The Bayh-Dole Act at Twenty-Five Years: Looking Back, Taking Stock, Acting for the Future

Michael J. Remington, JD

Abstract
This article catalogs and discusses challenges to the Bayh-Dole Act from a perspective broader than legal, industry, and university. Because the act is a congressional enactment placed in the federal patent law and the author served for many years as chief counsel of the House Judiciary Committee’s Subcommittee on Intellectual Property and worked on the 1984 amendments to the Bayh-Dole Act, this author’s perspective is a political one. On behalf of the Wisconsin Alumni Research Foundation, the author presented a variation of this paper to the AUTM Annual MeetingSM in February 2005. The author asks for a celebration of the act’s twenty-fifth anniversary and issues a call to action for those engaged in technology transfer to defend the act.

Introduction
In the United States, technology transfer is understood not only by government officials, advisers to the government, university administrators and faculty, and pharmaceutical and biotechnology companies, but also, increasingly by foreign observers who sometimes are more keenly aware than are Americans about what is good and bad in American society. Economic growth depends
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on our societal ability to develop and apply new technologies. American universities are at the vortex of research, innovation, and technology transfer. The private sector wields the laboring oar at staggering expense to bring innovative fruits to the marketplace. The returns to the public—in terms of the flow of expertise, the creation of new products and startup companies, and the stimulation of jobs—are impressive.

Since enactment of the seminal Patent and Trademark Law Amendments of 1980 (commonly known as the Bayh-Dole Act, named after its two lead sponsors in the U.S. Senate, Birch Bayh [D-IN] and Robert Dole [R-KS]), federal patent law provides contractors, grantees, and cooperative-agreement funding recipients the opportunity to retain ownership (that is, patent) rights to inventions that they create as part of a federally funded research grant and then benefit from downstream commercialization of the inventions. Because many inventions arise primarily from the results of basic research, patents stimulated by the act can produce the basis for whole new products or even industries. The two major scientific trends of the late-twentieth century—biotechnology and information communications technology—were spawned in universities and moved toward commercialization as a result of processes established by the Bayh-Dole Act. Finally, the act dramatically changed university-private industry relationships, creating a new profession of technology transfer officer at the university level and stimulating the creation of a large number of incubated companies and licensing opportunities with established companies particularly in the pharmaceutical industries. Yet, currently, the act is also being subjected in certain quarters (mostly within the university sector itself) to growing criticisms.

On December 12, 2005, the act will be celebrating its twenty-fifth anniversary. The anniversary year is worthy of celebration and reflection. With a political perspective, and a bias in favor of the Bayh-Dole Act, this article looks back at the creation of the act, submits that the act is successful beyond expectations, takes stock of the fact that the act’s successes are being questioned, catalogs current challenges, and concludes with a call to action to defend the act.

The Bayh-Dole Act Has Been Successful

Ever since the founding of the nation more than two hundred years ago, the U.S. patent system has played a lead role in stimulating technological inno-
vation by providing property protection to inventions and discoveries of every description and by disseminating useful technical information to the public about them. The view that universities are more than ivory towers serving just faculty and students and that universities can contribute to innovation and the development of new products and processes for the betterment of society is deeply embedded in American history. The patent law is a hospitable place for the Bayh-Dole Act because it promotes the progress of science for the betterment of the public. Today, the societal benefits of university innovation are palpable and increasingly recognized. Examples of technologies and products emanating from university discoveries during the past three decades in the life sciences are truly impressive, among them: vitamin D metabolites and derivatives, University of Wisconsin; recombinant engineering co-transformation process, Columbia University; hepatitis B vaccine, University of California and the University of Washington; synthetic penicillin, Massachusetts Institute of Technology (MIT); Citracal calcium supplement, University of Texas Southwestern Medical Center; Cisplatin and carboplatin cancer therapeutics, Michigan State University; Leustatin chemotherapy for hairy cell leukemia, Brigham Young University; and metal oxide process for Taxol antitumor cancer treatment, Florida State University. Universities' inventions yield products and processes that save lives, diagnose diseases, reduce pain and suffering, improve health, make people see and smile. The net result is patient cures, jobs, a vibrant economy, and continuing innovations.

