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Bayh-Dole at 25





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Editor's Preface

Twenty-five years ago, Congress enacted the Patent and Trademark Law Amendments of 1980 (Public Law 96-517). Further amendments were included in Public Law 98-620 that was enacted into law in 1984. Commonly known as the Bayh-Dole Act in recognition of its two lead sponsors in the U.S. Senate, Birch Bayh (D-IN) and Bob Dole (R-KS), this act has been hailed as "possibly the most inspired piece of legislation to be enacted in America over the past half-century."[1] The Bayh-Dole Act has been credited with unlocking federally funded inventions and discoveries and providing platform technologies that have fueled our nation's economic growth.

In this issue of the *AUTM Journal,* our contributing authors reflect on the Bayh-Dole Act twenty-five years after its enactment. Those of us in the university technology transfer community are well-aware of the impact that the Bayh-Dole Act has had upon the growth and development of our profession. The articles that follow will be of interest to our readership as the authors discuss the Bayh-Dole Act from global, political, and legal perspectives.

The first article, "Technology Innovation and Development: Using the Bayh-Dole Act to Advance Development Goals," was written by Pamela Passman, JD, Betsy Brady, JD, and Bill Guidera, JD, all of whom are members of Microsoft Corp.'s Legal and Corporate Affairs Department. These authors state that the "Bayh-Dole Act has been remarkably successful in promoting the transfer of technology from federally funded research labs to the private sector," and they propose that the United States should undertake initiatives to assist developing countries in utilizing components of our nation's technology transfer system.

Passman and her co-authors provide a brief but thorough description of our nation's experience of the Bayh-Dole Act and its effects on technology transfer and economic growth. They then describe technology development policies in other nations and provide examples of the adoption by other developed nations of policies similar to those contained in the language of the Bayh-Dole Act. The authors express curiosity as to why more attention has not been paid to Bayh-Dole-type policies in developing economies and

recipients to forfeit their patent rights if they do not fulfill the obligations detailed in the act.

Locke and Guttag provide a framework for their discussion of *Campbell Plastics* by first reviewing for the recipients of federal funds their obligations under the Bayh-Dole Act. According to the authors, prior to *Campbell Plastics,* the risk of losing patent rights for failure to comply with these obligations was perhaps believed to pose only a theoretical threat. In the analysis of *Campbell Plastics* that follows this statement, Locke and Guttag provide ample evidence that such a belief is no longer justified. In the conclusion of their article, they provide recommendations for universities and other federally funded entities that desire to ensure compliance with the provisions of the Bayh-Dole Act.

This issue of the *AUTM Journal* concludes with a letter to the editors from Christopher T. Hill, PhD, PE, professor of public policy and technology, School of Public Policy, George Mason University and former president, George Mason Intellectual Properties Inc. Hill comments on the set of articles on university-based startups that was presented in the Fall 2004 issue of the *AUTM Journal* and identifies a key factor that was missing from all of the articles. According to Hill, a fundamental issue is whether or not the nature of the technology itself, in combination with the markets it is expected to serve, conditions whether a startup makes sense. Hill expands upon this issue, and we commend his comments to your attention.

The editors are grateful to the authors of these articles and letter for their willingness to share their thoughts and concepts with the readers of the *AUTM Journal* and devoting the time and energy necessary to produce these articles and work through the editing process prior to publication. The members of the Editorial Advisory Board also are deserving of gratitude for assisting in the selection of abstracts, and then, carefully reviewing and commenting upon various draft versions of these articles. Thanks also to the *AUTM Journal* Managing Editor Lisa Richter and her colleagues at The Sherwood Group Inc. for their efforts in making this an outstanding publication.

We believe that you will find this edition of the *AUTM Journal* useful and informative. Planning for the second 2005 issue of the *AUTM Journal* is already under way. We trust that our readers will join us in looking forward to this upcoming issue that will focus on "Licensing Success Stories."

Technology Innovation and Development: Using the Bayh-Dole Act to Advance Development Goals

Pamela Passman, JD, Betsy Brady, JD, and Bill Guidera, JD

Abstract

The Bayh-Dole Act has been remarkably successful in promoting the transfer of technology from federally funded research labs to the private sector. Although other governments are now looking to Bayh-Dole as a model, most of this interest has been limited to developed countries. This article examines the potential benefits of the Bayh-Dole framework for developing countries—both for local industries and to generate revenue for local nonprofit research labs. It also proposes initiatives that the United States should undertake to help developing countries establish the rules and institutional mechanisms necessary to promote technology transfer in their own countries.

Introduction

As we survey the impact of the Bayh-Dole Act on this twenty-fifth anniversary of its enactment, there can be little doubt that the act has achieved the goals Congress envisioned for it. University patenting and licensing of inventions arising from government-sponsored research have grown dramatically, resulting in thousands of new commercial products, and substantial spillover effects in the form of greater private-sector innovation, increased economic activity, and job growth.[1] These achievements have not gone unnoticed beyond America's shores. Since 1980, several nations have adopted laws that emulate key provisions of the Bayh-Dole framework, while international organizations and think tanks have devoted entire programs to analyzing the benefits of technology development policies modeled on the Bayh-Dole Act.[2]

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indicates that no fewer than 472 new commercial products utilizing university-owned technologies were introduced to the market in 2003, bringing to 2,230 the total number of such products introduced since 1998.[4] These include innovative products in the areas of health care, electronics, software, agriculture, and energy.[5] Nearly 26,000 licenses and options to university-held inventions were in force in 2003, providing access to technologies protected by the more than 32,000 patents obtained by universities since 1993.[6] By comparison, fewer than 250 patents on average were issued annually to U.S. universities in the years preceding enactment of the Bayh-Dole Act.[7]

It is also widely recognized that the Bayh-Dole Act has generated important spillover benefits beyond those specified in the statutory language. First, licensing royalties from university-owned technologies have provided an additional source of funding for universities and, more importantly, generated supplemental private-sector support for universities in the form of research grants, endowments, and contributions for capital investments.[8] Gross income from licenses and options to university-owned technologies reached $1.31 billion in 2003, an increase of 6 percent from the $1.235 billion in revenues realized in 2002.[9] University-licensed technologies are now a significant resource for many technology industries, particularly in such areas as biotechnology and information technology, and have fostered the creation of thousands of startup firms. Since 1980, more than 4,000 new companies have been formed based on technologies licensed from academic institutions, including 374 company startups established in 2003.[10]

Finally, the licensing and commercialization of university-owned inventions have benefited society through the creation of innovative new products and services, which, in turn, have generated additional economic activity and employment. It is estimated that the licensing of inventions by universities, teaching hospitals, research institutes, and related organizations added more than $40 billion to the U.S. economy in 1999 and supported an estimated 270,000 jobs.[11]

The Bayh-Dole framework comprises a complex set of rules, incentives, and procedural safeguards. Its success is attributable, in large part, to the nuanced way in which these various elements interact. That said, three pillars of the Bayh-Dole framework are particularly noteworthy in terms of its advance over the regulatory structure that it replaced.

