and Harrison Schmitt (R., NM). A key difference between Bayh–Dole and Stevenson–Schmitt was that Stevenson–Schmitt argued that the economy was really driven by large companies and their exclusion from Bayh–Dole was a major weakness in that bill. Stevenson and Schmitt's model was the Department of Defense, which, despite Rickover's strongly held views, routinely granted administrative waivers and allowed its contractors, which were universally large companies, to own the patents that resulted from research they had funded. On February 5, 1980, Senators Cannon, Stevenson, Packwood and Schmitt wrote their Senate colleagues:

> When the Senate takes up S. 414, a bill to establish a uniform federal patent policy for small businesses and nonprofit organizations, we intend to offer an amendment extending this policy to all government contractors.

Senator Russell Long was implacably opposed to big business getting ownership of government-funded patents. He told Allen: "This is the worst bill I have seen in my life." Eventually, Bayh and Dole were able to defeat the Stevenson–Schmitt bill.

Another pending bill, which later became the Stevenson–Wydler Act, would have led to a Japanese MITI-style federal role in economic development by establishing centers for managing technology throughout the country. It also established the Federal Laboratory Consortium.

The Bayh–Dole Bill came to the Senate floor for debate and on April 23, 1980, was approved on a 91–4 vote. Announcing the victory, Birch Bayh said:

> What sense does it make to spend billions of dollars each year on government-supported research and then prevent new developments from benefiting the American people because of dumb bureaucratic red tape?

However, trouble was brewing on the other side of the Capitol. The Carter Administration's bill, the Kastenmeier Bill (Robert Kastenmeier, D., WI) was passed out of the House Judiciary Committee as HR-6933. On September 24, 1980, Russell Long wrote to Bayh expressing his concerns about the big business aspects of HR-6933. On September 26 Bayh wrote back to Long promising to amend HR-6933 when it came to the Senate. However, time ran out and Congress adjourned for the 1980 elections with Bayh–Dole having no corresponding House counterpart that could lead, after a House-Senate conference, to a bill that the President could sign.

The 1980 elections produced one of the major changes in the course of American history. Ronald Reagan defeated Jimmy Carter and the Republicans won control of the Senate for the first time since the Truman Administration. Birch Bayh was defeated by Dan Quayle. Adlai Stevenson retired. Robert Kastenmeier barely won reelection. Legions of staffers would be out of work come January 15, 1981. Washington was turned upside down and all bets were off.

However, Congress had adjourned without passing the budget and had to return for a lame duck session, so there was one last opportunity to pass Bayh–Dole before one of its two named sponsors departed Capitol Hill forever. First Allen tried to add Bayh–Dole to several "must pass" House bills with the help of the Small Business Committee staff, but no suitable vehicle could be found. Then Bruce Lehman, who was on Kastenmeier's staff and who would one day become Commissioner of the U.S. Patent and Trademark Office, called Allen with a deal. The House Judiciary Committee, which Kastenmeier chaired, had passed out an Omnibus Patent Bill. Kastenmeier would add the provisions of Bayh–Dole to his bill in the House if Bayh would agree to accept the other parts of the House bill affecting the operations of the Patent and Trademark Office. Bayh had competing bills in the Senate on these provisions but Allen accepted the deal. The House then passed HR-6933 with Bayh–Dole inserted. However, to become law the identical legislation needed to be passed in the Senate before proceeding to the President for signature into law. Because of this quirk of history, the official record shows the legislative history of HR-6933 as the legislative history of Bayh–Dole, not the legislative history of S. 414, which could be problematic if a court is ever called on to divine what the intent of Congress was when it passed Bayh–Dole.

The rules of lame duck sessions are harsh. There is no time for debate, so bills can only be passed by unanimous consent and a single Senator can block a piece of legislation by simply placing a "hold" on the bill, meaning that they object to it being considered for passage. By now there were only a few days of the lame duck session left.

Allen's first concern was Russell Long who had been an implacable opponent of Bayh–Dole. He could now, by himself, kill the bill and, given the duration, extent and passion of Long's opposition, Allen was not optimistic. Wiley Jones, Long's staffer, met with Allen in the final days of the session and asked him two questions:

First he asked a question from Long: "Does Birch really want this?" Allen answered quite simply "Yes, he really wants it." The next question was more difficult. With Bayh defeated, Allen was also out of a job. If the bill was defeated in the current Congress, Allen could use his intimate knowledge of the issue to get hired by a returning Senator who would then reintroduce the bill in the next Senate. Jones asked Allen his own question, staffer to staffer, friend to friend, "Is this bill good for you, Joe, and do you really want it?" Allen didn't blink. "Yes, I really want it." "OK", said Jones, "As a farewell present to Birch, you've got it." The U.S. Senate is rightly proud of its tradition of Senatorial courtesy, and Long's willingness to yield on an issue on which he felt so strongly is a stunning example of this courtesy. It is hard to imagine an act of such Senatorial courtesy in the current climate in Congress.

Allen thought he was home free. However, on November 21, 1980, as the 96th Congress ground to a close, Allen found that Majority leader Robert Byrd's staff (D., WV) had received a hold on considering the bill from a Democratic Senator. The identity of the dissenter was not revealed to Allen, but he worked out that it had

to be Adlai Stevenson. Allen dealt with that ruthlessly but simply. Stevenson's "memorial" bill was to be the Stevenson–Wydler Act, also in the queue for consideration in the lame duck session. Allen tracked Stevenson's staffers to the Senate Cafeteria and told them that if Stevenson didn't remove his hold, Bayh would put a hold on Stevenson–Wydler. When they realized they were in a stalemate, Stevenson's staff promptly got Stevenson to remove his hold. Both bills were put on the calendar and would come up for consideration in the waning hours of the session. Again, Allen thought he was home free.

Byrd informed Allen that Bayh–Dole would be called up in 15 minutes and that if this window was missed it would lose its place in line. Allen called for Bayh from the Senate cloakroom and found that he was tied up in a press conference with journalists from Indiana discussing his defeat and wasn't going to be able to be on the Senate Floor in time to present the bill. Looking around, Allen found Bob Dole on the Senate floor, explained Bayh's absence and Dole agreed to call up the bill and read Bayh's floor statement on the bill. On November 21, 1980, the Bayh–Dole Act was finally passed by the Senate by unanimous consent.

Again, Allen thought he was home free. However, the rules for Presidential signature of a Bill are different in a lame duck session. The United States Constitution, Article 1, Section 1 states:

> 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.
>
> (emphasis added)

Jimmy Carter had 10 days to sign the bill and indications were that there was significant resistance, particularly at the Department of Energy, to its enactment. Again, Allen turned to a friend, Milton Steward, who headed up the Office of Advocacy in the Small Business Administration and would go on to found *Inc.* magazine. Stewart had organized President Carter's small business summit and knew several small business leaders with connections to Carter's chief of staff, Stuart Eisenstadt. They all applied pressure on the White House and these efforts finally persuaded Carter to sign the bill. On December 12, 1980, Bayh–Dole became law by amending Title 35 of the United States Code, entitled "Patents", by adding a new chapter 30. This was the last day for Carter's signature before inaction would have resulted in a "pocket veto" of the bill.

Still Allen's battle wasn't over. The next step was the implementing regulations—37 CFR Part 401 and 35 USC 200–212. The drafting of these fell to the next Administration and grew into a drag down, knockout fight, with the DOE fighting every step of the way to limit the scope of Bayh–Dole. For example, at one point DOE proposed exempting every technology that was covered by the Export Control List from Bayh–Dole. By now Allen was working as a lobbyist for an intellectual property trade association in Washington, DC and Norman Latker took over the stewardship of Bayh–Dole at the Office of Federal Procurement Policy which was initially assigned responsibility for implementing the new Act. When Latker and Allen later teamed up at the Department of Commerce, Dole amended Bayh–Dole to move oversight to Commerce, where the responsibility remains. The battle over the implementing regulations was not finally settled in favor of Latker and Allen until 1984. DOE's resistance led Senator Dole to amend Bayh–Dole with a series of amendments, one of which included adding university-operated federal laboratories to the coverage of the law.

Almost immediately the attempts to limit the scope and coverage of Bayh–Dole started. One of the first was in 1982, when a very young Rep. Al Gore on the Science and Technology Committee of the House proposed exempting any inventions to do with biotechnology from Bayh–Dole, arguing that this was far too important an area of technology to be left to universities to manage.

The incoming Reagan Administration had a decisive say in what happened next. The 96th Congress had left two freshly signed bills on Reagan's desk which were diametrically opposite in their spirit and intent. On the one hand, Bayh–Dole devolved responsibility for commercializing the results of federally funded research to the local level by giving responsibility and control to the universities that had carried out the research. On the other hand, Stevenson–Wydler would have centralized control in the government's hands

through a network of federally funded technology development centers. In his Presidential Memorandum on Patent Policy of 1982, Reagan backed the Bayh–Dole approach. Whether this was the result of blind adherence to political philosophy, inspired government insight or simply the easier choice for a young administration fighting another oil price shock by avoiding the need to create a whole new bureaucracy will probably never be known.

Acknowledgments

This article is based on a talk given by Joseph Allen, President of the National Technology Transfer Center at the AUTM Directors' Forum in Naples, Florida in December 2002 and on an extensive interview with Joe at the 2003 AUTM Annual Meeting in Orlando, FL. I thank Joe for his time and for reviewing the draft of the manuscript to make sure that my slow longhand had kept up with his impassioned account of these events, a passion undiminished by the passage of 25 years. My thanks to Janine Anderson for proof reading the manuscript. I submit nothing for publication without her imprimatur.