The standard rationale for the patent law is that it provides an efficient method of enabling the benefits of research and development to be realized, thereby promoting technological progress and innovation. Data reported to the Association of University Technology Managers (AUTM) for 2003, and reflected in the AUTM Licensing Survey, show that there are powerful reasons in favor of creating property rights in inventions funded by federal research. The results are quantifiable. A recent study conducted by the Milken Institute found that for every one job in the biopharmaceutical industry, 6.7 additional jobs were directly created. America’s biopharmaceutical companies are responsible for creating more than 2.7 million jobs across the United States. Although not all of these jobs are attributable to technology transfer, many of them are. And, despite the fact that most of the technological advances developed by recipients of federal funds have
been in the life sciences, technology transfer has created jobs in telecommunications, information technology, agriculture, environmental protection, and transportation. Lita Nelsen, director of the Technology Licensing Office at MIT, provides an apt final word: “. . . the Bayh-Dole Act is one of the most successful pieces of economic development and job-creation legislation in recent history.”

Why Question Success?

To question success and to proffer that, despite the effective functioning of our laws and institutions, the United States can both do better and confidently face the future is a salient factor of American political and legal history. In a prescient letter, Thomas Jefferson taught: “Laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths disclosed, and manners and opinions change with the change of circumstances, institutions must advance also and keep pace with the times. We might as well require a man to wear still the coat which fitted him when a boy, as civilized society to remain ever under the regimen of their barbarous ancestors.”

Almost a century later, Theodore Roosevelt observed that the rapid expansion of American industry had contributed to our economic well-being but had also caused much social anxiety. “There is no good reason why we should fear the future,” he reassured the country, “but there is every reason why we should face it seriously, neither hiding from ourselves the gravity of the problems before us nor fearing to approach these problems with the unbending, unflinching purpose to solve them aright.”

The Bayh-Dole Act is subjected to review every five years by the comptroller general of the United States. Federal agencies themselves have the authority and responsibility periodically to audit grantees and contractors for compliance with the act. To assist grantees and contractors, agencies may also issue guidance materials. In 2000, Congress passed the Technology Transfer Commercialization Act, which requires federal agencies with laboratories and technology transfer programs to provide the Office of Management and Budget (OMB) with annual reports on their activities as part of the budget process. In light of different agency practices and attitudes toward technology transfer, this annual-reporting requirement
should stimulate interest at the highest levels of government (including by the president and cabinet members) and should formalize a significant role to be played by the OMB and the Department of Commerce in the oversight of and accountability for technology transfer. The Bayh-Dole Act also falls within the purview of congressional oversight, and it may be amended at any time. Last, the act is subject to the court of public opinion. Currently, it has attracted a vocal group of critics and detractors, many of them coming from academic institutions, who claim that the Jeffersonian coat no longer fits the man. Among others:

- Drug-price advocate James Love demeans current practices, stating, “the taxpayers pay for the invention of a promising treatment... then give a marketing monopoly to one company... And the company’s role is? To agree to sell it back to us.”
- Harvard Medical School professor emeritus Arnold Relman and senior lecturer Marcia Angell opine that “whether the Bayh-Dole Act has been an overall success is [questionable].”
- Economist Richard R. Nelson, professor of international and public affairs, business, and law at Columbia University, argues that “universities have become extraordinarily greedy and aggressive in prosecuting their patents and, in the process, have backed away from their responsibilities as defenders of open science.”

Questions about the act are not only stimulated by the spirit of keeping pace with the times. Opposition to the act stems from a mistrust of the patent law and property rights, an arguable lack of objective economic standards to measure the success (or failure) of intellectual property statutes, societal concerns about escalating drug prices, a growing worry that universities are for sale, and a fear that we, as a country, are tilting toward an “anticommons.”

Nonetheless, an examination of the act, using the act’s statutory objectives as a benchmark, shows that it is as good as the day it was tailored in 1980, with minor alterations in 1984. It not only goes hand in hand with the progress of the human mind, but it promotes advances to knowledge. Social, economic, and academic anxieties no doubt exist, caused by tremendous changes in the nation’s material well-being. These anxieties are deserving of full consideration, but they are not enough to turn back “the full tide of successful experiment.” Upon the success of the Bayh-Dole experiment, too much depends.
Challenges to the Bayh-Dole Act Can Be Cataloged

Today, technology transfer is a major effort in the academic environment. More than 230 U.S. universities and colleges have technology transfer offices. In the face of great complexity and breadth, success has not been uniform. Although the number of academic technology transfer entrants with little experience in patenting and licensing is growing, as an expression of federal policy, the Bayh-Dole Act suggests the need for more successes reflecting the breadth of this country. Other challenges are present.