First, the Bayh-Dole Act *delegates decision-making authority* on

technologies with less certain commercial potential a viable option.

These three pillars of the Bayh-Dole framework have helped foster an environment in which government-sponsored research now generates tremendous economic and societal benefits that were unrealized under the pre-existing regulatory structure. Critically, these gains have been achieved without any significant increase in public expenditures. Instead, the Bayh-Dole Act effectively "funds" these benefits by exploiting the previously untapped commercial potential of inventions arising from government-sponsored research and by leaving it to the market to sort out which inventions are worthy of commercial development.

Technology Development Policies in Other Nations

Drawing on the United States' experience over the past twenty-five years, several other nations have adopted policies that emulate aspects of the Bayh-Dole framework. A recent study by the Organization for Economic Cooperation and Development (OECD), for instance, found that most of the member nations of the OECD had adopted or were in the process of evaluating regulatory systems that made it easier for universities to claim title to and license inventions arising from government-sponsored research.[12]

Not surprisingly, this study also found significant variations in technology transfer policies among OECD countries. For instance, while many OECD members have reformed their laws to enable universities and other public research institutions to claim title to inventions arising from government-funded research, there appears to be less uniformity in the types of incentives for institutions and researchers to disclose, patent, and actively license inventions.[13] Indeed, one outgrowth of the OECD study is the need for governmeuts to give close attention to these incentives to maximize the commercial potential of such inventions.[14] More broadly, however, the OECD study and others like it largely confirm the U.S. experience that effective policies for enabling public and private research organizations to retain title to and license inventions arising from government-funded research can generate benefits for the public research organizations themselves, for firms that develop commercial products based on these inventions, and for society in the form of new products and economic growth.

Given this growing international consensus, it is somewhat surprising that there has not been more interest in the Bayh-Dole framework among

equal). Furthermore, many developing nations have only recently revised their intellectual property laws to extend protection to patentable subject matter. Even those that have enacted the necessary legislation may not yet have fully operational patent offices or sufficient qualified patent examiners. Also, many developing nations are focused on solving more pressing and intractable issues such as poverty, education, disease eradication, and, consequently, devote few if any resources to basic scientific research. Finally, given the significant resources necessary to establish and maintain technology transfer offices, obtain and enforce patents, and implement technology licensing, some nations might question whether the benefits of maintaining an effective technology transfer program are worth the costs.

For these nations, it seems reasonable to assume that there might be little benefit in adopting technology development policies along the lines of the Bayh-Dole framework. Even among those nations that do invest in basic research, many may lack the infrastructure, resources, and expertise necessary to support a Bayh-Dole framework.[20]

For these reasons, it seems reasonable to assume that the technology development policies discussed above will be less appropriate to some developing nations than to others, and that variations in the level of industrial development, resources, and infrastructure among developing countries will be important factors in evaluating which elements of such policies will be most relevant, if at all, to a given country. Nevertheless, there are grounds to believe that, for at least certain developing countries—particularly those with high-quality public research institutions and a significant pool of potential licensees—technology development policies along the lines of the Bayh-Dole Act might offer important benefits.

First, such policies would enable developing economies to make more efficient use of public funds. By giving public research organizations the ability to claim title to inventions arising from government-sponsored research, as well as meaningful incentives to license these inventions to the private sector, the Bayh-Dole framework allows governments to extract social and economic value from such research beyond the direct value of the research to the sponsoring agency. While there is undoubtedly a cost to tapping into this additional value in the form of technical infrastructure and support, most of these costs are effectively borne by the private sector through licensing royalties. Furthermore, the experiences of nations that

various and interrelated factors. At a minimum, however, these reasons suggest that the potential benefits of such policies for developing countries deserve greater attention, not only from these countries themselves, but also from all interested stakeholders—including the United States.

Recommendations for the United States Government and Universities

Recently, a number of institutions—including the Association of University Technology Managers (AUTM) and the International Intellectual Property Institute—have begun to assist policymakers in developing nations to evaluate and, where appropriate, implement legislation modeled on core aspects of the Bayh-Dole Act.[21] Yet the lack of more comprehensive efforts in this area—and, particularly, the apparent lack of more overt and coordinated support from the United States government—is surprising. Indeed, that the United States government has not been more active in this area may represent an important missed opportunity in the government's efforts to promote international development and global economic growth.

For the reasons outlined above, providing technical assistance and resources to developing countries that already invest significant governmental funds into basic scientific research could generate strong dividends in terms of helping those countries become more integral players in the innovation economy and could also provide a viable means of strengthening economic (and perhaps also security) ties between the United States and developing nations in a manner that complements current programs. Accordingly, the U.S. government and American research universities should give serious consideration to measures that would help developing countries establish the rules and institutional mechanisms necessary to promote technology development through the dissemination and commercial development of inventions arising from government-sponsored research. Although a comprehensive evaluation of such steps is beyond the scope of this article, an initial list of options includes the following.

United States Government

The United States government should explore opportunities to work with leading international institutions—such as the OECD, the World Intellectual Property Organization and the World Bank—and with key stakeholders—such as the U.S. Agency for International Development and university

have implemented technology development policies of their own. Coordinated international action not only would lessen the demands on U.S. officials in supporting such initiatives but also would give the host developing country the benefit of multiple perspectives on the types of intellectual property policies, incentives, and licensing models that can be used to actualize the goal of commercializing inventions arising from government-sponsored research.

University Technology Transfer Offices

Universities—and particularly university technology transfer officials—could also play a key role in this area. First, universities could advocate in favor of government initiatives to assist developing countries in adopting technology development policies, including initiatives such as those described above. Universities could also sponsor officials from sister institutions in developing countries for internships or short-term employment in the university's technology transfer office.

Universities could work collectively on initiatives, such as through AUTM or the Council on Governmental Relations, or perhaps in partnership with the World Intellectual Property Organization, which has undertaken several initiatives to help developing countries establish the legal and institutional frameworks needed to protect and enforce intellectual property rights. For instance, AUTM could build upon its existing initiatives in this area by creating an online portal through which developing countries or other interested parties could obtain instructional materials, find links to other resources, and pose questions to university technology transfer officials in the United States. Universities could also establish fellowships or grants for graduate students from developing countries to undertake advanced study or research in areas relevant to technology development.

Although the options listed above arguably represent the gold standard in developing-country outreach efforts, universities could also undertake less resource-intensive initiatives. For instance, universities could sponsor seminars or workshops, pairing the concepts of technology development and global economic development and inviting speakers from government, education, and the private sector. These seminars could explore ways in which licensing of government-sponsored research might be relevant to the more urgent issues confronting developing nations today, and how policies in this area might provide a catalyst for domestic innovation and economic growth.