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THE CHRONICLE OF HIGHER EDUCATION

Money & Management

From the issue dated December 3, 2004

Colleges Seek a Record Number of Patents

Survey reports almost $1-billion in licensing revenue for academe in 2003

By GOLDIE BLUMENSTYK

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Database: Showing licensing revenues and patent activity for fiscal 1998-2003

Table: Showing earnings from technology

Colleges and universities in the 2003 fiscal year filed for more patents, identified a greater number of scientific discoveries with commercial potential than ever, and signed a record number of licenses with companies seeking to turn academic inventions into drugs, devices, and other products, according to a report released this week.

The increased activity paid off for 165 institutions that responded to an annual survey of technology-transfer activity. They collectively received more than $968-million in licensing revenue in 2003, a one-year increase of about 1 percent.

The money came from companies that licensed academe's intellectual property for use in such products as computer-imaging technology, diagnostic tests for disease, and treatments for rheumatoid arthritis, Crohn's disease, non-Hodgkin's lymphoma, and menopausal hot flashes.

Survey participants also reported spinning off 348 companies based on college technologies and being issued a total of 3,450 U.S. patents.

The Association of University Technology Managers conducts the survey, which this year includes data from 96 of the 100 institutions that spend the most on research.

Licensing revenues include royalties that companies pay for the rights to use university inventions, as well as settlements and damage awards from patent-infringement lawsuits filed by colleges. The revenues also include cashed-out equity in spinoff companies that some institutions receive as part of their licenses with new companies.

Faculty members and students who have developed an underlying invention or process also shared in the increased wealth, since colleges often give the inventors 30 percent to 40 percent of the licensing income they receive.

A Few Earn the Most

As in past years, a relatively small number of institutions accounted for a significant proportion of both spinoff activity and the nearly $1-billion in licensing revenue.

view from the top joseph allen

When it comes to inventions, just don't mess with success

A PETITION THAT SOUGHT to use the authorities of the Bayh-Dole Act to force Abbott Laboratories to lower the price of Norvir, an important part of the AIDS "cocktail" used by many patients, was rejected on August 4 by the National Institutes of Health. Since Abbott had discovered Norvir at least in part with NIH funds, was the agency correct to reject the petition? The answer is yes.

The research alliances between US universities, federal laboratories and private industry are essential to our economic growth. However, it must be realized that commercializing federally funded inventions is a high-risk endeavor. It is clear that allowing the government to come in years later and second-guess product pricing would destroy the system.

Although it is little known by the general population, the Bayh-Dole Act of 1980 has been an essential part of the American economic renaissance. As The Economist Technology Quarterly said on September 14, 2002: "Possibly the most inspired piece of legislation to be enacted in America over the past half century was the Bayh-Dole Act of 1980....More than anything, this single policy measure helped reverse America's precipitous slide into industrial irrelevance."

Before the law's enactment few inventions were commercialized from the billions of dollars invested in federal R&D at our research universities. This is because they were warehoused in Washington and typically offered to private industry non-exclusively. The commercial sector was not interested without strong patent protections that justified significant development risks.

A study in the Johnson Administration was unable to find a single instance where any drug had been developed when the government owned the patent. Bayh-Dole provided incentives for schools and small companies to nurture inventions they make with federal funds. University inventors must receive a share of royalties and the remainder must be invested in research. Preference is given in licensing to small firms and those who will develop the resulting products in the US.

The basis for the petition to NIH, filed by the Washington-based consumer advocacy group Essential Inventions, was a misunderstanding of the rights of the funding agencies. A great fear when Bayh-Dole was debated in Congress was that companies might license university discoveries to stop their development when the discovery might threaten a company's existing products. Therefore, agencies were given the right to "march-in" if a licensee was not making good faith efforts to move the product toward market.

Because the universities are serving as stewards of the public interest, additional language required them to make their licenses available on "reasonable terms" for subsequent commercial development.

Through a misreading of the law and its legislative history (the hearings, committee report and floor debate leading to enactment) the public interest group developed a theory that somehow the university's requirement to license on "reasonable terms" provides federal agencies with the right to make sure that resulting products are available at reasonable prices.

Despite a joint letter to The Washington Post by former senators Bayh and Dole decrying such a misreading of their bill, a petition was filed to NIH asking the agency to "march-in" and regulate the price of Norvir.

If Congress had intended for government to regulate prices of resulting discoveries, surely it would have offered some guidance on how to define a "fair price." Senators Bayh and Dole would have been poor legislators, indeed, if they hid such an intent for almost 25 years. Legislation is not archeology!

If further clarification was required, Bayh spoke at the NIH meeting considering the petition again clearly explaining how the law worked. Ultimately NIH agreed, rejecting the petition. Trying to combine technology transfer legislation with product price controls would again doom federally funded inventions to the dustbin. As NIH reported to Congress, about 75 percent of licensed university patents were little more than a proof of concept. The vast majority of such patents are licensed to small firms.

Thomas Edison said invention is 1 percent inspiration and 99 percent perspiration. In the case of publicly funded R&D, government is typically financing the inspiration and industry the perspiration.

The Economist Technology Quarterly rightly concluded about Bayh-Dole: "A goose that lays such golden eggs needs nurturing, protecting and even cloning, not plucking for the pot."

If Congress had intended for government to set discoveries' prices, it would have offered some guidance on how to define a 'fair price,' says **Allen**

Joe Allen, a former Senate Judiciary Committee staffer, is head of the National Center for Technology Commercialization.

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You have to scroll down a little, but the story is very good. Features our very own Jon Soderstrom-- he's more than a pretty face...

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>
> Small Business: Moving Ideas Off Campus
>
> October 28, 2004
> By SHIRA BOSS-BICAK
>
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>
>
> It was the University of Arizona business school's annual
> Fame or Flame day, and faculty members were rating business
> ideas pitched by students in an entrepreneurship program as
> either first rate or feeble.
>

> To the disappointment of Sara Conrad and Daniel Berger, who
> were both juniors in the McGuire Entrepreneurship Program
> three autumns ago, the rating on their idea to develop
> customer-service kiosks in retail stores was flame. The
> judges said the project was unfeasible because it would be
> too easy to copy and would have a low return on investment.
> "We had to start all over again," Ms. Conrad said.
>
> To help them, a professor gave them a catalog compiled by
> the university's Office of Technology Transfer that
> described dozens of technologies developed in the
> university's physics, engineering and other scientific
> laboratories with the potential for being used
> commercially.
>
> The invention that grabbed their interest involved two
> professors in the medical school who had designed a
> portable device able to peer into children's eyes and
> photograph the retinas to detect shaken-baby syndrome. The
> two students reached an agreement with the researchers to
> develop a business plan to sell the product.
>
> The two students conducted focus groups, analyzed competing
> products, determined a target price and estimated the
> market size. The doctors had envisioned selling the device
> to ophthalmologists; the students added pediatricians,
> hospitals and emergency rooms as potential customers.
>
> "They had a device that was outstanding," Ms. Conrad said.
> "Dan and I took what they had and built it a little more to
> take it to a market they hadn't thought of, and built a
> financial plan they hadn't thought of."
>
> They proposed a price of $5,500, a third of what the
> least-expensive competing product was selling for. They
> incorporated the company as Optica Inc. and laid out an
> exit strategy with details of how the ownership would be
> divided among the founders if the company was acquired.
>
> After Mr. Berger and Ms. Conrad graduated the following
> year, the doctors sold the prototype and business plan to a
> local business group in return for shares in the company
> for themselves as well as Mr. Berger and Ms. Conrad. The
> company, now called Optica Technologies Inc., expects to
> have the Prism1 retinal camera instrument on sale within
> six months.
>
> "With the University of Arizona being such a center of
> research, there are all of these wonderful ideas there,"
> Ms. Conrad said. "We were able to celebrate what we were
> learning with a real, tangible device to work on. It was
> just waiting there."
>
> Since Congress passed the Bayh-Dole technology-transfer law

> of 1980, universities have enjoyed the ownership of
> research breakthroughs that were developed on their
> campuses with the help of federal financing and have been
> scrambling to turn them into commercial ventures.
>
> This transfer of technology from the campus to the
> capitalist marketplace has been a financial windfall for
> many schools. The top earners in the 2002 fiscal year, the
> most recent with figures available from the Association of
> University Technology Managers in Northbrook, Ill., were
> Columbia University ($156 million), the University of
> California system ($82 million) and New York University
> ($63 million). For all universities, the revenue generated
> from their researchers' inventions has nearly doubled, to
> $1.3 billion in 2002 from $699 million five years earlier.
>
> With the number of patents issued to universities rising
> to more than 3,600 in 2002 from fewer than 250 before the
> Bayh-Dole law was passed, the offices of technology
> transfer at universities are becoming overwhelmed with
> discoveries to assess and market. And increasingly, they
> are turning to a previously underused resource to
> investigate their potential: students in the
> entrepreneurship departments of their business schools.
>
> "We all want to increase productivity," said Ken Smith,
> interim dean of the Eller College of Management at the
> University of Arizona. "We do that by improving the
> relationship between the scientist and the business
> entrepreneur."
>
> The idea of teaming up with university researchers caught
> on slowly at first at university entrepreneurial programs,
> where students were more inclined to pursue their own ideas
> for companies. But having witnessed young entrepreneurs
> take a quick route to business success in the Internet boom
> of the 1990's, some have come to believe that working with
> ready-made technology is the best way to emulate them in
> the post-dot-com era, according to Jon Soderstrom, vice
> president for public policy at the technology managers'
> group. At the University of Arizona, for example, 12 of the
> 20 teams currently in the McGuire program are now working
> on business plans based on technology transfer.
>
> Universities themselves have started taking equity
> positions in start-ups or joint ventures founded on
> university-developed research, instead of charging
> royalties or licensing fees that young companies often
> cannot afford. (The state Constitution prohibits the
> University of Arizona from taking such an ownership stake,
> but there is a proposal on the November ballot to end the
> ban.)
>
> It is not just the financial bonanza that motivates a