Decreases in Federal Funding of Scientific Research Will Have a Deleterious Effect on Technology Transfer

In a deficit-spending economy, institutions of higher education must increasingly compete for finite dollars. Today, federal taxpayer support for basic research is both stagnated and diverted toward homeland security, national defense, and the Iraq war efforts. Funds previously directed toward biotechnology and health sciences may go to cyberterrorism prevention and stockpiling antidotes for germ warfare. States, many of which do not have authority to engage in deficit spending, are placed in a position of either raising taxes or slashing expenditures. They often opt for the latter, meaning that they must cut spending to the bone for public education and research infrastructure.

The Efficacy and Quality of the Patent System Are Being Questioned

Success raises questions and challenges, not only for technology transfer, but for the patent law itself. Concern is growing in certain quarters that something in the patent system has gone wrong or, at least, that justifications for the system cannot be quantified or omnibus improvements are needed. The patent freight train is portrayed by some as being “out of control, even if it has not yet jumped the tracks.”19 In October 2003, the Federal Trade Commission (FTC) issued a report that discussed and made recommendations for the patent system to maintain a proper balance with competition law and policy.20 Although the profound impact of federally funded research and development is discussed, the concept of technology transfer to the public is not. In 2004, the National Research Council of the National Academies of Science (NAS) issued its own report finding that the patent system is increasingly under strain.21 NAS, like the FTC, made a
number of recommendations to improve the patent system. Some of the NAS recommendations, such as shielding certain research uses of patented inventions from liability for infringement, could affect technology transfer as we know it today. Recently, both houses of the U.S. Congress commenced hearings on the current state of the patent law.

Requests for March-in Rights, the Beat Gets Louder
In July 2004, the National Institutes of Health (NIH) rejected a request by consumer activists to exercise march-in rights under the Bayh-Dole Act for Norvir (a pharmaceutical product to treat HIV/AIDS). The petition was based on an interpretation of the act that would permit the government to consider the prices of patented products: in the case of Norvir, with one or more patents owned by Abbott Laboratories. In September 2004, NIH issued a similar march-in rejection for Xalatan, a drug used for the treatment of glaucoma owned by Pfizer Inc. For both requests, NIH appropriately refused to grant the desired relief based on a reading of the plain meaning of the act along with its legislative history, finding that the drugs had achieved practical application, a direct objective of the act, and, in doing so, had also met health-and-safety concerns imposed by regulatory authority. NIH also opined that Congress exercised great care in drafting the statutory march-in language and, accordingly, the issue of drug pricing was best left for Congress to resolve.

After the NIH decision, a member of Congress characterized it as “insupportable” and requested the review of the secretary of health and human services.22 In addition, members of Congress and the public asked the FTC to investigate the anticompetitive effects of the price increases for Norvir. NIH agreed that the FTC is the proper forum for consideration of these issues.

Agencies Exercise Authority to Skirt the Bayh-Dole Act
The concept of a government-wide patent policy is increasingly on a collision course with government-unique procurement requirements. Agencies argue that, to take advantage of technological advances while not increasing costs, they must resort to the use of other-transactions authority, which was first applied to funding the Defense Advanced Research Project Agency (DARPA), which is not subject to the Bayh-Dole Act.23 Ostensibly, the invo-
cation of other-transactions authority is to entice more contractors to bid on primarily defense-oriented projects and also to permit the contracting agencies more flexibility in negotiating agreements. Currently, such authority is available to the Departments of Defense and Homeland Security. The expansion of other-transactions authority to the civilian (nondefense) agencies is occurring with the complicity of the private sector's dual-use contractors (those that engage in both defense and civilian projects).

Private-sector initiatives make clear that one of the purposes of exercising other-transactions authority is to facilitate the protection of patentable inventions as trade secrets, thereby defeating the disclosure-inducement theory of the patent system, which is the chosen vehicle for transferring technology under the Bayh-Dole Act. Under the act, if recipients of federal grants elect title, they are required to file patent applications, seek commercialization opportunities, and report back to the funding agency on efforts to obtain utilization of their inventions. Adopting the other-transactions loophole also eliminates some of the act's federal controls, such as licenses to the government and march-in rights. The net result is to permit a contractor to put a new invention on the shelf and not develop it in the public interest. A restrictive reading of the definition of a subject invention under the act to only inventions conceived in the performance under a contract and not those that might have been conceived earlier and then “reduced to practice” under the contract (the latter step being the purpose of transferring early-stage technology to the private sector for applied development in the marketplace) is arguably a step backward. In the pre-1980 days, although patent rights were owned by the government, contractors and grantees benefited from trade-secret protection, which was tantamount to the government subsidizing the private sector.