3. See Section 200 of the Patent Act, 35 U.S.C. § 200, which lists Congress's objectives in enacting the Bayh-Dole Act.
4. Association of University Technology Managers, *AUTM Licensing Survey: FY 2003* (Northbrook, IL: AUTM 2004): 3.
5. Id.: 4-11.
6. Id.: 4.
7. Association of University Technology Managers, "FAQs," available at http://www.autm.net/aboutTT/aboutTT_faqs.cfm#6.
8. See International Intellectual Property Institute, *South African University Technology Transfer: A Comparative Analysis* (Washington, DC: IIPI 2004): 6, 12–15.
9. Association of University Technology Managers, *AUTM Licensing Survey: FY 2003* (Northbrook, IL: AUTM 2004): 4.
10. Id.
11. Association of University Technology Managers, "FAQs," available at http://www.autm.net/aboutTT/aboutTT_faqs.cfm#6.
12. Organization of Economic Cooperation and Development, *Turning Science Into Business: Patenting and Licensing At Public Research Organizations* (Paris, France: OECD Publications 2003): 11-12, 21–35.
13. Id.: 11.
14. Id.: 12.
15. International Intellectual Property Institute, *South African University Technology Transfer: A Comparative Analysis* (Washington, DC: IIPI 2004): 29–30 (discussing Brazilian legal regime); Patent Facilitating Centre, *Instructions for Technology Transfer and IPR*, available at http://www.pfc.org.in/info/tt_ipr.htm.
16. International Intellectual Property Institute, *supra* note 15. See also United Nations Conference on Trade and Development (UNCTAD), *The Role of Publicly Funded Research and Publicly Owned Technologies in the Transfer and Diffusion of Environmentally Sound Technologies* (New York and Geneva: UNCTAD 2000): 74–77, available at http://www.unctad.org/en/docs/psiteiipd9.en.pdf.
17. UNCTAD, *supra* note 16.
18. Id.
19. Id.: 75.

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 Meeting℠ 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,[1] 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.[2] Economic growth depends 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.

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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.[4] Data reported to the Association of University Technology Managers (AUTM) for 2003, and reflected in the *AUTM Licensing Survey™*,[5] 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.[6] 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."[7]

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."[15]
- 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]."[16]
- 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."[17]

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."[18] 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

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 invocation 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

The Common Law of Experimental Use and Research Exemption Creates Controversy

A federal appellate court decision, *Madey v. Duke University*,[24] 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.[25] [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.*, [26] 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,"[27] the ambit of the common-law research exemption may arise in the Court's final decision.[28]

[*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(e)(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

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."[29] 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

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.[32] 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

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.
4. William M. Landes and Richard A. Posner, *The Economic Structure of Intellectual Property Law* (Cambridge, MA: Harvard University Press, 2003), 294. (Explaining that the patent system may also be a response to economic problems inherent in market structure and trade secrecy).
5. Association of University Technology Managers, *AUTM Licensing Survey™: FY 2003 Survey Summary* (Northbrook, IL: Association of University Technology Managers, 2005), available at http://www.autm.net/events/File/Surveys/03_Abridged_Survey.pdf.
6. Milken Institute, *Biopharmaceutical Industry Contributions to State and U.S. Economies: United States Overall Summary* (2003), http://www.biopharmaimpact.com/index.taf.
7. Lita Nelsen, "The Rise of Intellectual Property Protection in The American Universities," *Science*, March 6, 1988, 1460.

20. *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Report of the Federal Trade Commission (October 2003), http://www.ftc.gov/os/2003/10/innovationrpt.pdf.
21. National Research Council, *A Patent System for the 21st Century*, ed. Stephen A. Merrill, Richard C. Levin, and Mark B. Myers (Washington, DC: National Academies Press, 2004).
22. See Sherrod Brown (D-OH) to Secretary of Health and Human Services Tommy Thompson, August 17, 2004, reprinted at http://www.house.gov/sherrodbrown/releases/archives/2004/norvir81704.html. No other members have joined forces with Rep. Brown.
23. See 10 U.S.C. § 2371 (2000).
24. 307 F.3d 1351 (Fed. Cir. 2002), cert. denied, 123 S.Ct. 2639 (2003).
25. *Madey v. Duke University*, 336 F. Supp. 2d 583 (M.D.N.C. 2004).
26. No. 03-1237, 125 S. Ct. 823 (2004), on writ of certiorari to the U.S. Court of Appeals for the Federal Circuit, 331 F.3d 860 (Fed. Cir. 2003).
27. 35 U.S.C. § 271(e)(1)(2000).
28. *See Integra LifeSciences I, Ltd. v. Merck KGaA*, *supra*, 331 F.3d at 872 (dissent of Honorable Pauline Newman).
29. U.S. Gen. Accounting Office, *Report to the Chairman, Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision* (1999) (GAO/RCED-99-242), available at http://www.gao.gov/archive/1999/rc99242.pdf. Executive Order 12591 of April 10, 1987 (Facilitating access to science and technology), 52 Fed. Reg. 13414 (April 22, 1987), instructs federal agencies how to administer the act.
30. Arti K. Rai and Rebecca S. Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine," *American Scientist*, January/February 2003, 52, 59.
31. PCAST report, *supra* note 1, at ii.
32. See *AUTM Licensing Survey™ FY2003*, *supra* note 5, at 5-11.

Losing Patent Rights for Failing to Comply with the Bayh-Dole Act: The Implications of *Campbell Plastics* on Federally Funded University Research

Scott D. Locke, JD, and Eric W. Guttag, JD

Abstract

Federal funding, typically in the form of research grants, is often used to support university research. Most universities are aware that the Bayh-Dole Act allows them to retain title to patent rights in snch research. What universities may not know is that the Bayh-Dole Act is a two-edged sword: patent rights can also be lost if the subject invention is not timely disclosed to the federal funding agency. This was sadly brought home by the recent case of *Campbell Plastics Engineering & Mfg., Inc. v. Brownlee*, where the Court of Appeals for the Federal Circuit affirmed an administrative ruling that a federal defense contractor forfeited its patent rights under the Bayh-Dole Act for such failure to timely disclose.

Introduction

Federal grants provide the majority of funding for university-based research. Most universities are aware that the Bayh-Dole Act[1] allows them to retain title to patents derived from such federally funded research. What universities may not appreciate is that the federal government, to protect the public's investment in such research, imposes many obligations on those who receive those funds, including a requirement that potential inventions from such research be disclosed in a timely manner to the funding agency. There was always the legal, but generally unenforced, possibility that failure to comply with this and other obligations could cause loss of these valuable patent rights.

That legal possibility now has become an enforced reality, as was brought home by the recent case of *Campbell Plastics Engineering & Mfg.*,

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the different funding agencies to administer their contracts in an essentially uniform manner. While agencies can, to a small degree, modify and tailor contract clauses, this standard patent rights clause also enables a university to understand and to comply more easily with its contractual obligations.