> university to promote its researchers' inventions. These
> universities are also under pressure to create businesses
> that generate jobs for the local economy, Mr. Soderstrom
> said. From 1980 to 2002, more than 4,300 companies were
> formed based on academic discoveries, according to his
> group, resulting in the creation of tens of thousands of
> jobs. Yale University, for example, has spun off 18
> bioscience companies in Connecticut. The companies employ
> more than 880 people and have raised $1.1 billion in public
> and private financing in the last five years, according to
> Connecticut United for Research Excellence, a nonprofit
> organization that promotes the bioscience industry.
>
> "This is being multiplied all over the country," Mr.
> Soderstrom said. "It's not only the Stanfords and the
> M.I.T.'s anymore."
>
> The McGuire program is increasingly working with the
> university's technology-transfer office to link inventors
> with students who will develop business plans. Scientists
> welcome the collaboration, says Jim Jindrick, an
> entrepreneurship professor at the University of Arizona,
> because they recognize they lack business and marketing
> expertise.
>
> The university formally recognizes a business plan as
> proprietary intellectual property, and student teams
> working with researchers are required to draw up a "memo of
> understanding," which recognizes each party's stake in the
> project.
>
>
>
> Cooperation between students and researchers on commercial
> products is extending beyond the university. This summer,
> the University of Arizona sent several entrepreneurship
> students to work at research institutes in Mexico to
> evaluate technologies developed there. One team of six
> students ended up scrapping the two business ideas they had
> come up with and adopting a new technology for detecting
> oil leaks that was developed at an institute in Ensenada.
>
> "We said, 'Hey, why don't we try this idea?' " said Sandy
> Chen, an M.B.A. student on the team, who is now writing a
> business plan for a company called Leak Hound that will
> develop leak-detection equipment. The students are spending
> the next several months exploring additional applications
> of the technology, identifying possible markets, and
> building financial models.
>
> It is not just research institutions that are benefiting
> from working with business schools. Companies, which have
> long sponsored research by faculty members, are tapping
> into the brains of business students by sponsoring

> business-plan competitions. Honeywell started such a
> competition last year, with an award of $150,000 to the
> winning team and its school. It gives student teams
> technologies that are being used in the company's aerospace
> division and asks them to come up with other possible
> applications.
>
> "We were looking at how we can increase the number of
> business plans we have to look at," said Wayland Adams, a
> product line manager and chairman of the committee that
> runs the Honeywell Growth Challenge. Last year's
> competition generated 14 business plans, each of them being
> evaluated by Honeywell. "We might miss things that the
> students might see," Mr. Adams said.
>
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Recollections: Celebrating the History of AUTM and the Legacy of Bayh-Dole

Editors

Ann Hammersla, J.D., Massachusetts Institute of Technology, President
Patricia Harshe Weeks, Fox Chase Cancer Center, Immediate Past President
Catherine Innes, University of Washington, Vice President for Communications

Contributors

Joseph P. Allen, National Technology Transfer Center
Birch Bayh, Venable LLP
Howard Bremer, J.D., Wisconsin Alumni Research Foundation
Earl Freise, Ph.D.
Lawrence Gilbert, J.D., California Institute of Technology
Norman Latker, J.D., Browdy & Neimark
Ray E. Snyder, J.D., M.B.A.

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Introduction

For the those of you lucky enough to attend the 2004 AUTM Annual Meeting[SM] in San Antonio, you know firsthand the synergy, camaraderie and boundless enthusiasm that permeated this event. Nowhere was this more apparent than during the plenary session marking the 30th anniversary of the founding of the association. A very special lineup of technology transfer luminaries and AUTM founders — such as former U.S. Senator and co-author of the Bayh-Dole Act Birch Bayh and AUTM Founder and Bayh-Dole Advocate Howard Bremer, J.D., Wisconsin Alumni Research Foundation — highlighted this once-in-a-lifetime celebration. Attendees of this momentous event were privileged to hear personal accounts of the humble beginnings of the association, as well as the struggle that marked the passage of Bayh-Dole.

Time would not permit us to hear from every one of the special people on the stage that day. But this history is too precious to be lost forever. So, among these pages, we are pleased to present you with a small slice of this historic event by reproducing excerpts from the speeches that were given, or in some instances, prepared for the plenary session.

As I read this document, I realized how much more this publication is than just an historical account. These stories offer inspiration and hope to the technology transfer professionals everywhere who will carry on the legacy of these great and visionary men.

I also feel such gratitude to these visionaries for having the foresight and courage of their convictions to make so much possible. And although we can surely never express our deep appreciation for their great work, let me say, on behalf of all the AUTM members, thank you.

Ann Hammersla, J.D., AUTM President
Massachusetts Institute of Technology

A Quick History of Bayh-Dole

By Joseph P. Allen

Also present at the plenary session celebrating the 30th anniversary of AUTM was Joseph P. Allen. Allen, who was president of the National Technology Center from 1995 until earlier this year, presented a well-received "Quick History of Bayh-Dole." Throughout this booklet, you will find pertinent quotes from key players in the Bayh-Dole Act's birth that Allen used to illustrate his remarks.

Still collaborating: Joe Allen, former president of NTTC, (left) confers with Birch Bayh, former U.S. senator and co-author of the Bayh-Dole Act of 1980, during the 2004 AUTM Annual Meeting plenary session.

Joseph P. Allen was named president of the National Technology Transfer Center in 1995. Prior to joining the NTTC, he served as director of the Office of Technology Commercialization in the U.S. Department of Commerce. The office provided policy and guidance for developing and implementing technology transfer laws. There he was involved in the passage of major commercialization laws, including the 1986 Federal Technology Transfer Competitiveness Act,

Bayh-Dole First Introduced*

"A wealth of scientific talent at American colleges and universities — talent responsible for the development of numerous innovative scientific breakthroughs each year — is going to waste as a result of bureaucratic red tape and illogical government regulations....."

"Unless private industry has the protection of some exclusive use under patent or license agreements, they cannot afford the risk of commercialization expenditures. As a result, many new developments resulting from government research are left idle."

— Sen. Birch Bayh's introductory statement, Sept. 13, 1978

which opened federal laboratories to doing R&D partnership with U.S. industry. Allen was the key negotiator in several international agreements, including the U.S.-Japan Science and Technology Agreement, which brought U.S. international agreements into alignment with U.S. technology transfer laws. He was a professional staff member of the U.S. Senate Judiciary Committee, where he guided the Bayh-Dole Act of 1980 into enactment. In 1999, he received the prestigious Bayh-Dole Award from AUTM for his service in technology management. Recently, he co-authored Technology Transfer for Entrepreneurs, *published by Praeger Press.*

Plenary Session: Celebrating 30 Years of AUTM and the Bayh-Dole Act

By Birch Bayh

During the 2004 AUTM Annual Meeting, former U.S. Senator Birch Bayh shares his account of the development, passage and impact of the Bayh-Dole Act.

It is quite an honor to have the opportunity to share my thoughts with you this afternoon. It is particularly meaningful to share the stage with the founders of your internationally recognized organization. I feel a kinship with those who started this new professional society these many years ago. They had a dream and a vision, and, today, we are grateful that their vision has come true.

Tom Brokaw has recognized those American citizens of the World War II generation as what he rightly calls the Greatest Generation. Today, we are honoring the founders of AUTM, who can be called the Greatest Generation of a Technology-Driven World. They not only founded AUTM, they also fundamentally changed the American economy when they laid the groundwork for coupling our research universities with innovative American companies. Today, with almost 25 years of hindsight, this relationship is too often taken for granted. This is a serious mistake. All too many Americans are unaware that the technology explosion that they take for granted didn't just happen.

Like the generation that won both our political and economic freedom in World War II, succeeding generations also have a duty to defend these hard-won freedoms or they begin slipping away. This is also true of the technological inheritance that the founders of AUTM have given us. The need to protect this inheritance is the theme that I would like to share with you today.

When we began the struggle to pass what came to be known as the Bayh-Dole Act, I felt like the old Hoosier farmer I once heard about. It seems that a Chicago banker got lost on the back roads of Indiana on his way to an important meeting. Finally, realizing that he had no idea where he was and that his confusion was getting worse, the banker saw a farmer turning his cows out to pasture. Stepping out of his Cadillac, he hailed the farmer asking, "How do I get to Indianapolis?" Pausing for a good long minute the farmer replied, "Well, if I was you, son, I sure wouldn't start from here."

Like the banker, we didn't have any choice but to start from "here." "Here," in 1978, was not a very pleasant place. It seemed to us as though many of our citizens had lost confidence in America's ability to right itself both politically and economically.