Agencies also sometimes attempt to avoid the ambit of the Bayh-Dole Act by exercising other administrative strategies. Agencies utilize a Declaration of Exceptional Circumstances (DEC) under the act that permits agency retention of title to an invention despite the fact that it was generated under a federal-funding agreement. Because the act and the regulations promulgated thereunder expected DECs to be used only in truly exceptional circumstances, increasing use of DECs appears to be inappropriate. Through its Advanced Technology Program (ATP), the National Institute of Science and Technology has foreclosed the terms and provisions of the
Bayh-Dole Act from applying to inventions made under ATP funding. Lastly, the Small Business Technology Transfer Program has been construed as permitting a waiver of the Bayh-Dole Act’s directives if there is an agreement to do so between the parties, even when federal funding is involved.

The Common Law of Experimental Use and Research Exemption Creates Controversy

A federal appellate court decision, *Madey v. Duke University*, created heated debate in the technology transfer community. In *Madey*, the U.S. Court of Appeals for the Federal Circuit reversed a district court decision in favor of Duke, applying a common-law experimental-use exemption in the patent law to academic scientific research, even when that research is manifestly noncommercial. In overturning the lower court, the circuit court held that the exemption is not available to nonprofit universities merely because scientific research at those universities serves legitimate educational purposes. Unfortunately, the Federal Circuit categorized universities as commercial entities in their solicitation of funds to carry out research. Consequently, it opined that any research exemption must be narrow. Upon remand, Duke argued that it has a license to practice Madey’s patents for government-research purposes pursuant to the Bayh-Dole Act. The district court recently ruled that it needs to receive more evidence on this issue before the case goes to trial. [For more on *Madey v. Duke University*, see “Immunizing University Research from Patent Infringement: The Implications of *Madey v. Duke University*” in the 2003 issue of the *Journal of the Association of University Technology Managers*.

The common-law research exemption may also be implicated in a case, *Merck KGaA v. Integra LifeSciences I, Ltd.*, currently pending in the U.S. Supreme Court. Although the question presented to the Court revolves around the statutory safe harbor that exempts from an infringement charge activities “solely for uses reasonably related to the development and submission of information under a Federal law which exempts the manufacture, use or sale of drugs,” the ambit of the common-law research exemption may arise in the Court’s final decision.

[Editor’s Note: In *Merck KGaA v. Integra LifeSciences I, Ltd.*, the U.S. Court of Appeals for the Federal Circuit had interpreted the “safe harbor” of Section 271(c)(1) of the U.S. Patent Laws to apply only to “clinical testing.
to supply information to the FDA.” On June 13, 2005, the U.S. Supreme Court vacated the lower court’s ruling and remanded for further proceedings in the case (U.S. Supreme Court, No. 03-1237, argued April 20, 2005; decided June 13, 2005). In its decision the U.S. Supreme Court interpreted the safe harbor provision more broadly, stating in part that “(t)he use of patented compounds in preclinical studies is protected under Section 271(e)(1) at least as long as there is a reasonable basis to believe that the compound tested could be the subject of an FDA submission and the experiments will produce the types of information relevant to an IND or NDA.” This decision would seem to benefit the large commercial enterprises that must seek regulatory approvals to bring products to the marketplace; the implications for small biotechnology companies and the university technology transfer community are less clear. However, concerns have been expressed by parties on both sides regarding the boundaries of the safe harbor provision that were not defined in the court’s decision.

Legislative Reforms Are Always Lurking
During the past two decades, legislative proposals were introduced in the House and Senate to alter delicate balances in the Bayh-Dole Act. Most of these proposals were rooted either in a desire to impose price controls for pharmaceutical and biotech products, medical devices, and research tools discovered with the support (even if partial) of federal funding, or to improve the administration of the act.

Pricing Proposals
Some in both the House and the Senate use financial arguments for challenging the fabric of the Bayh-Dole Act, arguing that the price of drugs in the United States is way too high. They also submit that taxpayers have to pay twice for innovation: first by paying taxes to support federally funded research, and, second, by paying for the final product. This argument ignores the high and escalating costs of developing drugs for the market through the extensive regulatory process, a cost borne by the private sector’s university licensee.