For universities conducting federally funded research, there are fifteen obligations pertaining to patent rights under a standard funding agreement; the first five obligations are of particular importance to the patent filing:[3]

- Disclose each subject invention to the funding agency within two months after the inventor discloses the invention to the person who is responsible for patent matters at the university, for example, the university's director of intellectual property.
- Within two years of disclosure, notify the funding agency in writing whether the university elects to retain title.[4]
- No later than one year after electing to take title,[5] file an initial United States patent application.[6]
- Notify the funding agency of any decision not to prosecute a patent application, not to pay maintenance fees for a patent, or not to defend a challenge to a patent.
- Include a statement in the filed U.S. patent application that indicates the invention was made with the support of federal funds, identifies the funding contract(s) and agency or agencies, and provides notice that the federal government has rights in the invention.[7]
- Agree to execute or to deliver promptly to the funding agency all instruments necessary to establish or to confirm the rights that the federal government has in the invention(s) to which title is retained throughout the world.
- Implement a policy (by written agreement) requiring university employees to disclose promptly to the university person responsible for patent matters all inventions subject to a funding agreement.[8]
- Include the standard patent rights clause in university subcontracts.
- Agree to submit periodic reports on request, but no more often than annually, on utilization of the subject invention or efforts to obtain such utilization by the university, its licensees, or assignees. [9]
- Require any exclusive licensee or assignee to agree that any products that embody the subject invention, or are produced through its use, will be manufactured substantially in the United States.[10]

Campbell Plastics

In *Campbell Plastics*, the predecessor of a federal contractor (collectively referred to as contractor) entered into an agreement with the Army Chemical Research Development Engineering Center to develop certain components of an aircrew protective mask. The agreement also contained a patent rights retention clause, including a provision that would allow the Army to obtain title to a subject invention if the contractor failed to disclose that subject invention within two months from the date on which the inventor disclosed it in writing to contractor personnel responsible for patent matters.[15] The agreement also provided that the contractor should disclose subject inventions on a specified form (DD 882) in annual interim reports, as well as in final reports within three months after contract work was completed.[16]

Between September 1992 and September 1994, the contractor filed three interim reports with the Army on form DD 882 that did not identify or disclose any subject inventions developed under the agreement.[17] After September 1994 and through August 1997[18] when the contractor contacted its patent attorney about drafting a patent application on the subject invention (sonic welding of mask components) that became the focus of *Campbell Plastics*, the contractor filed no more interim reports on form DD 882. In June 1997, the Army published a report (the June 1997 report) on research conducted by the Army from October 1991 through July 1995, including research on sonic welding of mask components that became the basis for the Army's subsequent joint ownership claim.

During this same timeframe, the contractor submitted to the Army at least sixteen progress reports and drawings on the development under the agreement of sonic welding of mask components. A patent application on sonic welding of mask components was filed by the contractor on October 9, 1997. For the limited purpose of making a secrecy determination, the Army received and reviewed a copy of the subject patent application no later than January 30, 1998. The subject patent application eventually issued on April 20, 1999, as U.S. Patent 5,895,537 (the '537 patent).

The '537 patent identified the contractor's agreement with the Army and expressly reserved to the federal government a paid-up license, as well as "the right in limited circumstances to require the patent owner to license others on reasonable terms" as provided for in the contractor's agreement.

all features" of the subject invention to the Army throughout the agreement period. Instead, the Federal Circuit said that the agreement's requirement "of a single, easily identified form on which to disclose [subject] inventions is sound and needs to be strictly enforced." The Federal Circuit was particularly concerned about whether the Army would ever be certain of what subject inventions were being disclosed if "any piece of paper or oral statement" from the contractor "might be part of an overall invention disclosure."

The contractor also argued that such "forfeiture" of its rights under the '537 patent was legally disfavored. The Federal Circuit was not impressed with this argument. Instead, the Federal Circuit emphasized that the contractor "cannot use the proposition that forfeiture is a disfavored remedy as an absolute shield to thwart the government's right to enforce the terms" of an agreement that the contractor had willingly signed.

The Federal Circuit finally considered whether the Board was correct in determining that the Army (through its ACO) had not abused its discretion in taking title to the subject invention of the '537 patent. As it had argued to the Board, the contractor argued to the Federal Circuit that the ACO abused his discretion by demanding title because the federal government had allegedly suffered no harm. The Federal Circuit rejected this argument, holding that "harm to the government is not a requirement in order for the ACO to insist on forfeiture and remain within the bounds of sound discretion." Instead, the Federal Circuit found that the Board had "correctly applied the proper test in deciding that no abuse of discretion" was committed by the ACO in demanding title to the '537 patent.

The Implications of *Campbell Plastics* and its Unresolved Issues

The Federal Circuit in *Campbell Plastics* sent several very clear warnings about complying with contractual obligations based on the Bayh-Dole Act:

- *Loss of patent rights is an appropriate consequence when the contractor fails to disclose the subject invention to the funding agency.* Whether the contractor will actually lose those patent rights is entirely up to the "sound discretion" of the funding agency.
- *The funding agency can dictate, within reason, at least the form of compliance.* For example, disclosing the subject invention to the funding agency in a format other than that specified in the funding agreement is extremely risky.

Conclusion: What Can Universities Do to Comply with the Bayh-Dole Act?

Campbell Plastics merits the serious attention of any university administrator involved in federally funded research. The possibility of a university losing its valnable patent rights from federally funded research becanse of a failure to comply with its Bayh-Dole Act obligations can no longer be ignored. In addition to the loss of licensing income and potentially being subjected to financially costly lawsuits by others (e.g., the licensee) who are adversely impacted by such failure to comply, the university could suffer other significant consequences such as damage to the university's reputation with its faculty and staff, as well as with the research community in general. Indeed, and especially if such failure to comply becomes or is perceived to be a systemic problem, the university could be branded as being unable or unwilling to comply with its funding agreements, thus potentially jeopardizing future funding opportunities.

So what can universities do to avoid the loss of patent rights, as well as other potentially undesirable consequences, in view of *Campbell Plastics*? Here are some recommendations:

- *Review the relevant provisions in the federal funding grant or agreement and make sure that there is a clear understanding of how the funding agency wants the university to comply with its obligations under the Bayh-Dole Act. Campbell Plastics* held that the funding agency can dictate, within reason, how to comply. Following the format that the funding agency requires is, thus, mandatory, so the university must understand what that format is.
- *Educate all key university players as to what their Bayh-Dole Act obligations are under the federal funding grant or agreement.* This not only includes university grant and intellectual property administrators, but any faculty, staff, student, etc., who is connected with the federally funded research.
- *Institute formal procedures to ensure that there is compliance with Bayh-Dole Act obligations under a federal funding grant or agreement.* This is particularly important with regard to any events directly connected to securiug patent rights, including disclosing inventions to the funding agency in a timely manner, taking title to inventions disclosed to the funding agency in a timely manner, and timely informing the

** The views expressed herein are solely those of the authors and do not necessarily reflect the views of Kalow & Springut LLP, Jagtiani + Guttag, or AUTM.*