Our journey out of the wilderness began with a call to my office in the summer of 1978 from Ralph Davis of Purdue University. Like many other universities, Purdue was making cutting-edge discoveries with federal dollars, but the government's policy of taking patents away from universities killed the incentives necessary for innovative companies to develop new ideas. We invited Ralph to my office to discuss the problem. Ralph brought along Howard Bremer [an attorney at the Wisconsin Alumni Research Foundation] and Norman Latker [department patent counsel with the Department of Health, Education and Welfare] — two individuals whose vision would be critical to our success.

One lesson we should underscore right here is: Don't underestimate your power in Washington. Your senators and congressmen take their constituent universities very seriously. Whenever Purdue contacted my office, we responded because I saw Indiana's universities as important cornerstones to our prosperity. The same is true for all states.

The result of that meeting with Howard, Norm and Ralph was the introduction of new legislation. I asked Sen. Bob Dole to join me, and the battle began. While Bob and I didn't always see eye to eye, we both agreed that the U.S. could no longer afford to waste billions of dollars on university and small-business research.

My opening statement for the first hearing on Bayh-Dole is still timely: "The United States has built its prosperity on innovation. That tradition of unsurpassed innovation remains our heritage, but without continued effort, it is not necessarily our destiny. There is no engraving in stone from on high that the U.S. shall remain No. 1 in international economic competition. In a number of industries, we are no longer even No. 2. New incentives and policies are needed to reverse this trend. The University and Small Business Patent Procedures Act (this was the original name of Bayh-Dole) will be a step in the direction of encouraging innovation and productivity in the United States..."

It is in everyone's interest to ensure that the fruits of American inventive genius are delivered to the marketplace as quickly as possible and are not simply left to gather dust at the Patent and Trademark Office because of indifference or bureaucratic delays.

Standing squarely in our way was Adm. Hyman Rickover, father of the nuclear navy. To the admiral, allowing universities and small businesses to own inventions made with government support made no sense. Adm. Rickover asked to testify against our bill.

While we had strong backing on the Judiciary Committee because of the calls from the universities and small companies in support of our efforts, someone as formidable as the admiral could shake that support. We needed effective counter witnesses. We turned to your founders. Howard Bremer and Niels Reimers [Stanford University] agreed to testify and did an outstanding job. They were our first pillars. The other essential pillars were equally strong testimony from our small-business witnesses. Combining universities and small businesses was the key to our success.

Illustrating the power of this combination, I remember one afternoon when I was at my desk on the Senate floor, and an excitable Joe Allen [a Congressional staffer at the time] came bounding up to report some good news. "Senator, we just got two more sponsors. Senators Kennedy and Thurmond just signed on," he beamed. Well, getting Ted Kennedy and Strom Thurmond to agree was certainly an achievement, but I couldn't help but kid Joe by asking, "Are you sure this bill makes sense?"

As you know, the task of enacting legislation, like making sausage, is not for the dainty. We would pass one hurdle, only to face an even greater one. What kept us going was a deep belief that what we were doing was important for the nation's future. The more we looked into the problem of renewing American innovation, the more vital it became to free our universities from mindless bureaucratic red tape. It was equally important to allow those who were really driving our economic growth, entrepreneurial small businesses, to secure federal funding without jeopardizing ownership of resulting products.

Let the Game Begin*

"Prior to the effective date of the IPA, Dec. 1, 1968, no invention made at the University of Wisconsin with funds from DHEW had been licensed to industry — one invention not falling under the IPA was licensed after that date."

— Testimony of Howard W. Bremer, WARF

"In my opinion, government contractors — including small businesses and universities — should not be given title to inventions developed at government expense. That is the gist of my testimony. These inventions are paid for by the public and, therefore, should not be available for any citizen to use or not as he sees fit."

— Testimony of Adm. Hyman B. Rickover, "Father of the Navy"

— Hearings before the Senate Judiciary Committee on the University and Small Business Patent Procedures Act (May 16 and June 6, 1970)

Another factor in our determination to press on was that the core group who started this organization never lost faith, even when it cost them personally. It is not every day that a civil servant risks his career for an ideal. Yet this is what happened to Norm Latker when he ran afoul of his political bosses because of his support of our efforts. He lost his job. Bob Dole and I were proud to stand by him in his time of need and to get his job restored.

We finally succeeded in passing the bill because of the active university and small-business support we received. Through Howard Bremer's efforts, the University of Wisconsin made Rep. Bob Kastenmeier aware of the impact Bayh-Dole could have on his district. Bob was chairman of the house subcommittee with jurisdiction over patent policy, and he offered to accept our patent policy in exchange for our accepting administration proposals in other areas of intellectual property reform. We accepted.

Small businesses persuaded the White House to sign the bill. Even so, as you heard previously, bureaucratic resistance continued trying to undermine the law until two years after passage, Norm Latker succeeded in putting the administrative procedures of Bayh-Dole in place. The legal and policy framework was in place to help this bold experiment produce. And produce you did!

AUTM has done a great job of capturing the impact that Bayh-Dole has had over the years. At a time of significant job loss, universities should be proud that 450 new companies were formed from university technologies in your last survey, and more than 4,000 since passage of the law. You also launched 569 new commercial products in FY02 alone. Technology transfer in FY99 involving the licensing of inventions from universities, teaching hospitals, research institutes and patent-management firms added approximately $40 billion to the domestic economy and was responsible for creating 260,000 jobs. Experts like Alfred Berkeley III here today see university technologies as significant drivers of the Nasdaq stock market.

I must admit that I was very proud to read the thoughts expressed in the *Economist* in December 2002 that said: "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 augmentation 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 measure helped to reverse America's precipitous slide into industrial irrelevance."

The just-issued report of the President's Council of Advisors on Science and Technology lists as its first recommendation, "Existing technology transfer legislation works and should not be altered." To that I say, Amen!

However, it is being altered. We have seen that DARPA [Defense Advanced Research Projects Agency] and now Homeland Security are consciously moving away from Bayh-Dole for their technology transfer practices. Articles are constantly appearing questioning whether Bayh-Dole is sophisticated enough for the current challenges facing R&D agencies. The old siren call of more centralized technology-management schemes (that is bureaucrats in Washington) are once again being heard. This trend must be stopped and reversed.

Let me challenge you, the present and next generation of AUTM. Policy-makers are sincerely trying their best to secure our future. They need and deserve your input. Never think that you can sit idly by and assume that someone is making your case for you. Don't assume that members of Congress and their staffs understand the fragile structure that supports our current success. One of our biggest concerns in writing Bayh-Dole was selecting an agency to oversee and protect it. Frankly, today, I do not see an effective countermeasure in the executive branch to those who are chipping away at the base of Bayh-Dole.

Let's be blunt. You must defend yourselves. We must say to the revisionists, stop! And, we must take the steps to see that they do. This is the task before you today if you hope to pass on the torch that these previous innovators have successfully handed to you. Don't underestimate your weapons. Don't fear the struggle. One advantage you have is that you now have a documented record that providing incentives to university and small-business innovators works. You performed in the hard, cold light of day. You have succeeded year after year, always reaching higher than before. You have proven again and again that, while it may appear to be messy to some, relying on the entrepreneurial character of America remains our best bet. Decentralized technology management still runs rings around systems relying on centralized government bureaucracy.

Let me share another story. Twenty-five years after President Lincoln made the Gettysburg Address, a prominent minister was chosen to read the speech at the battlefield. Dignitaries were gathered from around the country. Fearful of making any mistake in the well-known text, the minister worked for weeks to memorize the address.

Finally, the moment of truth came, and he recited a letter-perfect rendition to the massed audience.

Later a crowd gathered around him offering their congratulations for a job well-done. Out of the corner of his eye, the minister spied an old man who alone was not beaming. Finally, the man slowly approached the minister. "Son," he said, "You made an awful mess of Lincoln's talk." Taken aback, the minister replied, "Well, I'll have you know that I gave it line for line as President Lincoln did himself. What makes you think it was wrong?"

The old man replied: "You see, sir, I was right here when Lincoln spoke. You said the right words, but you still got it all wrong. You see, when you said, 'Government by the people, of the people and for the people,' you emphasized *government*. Son, Abe Lincoln emphasized the *people*."

Bayh-Dole didn't emphasize the *government*, it emphasized the *people*. And you of AUTM are the people. The people of AUTM have made it possible for Bayh-Dole to exceed our wildest dreams. Let me challenge you here today, each of you, to stand up, join together, to combat those bureaucrats who threaten the future of Bayh-Dole. Let us send a clear message. Get back behind your desks and permit the American free-enterprise system to ensure that the future of Bayh-Dole is as glorious as its past. Together we can do this. We must.

One final thought. I have mentioned the Bayh-Dole bill several times. In all honesty, if we consider the countless efforts that made it possible to pass this legislation, it should be called the Joe Allen bill.