For example, in the 108th Congress, the Free Market Drug Act (H.R. 5155) was introduced by Rep. Dennis Kucinich (D-OH) shortly after he left the presidential campaign trail. The proposed legislation requires the direc-
tor of NIH to monitor the results of research conducted or supported by NIH and other public or private entities to identify “candidate discoveries.” By permitting citizen lawsuits for protection of federal ownership of patents, its apparent goal is to reduce drug prices. To achieve price reductions, H.R. 5155 rolls back basic principles of technology transfer to pre-1980 and even earlier when the inoperative climate for drug development was prevalent. It is possible that H.R. 5155 would reduce drug prices, but at the expense of basic research and technology transfer.

Similarly, legislation introduced by Sen. Ron Wyden (D-OR) in past Congresses would require that “reasonable” prices be charged for drugs discovered with federal funding including a specified formula for market price at time of licensure along with bidding by multiple potential licensees and return of at least a portion of royalties generated to the agency that initially supported the research. Wyden’s proposals have not garnered enough bipartisan and bicameral support for passage. If ever enacted, they would have a chilling effect on the transfer of technology in the public interest. As is the case for H.R. 5155, prices might be reduced but at a serious cost—that of less innovation. In 2000, Wyden did succeed in adding language to a conference report for the Department of Health and Human Services appropriations act for fiscal year 2001, asking NIH to prepare a plan to ensure that taxpayers’ interests are protected. NIH concluded that taxpayers’ interests were already being protected.

Public Administration Proposals
In August 1999, in a report to the Senate Judiciary Committee, the U.S. General Accounting Office (GAO) concluded that “Federal agencies and their contractors and grantees are not complying with provisions on the disclosure, reporting, retention, and licensing of federally sponsored inventions under the Bayh-Dole Act and Executive Order 12591.” The net result is that the government is not always aware of federally funded inventions to which it has royalty-free rights, and grantees receive windfalls from inventions funded with taxpayer monies. Recently, Rep. Edward Markey (D-MA) followed up with the GAO to examine whether federal agencies appropriately avail themselves of the government’s royalty-free license to federally sponsored medical/biotechnology inventions. GAO responded by reporting that agencies do a poor job.
Increasingly, intellectual property law professors who lay claim to representing the public interest are advocating a return to federal agency control of inventions made with federal funds including decisions on patenting and mode of licensing. For example, two professors argue that “the time is ripe to fine-tune the Bayh-Dole Act to give funding agencies more latitude in guiding the patenting and licensing activities of their grantees.”

Congress is essentially being asked to clarify that patenting and exclusive licensing are not always the best way to proceed. Giving the funding agencies more leeway would likely result in not being able to license a technological advance and would be extremely deleterious to startup companies that require significant investments. To date, not surprisingly, the proposals have received scant political traction.

Similarly, the American Bar Association, at the behest of its Public Contracts Section, has under consideration a proposal to amend the act to benefit traditional government contractors by expanding other-transactions authority to all agencies. To the extent that the government is willing to negotiate lesser government rights or contractor obligations regarding inventions, the ABA posits that the incentive for commercial companies to do business with the government will increase.

After all is said and done, “existing technology transfer legislation works and should not be altered.”

Conclusion

Arranged marriages between universities and corporations, under the stern eye of the federal government, are not ideal. Universities’ fundamental goals are to teach students, develop new knowledge, and disseminate that knowledge. Corporations’ underlying missions are to produce profits and to build value for shareholders. The role of the federal government is to benefit the public and promote the general welfare of the people. The act requires a *quid pro quo* series of obligations from the various parties. Its underlying goal is that the parties mature into true partners in progress.

The Bayh-Dole Act stimulates memories of two fine senators departed from public service but whose names shine brightly in innovations and discoveries. The memories of others in the Senate and House of Representatives who supported the act, and amendments thereto, should not be forgotten. Nor should the successive administrations—from Jimmy
Carter to George W. Bush—that have supported and sustained the act. An anniversary celebration should not forget the changing face of political representation, with new members of Congress elected every two years, changes in party leadership in the House and Senate, and the constant churning of state officials, who are among the true beneficiaries of the act.

A celebration can be introspective by stimulating discussion, debate, and the development of measurement standards, and inclusive by inviting the naysayers to participate. As a commemoration, it should build for the future. As a bridge, it should identify where we are today with due consideration for the following factors.