Notes

1. 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.
2. 389 F.3d 1243 (Fed. Cir. 2004).
3. See 35 U.S.C. § 202(c); 37 C.F.R. §401.14. See also Scott Locke, "Patent Litigation and Other Federally Funded Inventions and the Failure to Comply with Bayh-Dole," *Virginia Journal of Law and Technology* 8 (2003), 3, for a more extensive discussion of these obligations under the Bayh-Dole Act. Other valuable sources of information and guidelines on complying with the invention reporting, patent filing, etc., requirements of the various federal agencies (e.g., NIH) under Bayh-Dole include the Interagency Edison Web site at https://s-edison.info.nih.gov/iEdison/, the Council for Governmental Relations Web site at http://www.cogr.edu, as well as the AUTM *Technology Transfer Practice Manual™* (2nd Edition), copies of which can be obtained through the AUTM Web site at http://www.autm.net.
4. This period can be shortened if an event such as publication, sale, or public use necessitates earlier filing of the patent. See 37 C.F.R. § 401.14(c)(6).
5. The deadline for filing may be sooner if an event such as publication, sale, or public use necessitates earlier filing.

knowledge, the federal government has never exercised its march-in rights. See Marie Thursby, Jerry Thursby, and Emmanuel Dechenaux "Shirking, Shelving and Sharing Risk: The Role of University License Contracts" (2004), 4, www.tiger.gatech.edu/files/gt_tiger_shirking.pdf. ("The fact that the federal government has never exercised its march-in rights under the Bayh-Dole Act has contributed to the view that perhaps these rights should be strengthened.")

12. There are numerous other provisions under which the federal government can acquire title to an invention. See, e.g., 42 U.S.C. § 5908. However, Congress was careful to specify that, with respect to nonprofit organizations (e.g., universities) and small businesses, the provisions of the Bayh-Dole Act take precedence. See 35 U.S.C. § 210.
13. 35 U.S.C. §§ 202(c)(1) & 202(c)(2); 37 C.F.R. § 401.14 (c)(1) & (c)(2); 37 C.F.R. § 401.14 (d). It is within the funding agency's discretion whether or not to receive title. See 37 C.F.R. § 401.14 (d).
14. See text discussion at footnotes 26-27 *infra.*
15. 48 C.F.R. § 52.227-11, also referred to as Federal Acquisition Regulation (FAR) 52.227-11.
16. 48 C.F.R. § 252.227-7039 (FAR 252.227-7039).
17. The first two interim reports were apparently prompted by a reminder from the Army.
18. August 1997 eventually became the key date/time period in establishing when the subject invention was in existence so that it should be disclosed to the Army. See text discussion at footnote 21 *infra.*
19. *In re Campbell Plastics Engineering & Mfg., Inc.*, 2003 WL 15183134 (A.S.B.C.A. March 18, 2003).
20. 35 U.S.C. § 202(c)(1).
21. Interestingly, an exact date or period for when the subject invention first existed (i.e., was first conceived or reduced to practice) was never determined by the Board or by the Federal Circuit, except by inference. For example, in support of its inventorship claim, the Army argued to the Board that the subject invention was in existence at least as early as June 1997, i.e., based on the June 1997 report. The Federal Circuit indirectly refers to the subject invention as existing at least by August 1997, i.e., when the contractor disclosed the sonic welding method of the '537 patent to its patent counsel. In practice, contractors need to

Letter to the Editor

Dear Editors,

Thanks to the editors and authors for a most interesting and useful set of articles on university-based startups in the Fall 2004 issue of the *Journal of the Association of University Technology Managers.* Undoubtedly, we will make use of the collective wisdom and insights in these pieces.

One of the key factors underlying the discussion of when to pursue the "startup" route to commercialization seems to be missing from all of the articles, perhaps because it is so fundamental that it escapes analytical treatment. In my view, the nature of the technology itself, in combination with the markets it is expected to serve, conditions whether a startup makes sense.

For example, when application of the technology would be realized through its integration into a complex technical systeru, the chances are small that it would be produced by any firm, established or startup, as a standalone product. An illustration of this case might be a new patentable mathematical algorithm that can be integrated into an existing commercial software system to improve the performance of that system on some measure. It is unlikely that one would start a company to manufacture and sell the algorithm, and it is equally unlikely that there would be a viable independent market for software based on the algorithm. At George Mason, for example, one of our faculty has developed and we have patented a new and better method for constructing straight-line segments in software. This method is of interest to makers of software for, for example, CAD systems. However, we have never contemplated trying to start a company to produce and sell straight lines or to sell a software module that draws straight lines.

Thus, the technology itself precludes basing a startup on it.

Hypothetically, one could envision any number of new, patentable engineering technologies that improve the performance of existing complex electromechanical-optical devices hut that would constitute only one element among tens to thousands of parts. Conceivably, such a new technology might be produced by a startup and sold to existing OEMs, but the business case for licensing the idea to the systems manufacturer is probably much stronger than it would be for producing one small element to be sold into a monopsonistic market.

Instructions for Contributors

Effective in 2004, AUTM increased the publication frequency of the *AUTM Journal* from annually to two times per year. In addition, the journal—which now publishes three or four articles per issue—has moved to a topic-driven format, allowing for in-depth analysis and discussion of the major issues of the day. Themes will be announced in the call for abstracts prior to each issue via the *AUTM Newsletter* and the AUTM Web site.

Submission Process: Abstracts

Once the call for papers has been issued, authors are encouraged to submit the following:

- an abstract of at least 300 words describing the paper and the source of information for the article (e.g., personal experience, interviews, or statistical research), followed by bulleted key points of the article
- the potential paper's relevance to the theme of the upcoming *AUTM Journal*
- a short explanation of why the paper would be of interest to AUTM members
- a summary of the author's professional background

To submit an abstract, send it to AUTM headquarters via e-mail at autm@autm.net. Please put "AUTM Journal abstract" in the subject line to ensure it is routed to the appropriate person.

The *AUTM Journal* also welcomes suggestions for potential authors. To submit recommendations for potential authors, send an e-mail to AUTM headquarters at autm@autm.net. Please put "AUTM Journal" in the subject line to ensure it is routed to the appropriate person.

Mission Statement

In accordance with this new direction and the journal's mission statement—to publish high-quality peer-reviewed articles for the technology transfer professional—the journal seeks papers that

- are well-suited to the theme of the issue
- are timely and relevant
- are original and unpublished
- are substantive, factually correct and well-researched, documented and supported

- represent a variety of viewpoints, including, but not limited to, legal, industry, and university perspectives

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Letters to the Editor

Letters commenting on the issues discussed in published articles or on other matters of interest to technology managers are welcome and will be considered for publication as Letters to the Editor or forwarded to the author for reply at the discretion of the editor.

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In my view, then, the nature of the technology and its foreseeable applications should be a key consideration in determining whether to pursue the startup route. This is not so much a consideration of the *risk* of a startup, but of whether a startup makes sense at all. In view of the enthusiasm for startups expressed by university administrators, political leaders, and the business press, it is important to keep in mind that they are simply not always appropriate commercialization vehicles.

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pay close attention to the timing of when the invention existed, not only for purposes of the Bayh-Dole Act, but also for dealing with the many subsections of 35 U.S.C. § 102 (novelty). See, e.g., 35 U.S.C. § 102(g) (proof of being the first to invent without abandoning, suppressing, or concealing the invention).