Birch Bayh is a partner in the Legislative and Regulatory Group of Venable LLP's Government Division, Washington, D.C. Since serving the state of Indiana as a U.S. senator from 1963 until 1981, Bayh has been representing individuals, corporate clients and public entities before all three branches of government during a law career that has spanned more than 20 years. During his Senate career, he served on the Judiciary Committee, the Appropriations Committee and the Environment and Public Works Committee. He also served as chair of the Senate Select Committee on Intelligence, the Senate Appropriations Subcommittee on Transportation and the Senate Subcommittee on the Constitution. Bayh also chaired the National Alcohol Fuels Commission and the Office of Technology Assessment Study on the Patent System. In addition to his work on behalf of the Bayh-Dole Act, Bayh authored two amendments to the Constitution — the 25th Amendment, which covers the presidential and vice presidential succession, and the 26th Amendment, which lowers the voting age to 18 — and is author of Title IX to the Higher Education Act, which mandates equal opportunities for women students and faculty.

Musings

By Howard Bremer, J.D.

Founding members and long-time leaders reminisced about early days of AUTM during the 2004 AUTM Annual Meeting opening plenary session. From left to right: Howard Bremer, J.D., Wisconsin Alumni Research Foundation; Norm Latker, J.D., Browdy and Neimark; Niels Reimers; Earl Freise, Ph.D.; Larry Gilbert, J.D., California Institute of Technology; and Ray Snyder, J.D., M.B.A.

In contrast to AUTM's *growing pains* over the last few years, generated by the university sector's success under the Bayh-Dole Act, as well as the acceptance of *technology transfer as a recognized profession,* the early years of SUPA could be categorized as experiencing survival pains. There were mixed feelings among its members as to whether another university-oriented organization was needed and whether the fledgling organization, *absent institutional support and membership,* could, in fact, survive.

We, on this stage, as well as many others, are pleased to see that the faith and efforts of the beginning few culminated in the growth and influence of AUTM that we witness here today.

The road was not easy. It could be considered to comport with Hannibal's comment in trying to cross the Alps to carry the battle to Rome: "If we cannot find a way, we must make one."

SUPA/AUTM did just that, through *education, persistence and perseverance, often in the face of what seemed like insurmountable odds.* Beginning as early as 1976, not an insignificant part of SUPA's activities was the participation in crafting and supporting, through given testimony and writings, as well as key collaborations and education, many activities and legislative efforts that became the evolution of the Bayh-Dole legislation and the ultimate establishment of a *uniform federal patent policy.* In the period beginning in about 1976 through the ultimate passage of the Bayh-Dole Act in 1980, a literal plethora of legislative bills was introduced into Congress to achieve that end. Each had its proponents and each had strong opponents, not the least of which were various government agencies, the most active of which were what is now the DOE [Department of Energy], NASA [National Aeronautics and Space Administration] and DOD [Department of Defense]. The opponents literally had a leg up on the university sector in that the rhetoric of the opposition lent itself readily to what I term as *sloganeering.* For example: "What the government pays for (namely research and invention derived from federal support) it should own." Also, "What the public pays for (in terms of tax dollars) should be available to the public free of charge." And in addition to that: "The public should not have to pay twice — first to support the research and then again in the form of assessed royalties." And, even further: "Permitting the universities to take title to inventions is a big giveaway of federal and taxpayer property." Even Ralph Nader made such accusations.

Needless to say, in this gathering, the case for the benefits from technology transfer does not lend itself to such simple statements. The education of the opposition to merely accept, but not necessarily embrace, the concepts underlying technology transfer was a long, slow and arduous task.

Even after the passage of the Bayh-Dole Act, several of the opposing government agencies drafted regulations under the act as a *voluntary gesture* — regulations, which upon close review, would have had the effect of controverting the act. Even today, the sloganeering goes on in some quarters.

Over the First Hurdle*

"The bill is designed to promote the utilization and commercialization of inventions made with government support....

Ultimately, it is believed that these improvements in government patent policy will lead to greater productivity in the United States, provide new jobs for our citizens, create new economic growth, foster increased competition, make government research and development contracting more competitive, and stimulate a greater return on the billions of dollars spent each year by the government on its research and development programs."

— Senate Judiciary Committee Report, Dec. 12, 1979, on S. 414, unanimously approved and reported to the Senate

SUPA also engaged in its early years in the judicial process through the filing or support of amicus briefs in the *[Parker v] Bergy and [Diamond v] Chakrabarty* cases — the latter case being the one to establish that life forms were patentable subject matter — and the *Dawson Chemical Co. v Rohm and Haas Co.* case, the decision in which an apparent loophole in process patent protection was closed. The SUPA/AUTM historical pamphlet, which was in your registration packet [*30 Years of Innovation*, also available on the AUTM Web site at http://www.autm.net], contains the names of many who made important contributions to SUPA/AUTM, including the list of its presidents. There are others whose names do not appear and who made significant contributions in the early and formative years.

In recognition, I will give you a few of those names:

- *William Fornell, University of Minnesota,* who was to have been SUPA's second president but could not accept the position because of an apparent conflict.
- *Bill Burke, University of Georgia, vice president for Eastern Region,* who actively promoted SUPA's agenda, arranged meetings and did whatever task he was asked to do.
- *Jesse Lasken; assistant to general counsel, National Science Foundation,* who was a major factor in drafting analytical papers and position papers that served to "sell" the concepts and precepts of a uniform federal patent policy, SUPA's interests and legislative initiatives.

- *Two of AUTM's past and deceased presidents: Roger Ditzel, University of California, and Ed MacCordy, Washington University.* Each of these gentlemen did yeoman's service on AUTM's behalf and was in attendance at that Case Western meeting 30 years ago.
- *Ray Snyder, University of Missouri,* who served in many capacities for SUPA and AUTM and still today is a strong advocate of the university sector's views and agenda in the ABA [American Bar Association]. Ray was one of the first aboard at SUPA's organization.
- *Allen Moore,* the organizer of the meeting at Case Western Reserve University in 1974, during the course of which SUPA was founded, and who challenged the university sector to get involved.
- *Vladimir Dvorkovitz, Dvorkovitz & Associates,* who gave SUPA many opportunities to have a forum in its lean financial years.
- *David Eden, special assistant to Betsy Ancker-Johnson, Ph.D.,* when she was assistant secretary for science and technology in the Department of Commerce and got SUPA members involved in legislative activities.
- *And last, but certainly not least, Mary Spores, Northwestern University,* who was SUPA's secretary for many years and kept the organization and its officers on an even keel with a real devotion to that duty and to keeping SUPA a viable organization.

Since this is, in a sense, a memorial gathering, it would be fitting to add many other names to this list who have contributed so much to the organization during the course of its existence. However, our focus and charge was to address the early years, which I have attempted to do in reciting the few names I have given you.

Let me close with an adaptation from a line in Lincoln's Gettysburg Address, which too was given as a memorial: "The world will little note nor long remember what we say here today, nor the names of those who have brought us where we are, but we should not forget what they did."

On a lighter note, the hallmark of the SUPA/AUTM learning and advocacy experience can be summed up by a few lines from the ballad of Pretty Boy Floyd: "As through this world you wander you'll meet lots of crooked men — some will rob you with a six-gun and some with a fountain pen."

A past president and early member of AUTM, Howard Bremer, J.D., emeritus patent counsel, Wisconsin Alumni Research Foundation, was instrumental in the passage of the Bayh-Dole Act and its predecessor, the Institutional Patent Agreement. For more than 20 years, in addition to his duties at WARF, Bremer spent countless hours lobbying for legislation, testifying before Congress, educating the public and mentoring others in the technology transfer profession. In addition, his contributions to AUTM are unparalleled and continue today. He serves on the AUTM Journal™ *Editorial Advisory Board; co-authored the latest* AUTM Educational Series™, *"Academic Technology Transfer: Driving Public Use of University Research;" and continues to represent AUTM nationally and abroad as a spokesperson and staunch supporter of AUTM and technology transfer. In 1980, Bremer received the first ever Birch Award (now the Bayh-Dole Award) from AUTM's predecessor SUPA.*

The Early Years

By Earl J. Freise

Other members of this plenary session panel have addressed issues and the background leading up to the enactment of the Bayh-Dole Act. I'd like to give my perspective as to the circumstances and environment that led to the need for and formation of the Society of University Patent Administrators, now AUTM.

In the mid-1970s, many research universities were required to develop and operate institutional patent management procedures in order to receive approval for an Institutional Patent Agreement from the government. The implementation of such procedures often fell to the sponsored research office at those institutions that did not have established patent programs such as MIT, Stanford or Wisconsin Alumni Research Foundation. Such was my situation at Northwestern University, where one of my responsibilities as a staff member in the sponsored research office was to act as liaison with the government on patent issues. Needless to say, I, like many of my colleagues at other universities, was anxious for help and knowledge in how to represent our faculty and our institution in patent and licensing matters. Therefore, when the idea of a society or association to provide networking and education in the area of university patents and inventions was proposed by George Pickar, Ph.D., I approached the administration at Northwestern University and asked that they become a supporting institution. They agreed and provided a payment of $100 to found the society.

At the first organizational meeting of SUPA at the Pick Congress Hotel in Chicago in 1975, the bylaws for the society were approved by the individuals attending the organizational meeting. Since I lived in the Chicago area, but at some distance from the hotel, I left before the organizational meeting was finished. The next day I received a phone call informing me that I had been elected to fill the position of secretary/treasurer. Obviously, I learned a lesson to never leave early from a meeting where elected offices or job assignments are being decided.