The success of the Bayh-Dole Act is apparent to those engaged in technology transfer who are closest to the act. For at least two reasons, to those who approach the act from a distance, the perception and understanding of success seems to decrease. First, the act is not well-known to the public and, more importantly, to elected officials. The operations of the act, and the patent law, sometimes even elude the understanding of university presidents and governing boards. Secondly, data associated with the act, like that gathered and reported by AUTM, although very helpful, do not measure the larger social and economic implications of the act. By expanding its focus from previous years and reporting on twenty-five technology transfer stories in the United States and Canada that achieved significant milestones in 2003, the 2003 AUTM Licensing Survey™ took a large stride forward, showing the actual effect of technology transfer on people, society, and the environment. The number of patents granted or amounts of research money spent, also reported annually, do not translate to benefits to the public.

Because of a political desire to replicate success and to be risk-averse, effective endeavors inevitably raise as many questions as ineffective ones. In the public’s mind, a declaration of success does not lead to the conclusion that positive results have been achieved. Effective laws are dependent on their societal and economic effects and not just public pronouncements.

- Answers to questions are increasingly being proffered by economists who have stepped into the breach. Economic analysis is helpful because it can bring into sharp definition issues of policy. But it is not the final word. Under our system of government, answers to policy questions are delegated to elected officials (national, state, and local) and, ultimately, to the voting public, which makes decisions based on its perception of
social and economic welfare.

- Proponents of the act have been somewhat hesitant to explain and quantify the successes of the act and have even shied away from engaging in public debate to justify what is essentially a political decision (a law enacted by the United States Congress and signed by the president of the United States).
- After twenty-five years, it is time for the proponents to step forward and assist in a realistic appraisal of the act.

Today’s reality is that scientific research requires infusions of substantial amounts of money. The academic community is a favorable habitat for basic research. Once the research is successful in identifying and reducing to practice inventions and sharing information about the inventions with the public, a patent grant is appropriate. Finally, the licensing of technology to the private sector stimulates the investments necessary to bring products to the marketplace and benefits local communities across the United States.

Above all, the twenty-fifth anniversary of the Bayh-Dole Act should be a call to action. Success should not be feared; it should be applauded. Politics is not a dirty business; it is the fabric of democratic governance. Partnerships and collaborations are stronger than the sum of their parts. The act is an inspired piece of legislation. Those involved in technology transfer should be inspired to defend the act, explain its effectiveness to their campus colleagues and political representatives, and, if it ever fails to keep pace with the times (which is not the case today), improve its provisions. The public will benefit, and the celebration will be more than a party.

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Notes
2. See, e.g., “Innovation’s Golden Goose,” The Economist, Dec. 14, 2002, 3. (“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 have been made in laboratories throughout the United States with the help of taxpayer’s money. More than anything, this single policy measure helped to reverse America’s precipitous slide into industrial irrelevance.”)

3. Pub. L. No. 96–517, sec. 6(a), 94 Stat. 3019 (1980) (codified as amended at 35 U.S.C. § 201 et seq. (2000)). The Bayh-Dole Act of 1980 (Patent and Trademark Law Amendments of 1980, Public Law No. 96–517) has been amended and supplemented by numerous statutes, regulations, and other instruments, including the Stevenson-Wydler Technology Innovation Act of 1980 (Public Law No. 96–480), the Trademark Clarification Act of 1984 (Public Law No. 98–620), the Technology Transfer Commercialization Act of 2000 (Public Law No. 104–113), and the Federal Acquisition Regulation. Depending upon the context, the phrase “the Bayh-Dole Act” in this article refers to the Bayh-Dole Act of 1980 or to this broader set of rules and policies that governs the terms under which universities and researchers may claim title to and license inventions arising from government-sponsored research.


10. Id.


14. See PCAST report, *supra* note 1, 9-10 (the Commerce Department may require additional funding to satisfy its responsibilities). The PCAST report makes other recommendations to the Commerce Department including that it should document “best practices” for technology transfer, as well as refine a set of metrics to better quantify practices and their effectiveness and also to add “education” as part of its technology transfer mission.


28. See *Integra LifeSciences I, Ltd. v. Merck KGaA*, supra, 331 F.3d at 872 (dissent of Honorable Pauline Newman).


31. PCAST report, *supra* note 1, at ii.