22. 35 U.S.C. § 202(c)(1); 37 C.F.R. § 401.14 (c)(1).
23. See, e.g., 35 U.S.C. § 202(c)(3) and 37 C.F.R. § 401.14 (c)(3). The funding agency can receive title to the subject invention in those countries where the contractor has failed to file patents within ten months of the filing of the first filed or "priority" application, usually the U.S. patent application.
24. See, e.g., 35 U.S.C. § 202(c)(5) on the right of the funding agency to require periodic reporting from the contractor on its efforts to obtain utilization of the funded research.
25. See, e.g., *Fenn v. Yale*, 2004 WL 2793274 (D. Coun. Sept. 29, 2004).
26. In *TM Patent v. IBM*, 121 F. Supp. 2d 349 (S.D.N.Y. 2000), the Southern District of New York held that failure to comply with the Bayh-Dole Act (i.e., 35 U.S.C. § 202) meant that the funded private party never acquired title to the invention. See also *Thermalon Industries Ltd v. United States*, 34 Fed. Cl. 411 (1995) where the United States Court of Claims held that the federal government acquired title when the subject invention had not been disclosed to the funding agency within a reasonable time.
27. The holdings in the *TM Patent* and *Thermalon Industries* cases that the federal government *automatically* gets title appear to be inconsistent with the discretionary language used in the Bayh-Dole Act. See 35 U.S.C. §§ 202(c)(1) & 202(c)(2) ("the Federal Government may receive title"). The holdings in these cases also are arguably inconsistent with the corresponding Bayh-Dole Act regulations. See 37 C.F.R. §401.14(d), which states, in part: "The contractor will convey to the Federal agency, *upon written request*, title to any subject invention." (Emphasis added.)

6. The need to file patent applications within one year of taking title potentially can cause the university decisional headaches, especially if the disclosed invention is not really ready for patenting. Unfortunately, the need to timely disclose the invention to the funding agency so as to be in compliance with the Bayh-Dole Act may lead to such premature disclosure "out of an abundance of caution." The university also must file foreign or international patent applications within ten months of the initial U.S. patent filing, or six months from the date of receiving a foreign filing license. See 35 U.S.C. § 202(c)(3); 37 CFR § 401.14(c)(3). This time period for filing a foreign or international patent application is at least two months less than the time provided by international treaty for such filing to rely on the initial patent filing for priority. Given the potentially great expense to file foreign/international patent applications, universities can again be faced with making some significant and potentially costly decisions with less time than they might otherwise have had if the research were not federally funded.
7. 37 C.F.R. § 401.14 (f)(4). The funding agency also retains a nonexclusive, nontransferable, irrevocable paid-up license to practice or to have practiced the subject invention for or on behalf of the United States throughout the world. See 35 U.S.C. § 202(c)(4); 37 C.F.R. § 401.14 (b).
8. 37 C.F.R. § 401.14(f)(2). The employees also must be required to execute the documents necessary for patent filings and be educated on the importance of timely reporting of inventions.
9. Should a march-in proceeding be undertaken, the university must supply additional requested information. See 35 U.S.C. § 202(c)(5); 37 C.F.R. § 401.14 (h).
10. A waiver of these requirements is possible. See 35 U.S.C. §§ 202(c)(8) & 204; 37 C.F.R. § 401.14 (i).
11. 35 U.S.C. §§ 202(c)(8) & 203; 37 C.F.R. § 401.14 (j). If the university refuses, the funding agency itself can grant the license. Historically, funding agencies have been extremely reluctant to invoke these march-in rights, even when under public pressure to do so. For example, in 2004, the National Institutes for Health (NIH) refused to invoke march-in proceedings in the face of widespread complaints about the cost of the drugs Norvir and Xalatan. See *In re Norvir*, NIH (July 29, 2004), www.ott.od.nih.gov/NewPages/Norvir; *In re Xalatan*, NIH (Sept. 17, 2004), www.ott.od.nih.gov/NewPages/xalatan.pdf. To the authors'

funding agency of and timely filing patents on disclosed inventions in the United States, as well as countries outside of the United States.

- *Undertake periodic internal due diligence reviews to check for compliance with Bayh-Dole Act obligations, especially with regard to federally funded research where invention disclosures have already been submitted, patents are pending, etc.* While this may be considered burdensome to do, the consequences of overlooking a failure to comply can be grave indeed. If a problem is discovered promptly enough, there may even be time to take remedial action to avoid the potential loss of rights.
- *Take prompt action to try to remedy any failure to comply with Bayh-Dole Act obligations.* All is not necessarily lost if such a failure is discovered in time, and a diligent, good faith effort is made to come into compliance. For example, if a subject invention was submitted to the university patent administrator more than two months earlier but before the patent is filed, promptly disclose that subject invention (on the correct form) to the funding agency. Most funding agencies are not interested in and do not have the resources to exploit inventions from federally funded extramural research, and some may not even be aware of the university's obligations under the Bayh-Dole Act. Again, the funding agency is more likely to exercise its "discretion" *not to take title* if the university proactively tries to remedy what may be a technical failure to comply with the Bayh-Dole Act.

Campbell Plastics may prompt funding agencies to focus more on the obligations of contractors, including universities and other nonprofit research institutions, under the Bayh-Dole Act. Indeed, this potentially heightened scrutiny could draw unwanted attention to these obligations under the Bayh-Dole Act for those who are recipients of federal funding. Congress may eventually reevaluate whether the arguably draconian results of *Campbell Plastics* are a fair and equitable way to obtain compliance, as well as articulate how much discretion should be vested in a funding agency for failure to comply. Meanwhile, universities need to be prepared and proactive to avoid losing valuable patent rights in federally funded research, as well as suffering other undesirable consequences from a failure to comply with the Bayh-Dole Act.

- *Alleging that the funding agency has not been "harmed" by the failure to comply is no excuse.* The impact on the funding agency due to the failure to comply is simply irrelevant to whether it has abused its discretion to take title from the contractor.

The Federal Circuit in *Campbell Plastics* also left many issues unresolved regarding failure to comply with the Bayh-Dole Act. Unless *Campbell Plastics* is taken to its ultimate extreme, the Federal Circuit did not specifically address whether disclosure of the subject invention on the required form, but outside the time period specified, could cause forfeiture. For example, what if the contractor in *Campbell Plastics* had disclosed the subject invention on the DD 882 form after October 1997 but before the patent was filed?