In the early years, the annual meetings of SUPA were held in conjunction with meetings that Vladimir Dvorkovitz's technology transfer company organized. He graciously provided meeting space and was a strong supporter of the society in its formative years. While SUPA had established a $10 initiation fee and annual dues of $30, as treasurer, I could not justify sending out invoices for renewal annual dues in the first few years since the society was not incurring any significant costs for its operating expenses or the annual meeting. I just couldn't see asking members for $30 each year when the society was not providing any services or training programs. How things have changed! Finally, Larry Gilbert put together some notes and how-to materials on patents and licensing and SUPA issued them as one of its first set of training materials.

One other fortunate event occurred in the early years. Since I didn't have the time or necessary desire to serve as secretary/treasurer for the organization, I asked my administrative assistant at Northwestern, Mary Spores, to take over the day-to-day paperwork and the maintenance of the membership records and accounts. She subsequently became the secretary/treasurer and served very well in that role during the growth years of the society.

I must say that I am absolutely amazed and astounded by the vitality and breath of activities that AUTM and its members provide today. In many ways, it is much more than I had ever envisioned in the 1970s. The extensive workshops and training activities are the core of the organization and am delighted to have played some small role in fostering the founding of an organization that can provide these much-needed activities. I can't wait to see what AUTM will be like in another 30 years.

No One Said it Would Be Easy*

"Dear Colleague:

When the Senate takes up S.414, a bill to establish a uniform federal patent policy for small businesses and nonprofit organizations, we intend to offer an amendment extending this policy to all government contractors."

— Feb. 5, 1980, to all senators from Senators Cannon, Stevenson, Packwood and Schmitt

"This is the worst bill I have seen in my life."

— Sen. Russell Long to Bayh's staff

Founding member Earl Freise, Ph.D., retired in 1999 after nearly 40 years in the academic sector. His career started as a full-time faculty member in materials science at Northwestern University in 1962. After a brief stint in industry with Western Electric, he returned to Northwestern in the newly formed Office of Sponsored Programs. Part of his duties was to liaise between faculty and patent attorneys and government agencies and potential commercial parties at a time — the early 1970s — when successful technology management programs were rare and many research office administrators handled the patent programs. Consequently, when the idea surfaced to form an organization devoted to the education and exchange of information among university patent administrators in 1973, Northwestern supported the effort. In addition to being a founding member, Freise went on to serve as the organization's first secretary/treasurer and later served as vice president for the Central Region, as well as chair of the Nominating Committee. Throughout the rest of his career, both at the University of North Dakota and the University of Nebraska — Lincoln, Freise continued to work for technology transfer and patent programs.

George Pickar and the Formation of AUTM

By Lawrence Gilbert, J.D.

Sometime in 1973 I received a call from Gene Mann, the then director of sponsored programs at the University of Miami. Gene asked if I would be willing to spend a few days at his university to consider the merits of forming at UM a technology transfer office.

I accepted, spoke with various deans and department heads about their programs, the size of their research budgets and other such details. I gathered the data and submitted a report to Gene in which I recommended that a program be adopted.

Little did I know that Gene had an ulterior motive in requesting that report. An old buddy of his, George Pickar, Ph.D., had recently retired from the law school at Miami and was looking for something to do. With my report in tow, Gene promptly hired George as the first director of the Office of Technology Transfer.

I Think I Can, I Think I Can, I Think I Can*

"What sense does it make to spend billions of dollars each year on government-supported research and then prevent new developments from benefiting the American people because of dumb bureaucratic red tape?"

— News From Birch Bayh, April 23, 1980, on the approval of S. 414 (Bayh-Dole) by the U.S. Senate on a 91-4 vote

During the following year, George contacted me frequently about forming a new organization solely to support technology transfer at universities. I wasn't really interested because I had made a commitment to head the LES [Licensing Executives Society] Technology Transfer Committee. Did we really need another organization? If nothing else, George was persistent. Would I support it, if he proposed the idea at an upcoming Case Western Reserve University meeting to be held in October of 1974? A private meeting was held there, and seven brave souls agreed to commit $100 each to legally form the organization and establish a banking account. George took on that responsibility, incorporated it in Florida and established a banking account there.

Although George became the first president, in truth, he did not seek it. He tried to pass that on to me, but I refused and instead nominated George. The rest is, as they say, AUTM.

Founding Member Lawrence Gilbert, J.D., is the director of technology transfer, California Institute of Technology, where he has been responsible for the formation of more than 60 startups based upon or associated with university research. Gilbert was formerly the director of patent licensing for Massachusetts Institute of Technology. His prior experience includes patent consultant to various universities, including Boston University, Brandeis, Tufts and the University of Massachusetts Medical Center and as the director of Patent and Technology Administration of Boston University. He is a member of the Executive Committee of the MIT/Caltech Enterprise Forum and formerly a member of the board of directors of the Southern California Biomedical Council and a member of the Advisory Committee of the Business Technology Center, a high-tech incubator sponsored by the Los Angeles County Community Development Commission. Throughout his career, Gilbert has been a frequent lecturer on patent and licensing matters and written several articles in the field.

The Evolution of Modern Technology Transfer

By Norman J. Latker, J.D.

In 1885, after Louis Pasteur saved a boy with rabies, patients flocked from all parts of the world to his office, but it was too small to receive them. The next year, before the Academy of Sciences, Pasteur declared, "There is a need for prophylactic measures against rabies. An anti-rabies vaccine should be created." The request from the father of microbiology resulted in an extensive, international public subscription generating a fantastic burst of generosity that built the Pasteur Institute as a clinic for rabies treatment, a research center for infectious disease and a teaching center, with Pasteur as director.

But, in subsequent years, as the early and fundamental discoveries in the life sciences evolved, it became clear that the resources necessary to bring them to practical life exceeded what their investigators could provide through their own efforts.

Indeed, Professor and Inventor Frederick Cottrell recognized "...a number of meritorious patents given to the public absolutely freely have never come upon the market chiefly because what is everybody's business is nobody's business." This observation led Cottrell to donate his patents and their royalty return from his electrostatic precipitator to fund the creation of the Research Corporation in 1913 to serve as the technology transfer agent for investigators isolated from the commercial marketplace.

In 1925, Professor Harry Steenbock made a similar donation of his vitamin D patents to fund the creation of the Wisconsin Alumni Research Foundation limited to serve as the technology transfer agent only for investigators at the University of Wisconsin at Madison. These targeted services were intended to provide greater attention to reported inventions than previously provided by universities.

During these early years of the century, the services of Research Corporation and WARF were clearly limited by their resources. The majority of investigators were left to determine on their own whether to pursue moving their discoveries into practical life.

The huge increase in funding of research and development by the federal agencies proposed by presidential science adviser Vannevar Bush following World War II brought with it the establishment of a patchwork of different policies covering the ownership of inventions resulting from this funding. Outside the Department of Defense, the policies were heavily weighted in favor of government ownership, resulting in either dedication to the public or nonexclusive licensing of the government's patent rights.

By the 1960s, it was clear to the science management at the National Institutes of Health that the department's title policy was an impediment to industry development of the life-science inventions resulting from NIH funding.

The problem was dramatized by increasing numbers of invention-ownership disputes involving inventions assigned without notice to NIH to industrial developers by NIH-grantee investigators motivated, as was Pasteur, to see their direct application to practical life.

Professor Charles Heidelberger, Ph.D., and the University of Wisconsin, after being publicly accused by Sen. Russell Long's staff of confiscating ownership of 5FU, a breakthrough cancer chemotherapy drug, and licensing it to an industry developer, successfully convinced the department that minimal government funds were involved in its conception.

Professor Robert Guthrie, a department grantee and the inventor of the then preferred test for PKU (Phenylketonuria) being marketed by an industrial developer under license, after being publicly pilloried for confiscating the invention, assigned ownership to the department.

These cases had a further chilling effect on industry involvement as they suggested that any amount of government funding touching an industry invention could result in a similar claim of right by the government.

Thereafter, in 1968, the Government Accounting Office added additional urgency to resolving the problem, by reporting that, due to department patent policy, inventions resulting from all of NIH's medicinal chemistry grants could not find the necessary industry support to continue development.

Over the First Hurdle*

"The bill is designed to promote the utilization and commercialization of inventions made with government support....

Ultimately, it is believed that these improvements in government patent policy will lead to greater productivity in the United States, provide new jobs for our citizens, create new economic growth, foster increased competition, make government research and development contracting more competitive, and stimulate a greater return on the billions of dollars spent each year by the government on its research and development programs."

— Senate Judiciary Committee Report, Dec. 12, 1979, on S. 414, unanimously approved and reported to the Senate

Finally, in 1969, responding to increasing internal pressure, the department changed its patent policy and established a uniform institutional patent agreement that left ownership to grantee institutions that agreed to staff a technology transfer office to manage and license these rights when they requested an agreement. The conditions attached to these agreements reflected the accepted practices of Research Corporation and WARF. The National Science Foundation followed with similar changes in 1972. Thereafter, DHEW [Department of Health, Education and Welfare] and NSF staff responsible for IPA policy joined together in a long series of interagency discussions aimed to establish the IPA policy throughout the government agencies.

In 1974, the newly established IPA holders formed the Society of Patent Administrators to enhance outreach to industry so as to overcome industry's continuing resistance to development of government-funded inventions because they were not made in the companies' laboratories.

In that same year, members of the society found their political legs by assisting in preventing the inclusion in legislation creating the Energy Research and Development Agency of a requirement for government ownership of inventions resulting from its funding.

By 1976, 75 IPAs had been negotiated and executed with institutions that received well more than 50 percent of the annual DHEW extramural funding, and GSA [General Services Administration] regulations expanding the IPA policy to the rest of the government agencies, not otherwise covered by statute, were accepted by the interagency Federal Council for Science and Technology and published for comment.

Also in 1976, NIH Director Donald Frederickson agreed, with the consent of the FCST, to permit the University of California and Stanford to administer the Cohen-Boyer gene-splicing patent under their IPAs. Stanford's nonexclusive licensing of Cohen-Boyer to dozens of commercial concerns sparked the start of the biotech industry.

Notwithstanding the clear record of increasing licensing by IPA holders, DHEW Secretary Joe Califano instituted a 1977 "reassessment" of the department IPA policy that stopped further invention processing on the ground that the introduction of new technology into the marketplace was escalating the price of health care, which required department oversight. Legislation was introduced in the Senate to provide the department with this oversight authority at the same time.

Simultaneously, Sen. Gaylord Nelson of Wisconsin initiated hearings to discuss the legality of IPAs and the GSA regulations expanding their use to all government agencies.

The Califano and Nelson actions served as the flashpoint for organizations having IPAs to pursue legislation to assure continuance of the 1969 department policies and their further expansion by the GSA regulations to other federal agencies having conflicting policies. Led by the University of Wisconsin, Stanford University, the University of California and Purdue, the IPA community, over a period of two years, was so successful in making their views known to the Congress that Bayh-Dole passed the Senate by a vote of 91-4.

Some suggest that the primary purpose for Bayh-Dole is the production of income for those who participate in the conception and delivery of inventions to the marketplace. I do not believe that was the primary motivation of the act's architects. Income, which was a distant possibility at the time of enactment, was viewed only as a collateral benefit of success. The act is structured so as to assist investigators in their pursuit of direct application of their discoveries to practical life up to the point of either success or definitive failure.

As such, investigators intuitively understand that the act provides to them the possibility of their advancing mankind, as Pasteur did, which explains their growing enthusiasm to participate.

Early AUTM member Norman Latker, J.D., has spent the last decade as managing attorney for Browdy and Neimark, a 35-person law firm specializing in intellectual property law. Prior to the law firm, Latker served as vice president, legal and technology affairs, for Maxwell Communications Corp. in the late 1980s. In addition, Latker has worked in several governmental agencies, including the Department of Commerce, Small Business Administration and the Department of Health Education and Welfare. It was while serving as department patent counsel for DHEW (predecessor to the Department of Health and Human Services) that Latker teamed with Howard Bremer, J.D., to negotiate the Institutional Patent Agreement, a precursor to the Bayh Dole Act, which Latker also helped to construct. In 1983, AUTM awarded Latker with the Birch Award for "unselfish commitment to establish and preserve the values of the technology transfer process."

AUTM/SUPA: A Brief History

By Ray E. Snyder, J.D., M.B.A.

There actually were a number of historical acts and events that long predated the formation of the Society of University Patent Administrators (now known as AUTM) that should be placed into context for a proper understanding of why AUTM exists today.

In the years prior to WWII and for several years thereafter, the licensing of intellectual property did not amount to much. There were a few exceptions, like the catalytic cracking of oil; but for the most part, the royalties generated were insignificant by today's standards.

In this same time span, patents were generally not very highly regarded. Many companies reckoned that, if they infringed another's patents, there was always a chance that they would not get caught. Or, if they did get caught, the damages would not be more than a slap on the wrist. When Howard Markey was appointed to the U.S Court of Customs and Patent Appeals — now the U.S. Court of Appeals for the Federal Circuit — all that changed. Markey believed that patents should be respected and enforced, and infringement became a very perilous activity.

The U.S. Supreme Court has also had an indirect hand in the formation of SUPA. The *U.S. v Dubilier* case, decided in 1933, dealt with the ownership of patent rights, in addition to other things. In essence, the court held that, in the absence of a written agreement, there was no obligation of an employee to assign the title to his invention to his employer — the employer retained only a shop right. You can bet that every major employer in the country corrected that situation in a hurry. Some employers have even gone so far as to claim employee inventions not made in, or even related to, the course of their employment. In today's world, the outcome may depend on the employee's bargaining power. However, if anyone now goes to work for a large employer in a technical capacity, it is unlikely that he will receive his first paycheck until this matter is resolved.

The significance of the *Dubilier* case to the universities became apparent in the post-Sputnik era when the federal government started to fund a large part of the universities' research. The attitude of the government sponsors generally was: If the company employers require the assignment of employee inventions and, if Uncle Sam is now paying the bills, why should not the inventions be assigned to Uncle Sam? It is difficult to argue with this logic.

The picture becomes clouded when one realizes that the U.S. government issues the patents on the inventions in the first place. To turn around and then take title to the selfsame patents is a little like a bank writing checks to itself on its own account. It may be legally possible to do so, but no one should be deluded into thinking that anything valuable is created thereby. An invention only takes on value when someone does something with it.

Not all government agencies required the assignment of inventions. At one time, the National Institutes of Health sent out a letter to all of its university and other institutional customers asking what was their policy on dealing with patents. Of the 18 or 19 universities that responded, all were given an Institutional Patent Agreement, which allowed them to retain title to their own patents. The NIH, in return, received a nonexclusive license for its own use, or shop right. It often pays to read and respond to one's mail.

The Department of Defense also had a less than rigid patent policy. This was demanded by its company contractors, which were reluctant to give up their patent rights, especially if they included background patent rights.

Other than these examples, the government agencies adopted a fairly rigid stand and demanded the assignment of any invention made in the course of research that they sponsored. In a few specific cases, an agency would release title to a university, but more often the agency's policy hinged on the intransigence of the person running their program.

This then was the environment within the government with which the universities had to contend.

At the 1973 annual meeting of the National Council of University Research Administrators, part of one afternoon was devoted to patents. Most of this involved the compliance with government requirements. Not an exciting undertaking. The truly significant part of this meeting was the principal luncheon speaker, Betsy A. Johnson, Ph.D. At that time, Johnson held the post of deputy secretary of commerce, and part of her duties included the oversight of the U.S. Patent and Trademark Office. The theme of her speech was astounding. She said that the government's treatment of the universities' inventions was disgraceful, and why did we not get together and do something about it.

That was invitation enough. Thus was formed the Society of University Patent Administrators. Within two years, there were more than 50 members.

In 1975, The Energy Research and Development Administration (the precursor to the Department of Energy) held some hearings on the government's patent policies. By this time, the government had taken title to more than 27,000 patents and the government's own statistics were quite revealing. Less than 4 percent were licensed to anyone. In a few cases, a professor who had developed and patented a piece of apparatus for use in his own laboratory was required to take a license. This counted in the 4 percent. Also, many of the licenses were royalty-free. The best that could be said for the government's patent program was that it was not working.

The Bayh-Dole Act had its start with the first oil crisis. The story as related by Ralph Davis (an AUTM founding member) was that a professor at Purdue University had invented a process for converting corn stover into a burnable liquid fuel (not Gasahol), and a number of companies had expressed an interest in developing the process. The research work had been sponsored by the Department of Agriculture, which held title to the invention, and it was necessary to obtain a release. This dragged on and on until all of the interested companies were long gone. This was Sen. Birch Bayh's introduction to the problem.

Apparently, someone in Kansas had a similar experience, which brought Sen. Robert Dole into the fray. This author recalls one invention made at the University of Missouri that brought the problem into focus. Two professors reported the invention, and no federal funding was involved. However, one graduate student who worked in the same laboratory had a National Science Foundation fellowship. On the strength of this involvement, NSF demanded title to the invention. The number of incidents like these began to multiply, and by the time the Bayh-Dole Act was introduced, it had 21 co-sponsors.

It became clear that there was a real interest in developing and bringing to market some of the universities' scientific achievements.

Thus, the goals of SUPA were clear to the members. The variegated and inconsistent government policies had to be changed! For a group of people who were trained and hired to deal with technical matters, this dabbling into politics was a real departure. Once dedicated to the task, it was amazing how effective these people could be.

There were a few individuals within the government who saw merit in what the universities were trying to do. Norm Latker, department patent counsel for the

Department of Health, Education and Welfare (predecessor to the Department of Health and Human Services), actually became a friend and supporter of the universities' cause. This did not set well with then DHEW Secretary Joe Califano, and Latker lost his job. Joe Allen initially served on Sen. Bayh's staff, and he too understood well what needed to be done. Allen and Latker have continued to be long-time supporters.

The Bayh-Dole Act was passed in 1980 arid signed by President Jimmy Carter in 1981. This was almost seven years after the formation of SUPA.

It is still a little early to measure the ultimate impact of this act. That it is having an impact cannot be denied. It is also worth noting that, in the passage of this legislation, no political contributions were made, no funding was required, and no one within the government, the universities, or the general public received a dime.

There may also have been a matter of fortunate timing. About the time the act was passed, there was the beginning of a groundswell in the formation of new enterprises, which is unabated today. At a technology exchange meeting in Dallas in 1985, David Birch of the Massachusetts Institute of Technology revealed that, in the month of September in 1983, more new jobs were created by new enterprises in the United States than were created by all of the Fortune 500 companies in the prior year, or by all of the European Economic Community in the prior 10 years. To many universities, the idea of a start-up company was still beyond their charters, if not downright repugnant. In time this attitude has mellowed and probably every state in the Union has jumped on the bandwagon. If you are going to educate young people for the new economy, why not find out what it is all about? And have some fun in the process. While the success rate for new enterprises generally is still low, the success rate for university start ups is considerably higher, and the few that succeed more than make up for all the losers. The chances for success are immeasurably increased if the participants have a vested interest in such enterprise. That is the American way, and that brings us to where we are today.