Another issue left unresolved is what action the funding agency can take for failure to comply where none is specified by the Bayh-Dole Act. In *Campbell Plastics*, it was clear what action the Army could take for the failure to timely disclose the subject invention.[22] Other sections of the Bayh-Dole Act are also fairly clear as to what action the funding agency can take if there is a failure to comply.[23] However, for most of the remaining Bayh-Dole Act obligations, it is completely unspecified or at least ambiguous what action the funding agency can take if there is a failure to comply.[24]

Campbell Plastics also did not address what happens if the funding agency neglects to take timely action regarding a failure of a contractor to comply with its Bayh-Dole Act obligations. For example, can private parties step in or at least raise such failure as a defense to a patent infringement action brought by the contractor? The courts have recoguized that the Bayh-Dole Act "does not provide for a private cause of action to enforce its provisions."[25] However, the inability to use the Bayh-Dole Act as a sword does not necessarily preclude its use as a shield. Indeed, at least one federal district court has held that failure of the contractor to comply *at all* with the Bayh-Dole Act is a good defense against patent infringement.[26] Nevertheless, there remains an open issue as to what the Federal Circuit will hold if a patent holder sues on a patent for which there was not compliance with the Bayh-Dole Act, and where the agency does not object to the contractor's failure to comply with its obligations.[27]

On April 28, 1999, the contractor finally notified the Army in writing of the existence of the '537 patent.

What followed this notification was an exchange of letters between the contractor and the Army about the Army's claim to joint ownership of the subject invention of the '537 patent based on what was described in the June 1997 report. The administrative contracting officer (ACO) for the Army then concluded that the contractor had forfeited title to the '537 patent because of its failure to comply with the patent rights clause when it did not timely disclose the subject invention to the Army.

The contractor appealed the ACO's decision to the Armed Services Board of Contract Appeals. The Board denied the contractor's appeal, ruling: (1) the contractor failed to satisfy its contractual obligation to inform the Army that it considered the sonic welding of mask components to be an invention; (2) any information that the Army obtained from its review in January 1998 of the subject patent application for its secrecy determination, as well as from its own June 1997 report, was not provided by the contractor, and, thus, forfeiture of title to the '537 patent was appropriate under the circumstances; and (3) while the Army had some discretion in determining whether to take title, it did not abuse that discretion.[19]

In affirming the Board's decision, the Federal Circuit acknowledged that it was dealing with "a matter of first impression for this court." The Federal Circuit first referred to the Bayh-Dole Act, and, specifically, the disclosure provisions of section 202(c)(1)[20] as providing the federal government with the means to protect its rights, including the right to a paid-up license to practice the subject invention, as well as the right to receive title to the subject invention if the contractor did not file for patents. The Federal Circuit then ruled that the language of the patent rights clause was "clear and unambiguous;" the Army could take title to any subject invention if the contractor failed to disclose the subject invention on the specified DD 882 form in a timely manner to the Army. The Federal Circuit further concluded that its "plain-meaning interpretation" of the patent rights clause was "buttressed by the policy considerations behind the Bayh-Dole Act."

The Federal Circuit also explicitly found that, at minimum, the contractor should have disclosed the subject invention on the specified DD 882 form to the Army by October 1997, but had not done so.[21] The Federal Circuit was unsympathetic to the contractor's argument that it had "continually disclosed

- Agree that the funding agency has the right to require the university, its assignees, or exclusive licensees to grant a nonexclusive, partially exclusive, or exclusive license (commonly referred to as *march-in rights*).[11]
- Not assign United States patent rights in the subject invention without the approval of the funding agency, except when assigned to an organization that has as its primary function the management of inventions.
- Share royalties collected with the inventors of the subject invention.
- Use income generated by licensing the technology that is not otherwise used to pay inventors or expenses to support scientific research or education.
- Make reasonable efforts to attract licensees that are small businesses.

Prior to *Campbell Plastics,* a university that failed to comply with these obligations under the Bayh-Dole Act was confronted with at least three potential problems. First, the funding agency could take title to the invention.[12] For example, if the university failed to disclose the subject invention within two months after receiving written notification from the inventor, the funding agency could, within sixty days of learning of this failure, require that title be conveyed to it.[13] Second, an accused patent infringer could allege that the university did not have title to the patented invention because of its failure to comply.[14] Third, a prospective business partner or licensee might discount the value of the patent because of the continuing issue of whether the university had or would retain title to the patent. That issue would linger like a sword of Damocles until the funding agency learned of the failure to comply, had the appropriate opportunity to exercise its right to take title, and refused or neglected to do so.

Universities that were aware of the possibility of losing patent rights for failure to comply with their obligations under the Bayh-Dole Act may have been justified in thinking that this was a theoretical threat that was largely ignored or unrecognized by funding agencies. After all, funding agencies would have little motivation or incentive to enforce compliance, especially because it would require an investment of resources or might generate undesired ill will from the university. That belief is no longer justified in view of what happened in *Campbell Plastics.*

Inc. v. Brownlee.[2] In *Campbell Plastics*, the Court of Appeals for the Federal Circuit affirmed an administrative ruling that a federal defense contractor had forfeited its patent rights under the Bayh-Dole Act for failure to timely comply with the invention disclosure provisions of its funding agreement.

While *Campbell Plastics* involved a federal defense contractor, it also has significant and potentially serious implications for federally funded university research, as well as federally funded research at other nonprofit research institutions. This article initially will provide an overview of the obligations under the Bayh-Dole Act that can potentially cause the loss of patent rights based on federally funded university research. This article will then review *Campbell Plastics*, including the important facts and factors that led to the loss of patent rights. Next, this article will discuss the implications of *Campbell Plastics* (e.g., the funding agency can dictate, within reason, the form of compliance) and especially will address what issues were left unresolved regarding compliance with the Bayh-Dole Act (e.g., what happens if the funding agency neglects to take timely action regarding failure to comply, or what action the funding agency can take regarding failure to comply where none is specified). Finally, this article will discuss what universities can and should do to comply with the Bayh-Dole Act (e.g., institute formal compliance procedures and due diligence checks, as well as try to remedy any unintentional failures to comply) and avoid what happened to the unfortunate contractor in *Campbell Plastics*.

Obligations under the Bayh-Dole Act for Those Receiving Federal Funds

When a university applies to a federal agency for a grant to fund a research project, the grant is awarded through a funding agreement with the university. The university is not obligated to apply for patent rights on the results derived from such federally funded research. However, even if the university does not wish to retain such patent rights, it still has certain obligations that it must fulfill to permit the federal government to do so. More importantly, it is likely to be in the university's pecuniary interest to keep its options open with respect to the ability to actively pursue patent protection because the true value of an invention is rarely realized at the time of its discovery.

Thanks to the Bayh-Dole Act, patent clauses in research funding agreements are fairly standardized. The use of a standard patent clause enables

8. Thomas Jefferson to Samuel Kercheval, "Reform of the Virginia Constitution," July 12, 1816, in *Writings: Thomas Jefferson, ed. Merrill D. Peterson (New York: Library of America, 1984),* 1401.
9. Theodore Roosevelt, "Address at the Inaugural Ceremony," March 4, 1905, in *Inaugural Addresses of the Presidents of the United States 1989* (Washington, DC: U.S. Government Printing Office, 1989).
10. Id.
11. 35 U.S.C. § 202(b)(3) (2000).
12. See, e.g., 37 C.F.R. Part 401.
13. Pub. L. No. 106-404, 114 Stat. 1742 (2000) (codified at 15 U.S.C. § 3701).
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.
15. Ralph Nader and James Love, "Looting the Medicine Chest: How Bristol-Myers Squibb Made Off with the Public's Cancer Research," *The Progressive,* February 1993, 26.
16. Arnold S. Relman and Marcia Angell, "America's Other Drug Problem," *New Republic,* Dec. 16, 2002, 27, 39.
17. Harry Goldstein and Ronil Hira, "The World's Biggest R&D Spenders Are Putting Their Money On Software and Service," *IEEE Spectrum Online,* Nov. 1, 2004, http://www.spectrum.ieee.org/WEBONLY/publicfeature/nov04/1104rd.html.
18. Thomas Jefferson, "Address at the Inaugural Ceremony," March 4, 1801, in *Inaugural Addresses of the Presidents of the United States 1989* (Washington, DC: U.S. Government Printing Office, 1989).
19. Adam B. Jaffe and Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress, and What to Do about It* (Princeton, NJ: Princeton University Press, 2004), 170.