Founding member Ray Snyder, J.D., M.B.A., was a patent licensing consultant for more than 20 years serving various institutions such as Loyola University of Chicago, California Polytechnic State University, Northern Illinois University, University of Hawaii, Rensselaer Polytechnic Institute, Vanderbilt University, San Diego State University, Northwestern University, Michigan State University and University of Missouri. In addition, Snyder has taught physics and lectured on licensing; served as an expert witness on patents, licensing and royalties; and held management positions in industry. His commitment to technology transfer pre-dates Bayh-Dole, as evidenced by his recounting of an incident that illustrated the attitude in government agencies prior to 1980: "In discussing the matter of patent rights with the legal counsel for one of the agencies, he said, 'Our main worry is that someone will pick up a piece of work that we sponsor and make a lot of money on it, which might subject us to criticism.' I responded, 'Well, if none of the work you sponsor is any good, you have nothing to worry about.'"

**As presented during Joseph P. Allen's "A Quick History of Bayh-Dole" during the 2004 Annual Meeting.*

Latker, Norman J. 1973. "Technology Transfer." Presentation to the National Congress on the Availability of New Technology to Industry from American Universities and Technological Institutes (April 1973).

Latker, Norman J. 1974. "Progress Towards a Uniform U.S. Government Patent Policy for Universities and Non-Profit Organizations." Presentation at the 2nd annual University/Industry Forum in Chicago (February 1974).

Latker, Norman J. 1974. "Intellectual Property Rights." Presentation at a conference on Technology Transfer—Opportunities and Responsibilities at Case Western Reserve University (October 1974).

Latker, Norman J. 1975. "The Protection of Intellectual Property Under the Fourth Exemption of the Freedom of Information Act." Presentation at the Academy of Pharmaceutical Sciences in Atlanta (November 1975).

Latker, Norman J. 1976. "Current Government Patent Policy as Applicable to Universities and Nonprofit Organizations." Presentation at the American Patent Law Association Meeting in Washington, DC.

Latker, Norman J. 1977. "Ethical and Economic Issues: University Policies for Consulting, Overload Instructional Activities, and Intellectual Property." Presentation at the annual Academic Planning Conference at the University of Southern California (January 1977).

Latker, Norman J. 1977. "Current Trends in Government Patent Policy." Presentation at the Conference on University Research Management at New York University (June 1977).

Latker, Norman J. 1973. "Technology Transfer." Presentation to the National Congress on the Availability of New Technology to Industry from American Universities and Technological Institutes (April 1973).

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LAW OFFICES
KRAUTHAMER & STAHL, CHARTERED
5530 WISCONSIN AVENUE, SUITE 801
CHEVY CHASE, MARYLAND 20815

(301) 951-0240
FACSIMILE: (301) 951-4436

HAROLD KRAUTHAMER
SHERRI M. STAHL
GILDA M. ZIMMET

OF COUNSEL
ALVIN M. EHRLICH

harold@krauthamerstahl.com
sherri@krauthamerstahl.com
gilda@krauthamerstahl.com

Website:
www.krauthamerstahl.com

ESTATE PLANNING QUESTIONNAIRE

Estate Planning Questionnaire for: _____

Date: _____

PERSONAL INFORMATION

	HUSBAND	WIFE
Name:		
Birth Date:		
Birthplace:		
U.S. Citizen:		
Social Security No.:		
Phone No.: (Work)		
(Home)		
Principal Residence:		
Any other possible domicile:		
Dates of such domicile:		
Community property acquired:		
Business or Profession:		
Still Active:		
Retired:		
Annual Salary:		

Current marital status: _____ _____

Date and Place of Marriage: _____ _____

Prior Marriage(s) (if any): _____ _____

Name(s) of former Spouse(s): _____ _____

Name(s) and age(s) of children of prior marriage(s):

_____

_____

_____

_____

_____

How and when prior marriage(s) ended:

_____

_____

ADVISORS

Principal Bank(s): _____

_____

_____

Principal Trust Officer(s): _____

_____

Location of safe deposit box(es): _____

_____

Accountant: _____

_____

Investment Advisor: _____

_____

Insurance Advisor: _____

_____

CHILDREN AND GRANDCHILDREN

Name	Date of Birth	Relationship	Domicile	Name of Spouse

(Designate which children or grandchildren, if any, are adopted, are stepchildren or are children of a prior marriage and whose prior marriage)

OTHER PERSONS WHO WILL BENEFIT UNDER THIS WILL

Name	Address	Relationship

FIDUCIARIES

Executor(s):

Name and Address:

_____

_____

Name and Address:

_____

_____

Successor(s):

Name and Address:

_____

_____

Name and Address:

_____

_____

Trustee(s):

Name and Address:

_____

_____

Name and Address:

_____

_____

Successor(s):

Name and Address:

_____

_____

Name and Address:

_____

_____

Childrens' Guardian(s):

Name and Address:

_____

_____

Name and Address:

_____

_____

Successor(s):

Name and Address:

_____

_____

Name and Address:

_____

_____

GIFTS MADE DURING LIFE

Donee: _____

Date of gift: _____

Type of property given: _____

Value of gift: _____

Donee: _____

Date of gift: _____

Type of property given: _____

Value of gift: _____

Outright or trust gift: _____

Was gift split with spouse: _____

If yes, who paid gift tax: _____

Marital deduction claimed: _____

Unified credit claimed: _____

FINANCIAL INFORMATION

A. REAL ESTATE (including condominium apartment)

Description Name on Title	Date Purchased	Cost plus Improvements	Current Value	Mortgage Payable	Net Current Value

B. STOCKS AND BONDS:

1. Closely-held Corporation(s)

Name & Address & Name on Certificate	Type of Business	Date Acquired	Original Value	% of Stock Ownership	Current Market Value

2. Cooperative Apartment(s)

Location & Name on Certificate	Date Acquired	Cost plus Improvements	Current Value	Outstanding Bank Loan	Net Current Value

3. Listed Securities (Stocks and Bonds)

Description and Name of Owner	No. of Shares or face value	Date Acquired	Original Cost	Current Market Value

4. U.S. Government Bonds (e.g. Series "E" Bonds)

Name of Owner	Face Value	Payable on Death to	Issue Date	Current Value

C. 1. CASH:

Name & Address of Bank	Name on Account and Number	Checking or Savings	Trust Account Beneficiary	Current Balance

2. MORTGAGES AND PROMISSORY NOTES:

Face Value	Name of Owner	Unpaid Balance	Date of Maturity	Interest Rate

D. LIFE INSURANCE:

Company and Policy Number	Named Insured	Named Owner	If Ownership Transferred, Date	Current Beneficiary	Face Value	Net Loan Proceeds

E. MISCELLANEOUS PROPERTY INTEREST:

	CURRENT VALUE
Household goods and personal effects:	_____
Collection (stamps, coins, art, etc.):	_____
Jewelry:	_____
Furs:	_____
Automobiles, boats, aircraft:	_____
Partnership or unincorporated business interest:	_____
Insurance owned on life of another:	_____
Interest in estates or trusts:	_____
Stock options:	_____
Leaseholds:	_____
Copyrights or patents:	_____

F. GENERAL POWERS OF APPOINTMENT:

Instrument conferring Power	Date power created	Value of Property subject to power

G. ANNUITIES AND DEATH BENEFITS:

Type of Plan	Annuity or Lump sum payout	Designated Beneficiary	Client's Contribution	Approx. Value

H. DEBTS, MORTGAGES AND LIENS:

	CURRENT VALUE
Debts owed:	_____
Mortgages on Property:	_____
Bank loans:	_____
Insurance policy loans:	_____
Installments contract:	_____
Contingent liabilities (guaranty, indemnity agreements):	_____

I. APPROXIMATE ANNUAL INCOME:

	Husband	Wife
Salary:	_____	_____
Fees:	_____	_____
Commission:	_____	_____
Interest:	_____	_____
Dividends:	_____	_____
Pension:	_____	_____
Annuities:	_____	_____
Royalties:	_____	_____
Trust Income:	_____	_____
Payments receivable on mortgages, installment sales, etc.:	_____	_____

J. FUTURE INHERITANCES:

Do you, your spouse or your children expect to inherit property?

From Whom? _____

Estimated Amount? _____

K. SUMMARY ASSETS CURRENT VALUE:

		Husband	Wife	Joint
1.	Real Estate:			
2.	Closely held corp. stock:			
3.	Cooperative Apartment(s):			
4.	Listed Securities:			
5.	Bonds			
6.	Cash:			
7.	Mortgage and Promissory Notes:			
8.	Life Insurance includible in Estate:			
9.	Miscellaneous Property Interest:			
10.	General Power of Appointment:			
11.	Annuities, death benefits: (if includible in Estate:			
12.	Gifts within last 3 years plus gift tax paid:			

TOTAL: _____

L. LIABILITIES:

		Husband	Wife	Joint
1.	Mortgage Payable:	_____	_____	_____
2.	Bank Loans:	_____	_____	_____
3.	Insurance Policy Loans:	_____	_____	_____
4.	Debts, etc.:	_____	_____	_____

TOTAL: _____

NET CURRENT ESTATE: _____