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

1. The President's Council of Advisors on Science and Technology (PCAST), *Report on Technology Transfer of Federally Funded R&D*, May 15, 2003, available at http://www.ostp.gov/PCAST/PCASTTechTransferReport.pdf. PCAST enables President George W. Bush to receive advice from the private sector and the academic community on technology, scientific research priorities, and math and science education.

in guiding the patenting and licensing activities of their grantees."[30] 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."[31]

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

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 director 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-

(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.

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.

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 mauners 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."[8]

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,"[9] 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."[10]

The Bayh-Dole Act is subjected to review every five years by the comptroller general of the United States.[11] 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.[12] In 2000, Congress passed the Technology Transfer Commercialization Act,[13] which requires federal agencies with laboratories and technology transfer programs to provide the Office of Management and Budget (OMB) with aunual 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.[14] 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

Since enactment of the seminal Patent and Trademark Law Amendments of 1980[3] (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 biopharmaceutical 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 innovation 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

20. Beyond these more pragmatic reasons, some developing nations may also have concerns that strong intellectual property rights are antithetical to their development goals and might, therefore, believe (mistakenly) that adoption of the Bayh-Dole framework and its attendant focus on patent rights would leave domestic firms and consumers worse off vis-à-vis competitors in the developed world.
21. For instance, AUTM has launched a program to provide scholarships for technology transfer professionals from emerging economies. See AUTM, *Scholarships for New Technology Transfer Professionals From Emerging Economies*, available at http://www.autm.net/contEd/NTTPEEScholarship.cfm. The International Intellectual Property Institute is advising South Africa on technology development policies along the lines of the Bayh-Dole Act. See IIPI, *South African University Technology Transfer: A Comparative Analysis.*

Conclusion

The economic and social divide between developed and developing nations has emerged as one of the greatest challenges of the post-cold war era. The Bayh-Dole Act offers a possible avenue for bridging this divide. Although enacted by Congress as a means of spurring American innovation and economic growth, the Bayh-Dole Act has the potential to provide similar benefits to countries with less developed economies. It would be misguided, of course, to attempt to export the entire Bayh-Dole framework to developing countries without regard to their unique needs and circumstances. At the same time, failure to assist developing countries in evaluating and implementing those policies that make sense to those governments would constitute an important lost opportunity for the United States to take a leadership role in this area.

Notes

1. See generally Association of University Technology Managers, *AUTM Licensing Survey: FY 2003™* (Northbrook, IL: AUTM 2004): 2-11.
2. For example, see Organization for Economic Cooperation and Development, *Turning Science Into Business: Patenting and Licensing At Public Research Organizations* (Paris, France: OECD Publications 2003); International Intellectual Property Institute, *Technology Transfer: Tapping Into Universities and Government Research Institutes for Economic Growth* (Washington, DC: IIPI 2002), available at http://www.iipi.org/activities/projects_tech_transfer.htm.

   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.

technology transfer officials—to develop a common set of resources that developing countries could use to promote technology commercialization domestically. A partial list of such resources might include the following:

- A set of metrics on key variables (e.g., level of funding for publicly sponsored research) that would enable policymakers to evaluate whether it would be worthwhile for a particular country to adopt policies along the lines of the Bayh-Dole Act.
- A questionnaire, checklist, or similar analytic tool that could be used to identify existing legal and technical impediments to university licensing of inventions arising from government-funded research.
- A model law on patenting and licensing of such inventions.
- A list of best practices and similar tools that would help developing countries implement effective technology development policies, including by identifying those resources (e.g., guidance for government funding agencies, additional staffing for patent offices, technology transfer offices, etc.) that the country would need to support such policies.

In addition, the U.S. administration should direct U.S. agencies to establish programs to provide technical assistance to developing countries in this area. For instance, the Office of Management and Budget, which currently provides periodic reports to Congress on U.S. agency compliance with the Bayh-Dole Act, could provide expertise to the State Department or other federal agencies to assist developing economies in introducing similar policies into their funding practices and research contracts. This could include assistance in identifying existing policies that may create disincentives or other obstacles to claiming title to and licensing university-owned inventions.

Similarly, because technology development policies require that public research organizations have the ability to obtain patent protection for inventions, the U.S. Patent and Trademark Office (USPTO) could play a useful role in providing technical training on patent law and procedures, including methods for evaluating the costs and benefits of obtaining patent protection in foreign jurisdictions. The USPTO could also sponsor U.S. patent examiners for internships in the patent offices of developing nations or provide internships for foreign officials to work in U.S. federal technology transfer offices.

Finally, the United States should examine opportunities for coordinating any initiatives that it undertakes in this area with those of other nations that

have adopted such technology transfer policies suggest that their benefits outweigh their costs by a significant margin.

Second, technology development policies along the lines of the Bayh-Dole Act would give companies in developing nations direct access to potentially valuable technologies. For years, efforts to integrate developing nations into the global economy have engendered debates over the concept of "technology transfer," which have typically focused on mechanisms for transferring technology from licensors in the developed world to licensees in the developing world. Inventions arising from publicly sponsored research, by contrast, offer a local and direct source of innovation to industries in developing economies. While it may be overly optimistic to believe that effective technology development policies alone would address these technology access needs for most developing countries, such policies should nevertheless open opportunities for local firms to obtain exclusive rights to exploit inventions on a global scale.

Third, as the U.S. experience under the Bayh-Dole Act demonstrates, policies that encourage licensing of university-owned inventions would generate benefits to developing nations' universities that extend well beyond royalty income. One of the most remarkable and successful aspects of the Bayh-Dole framework is the degree to which it has spurred collaboration between university researchers and industry beyond the simple licensing of university-owned inventions. University-industry cooperation fueled by the Bayh-Dole Act has generated greater private-sector support for university research programs in the form of grants, joint research projects, and capital investments, and, more broadly, has fostered the sharing of expertise and personnel between the public and private sectors.

Fourth, allowing public research organizations and researchers to claim title to and license inventions would foster a culture that values technology innovation and rewards efforts to bring innovations to the marketplace for the broader public good. One of the ongoing debates in the international trade and development communities has been whether intellectual property rights provide equal benefits and opportunities for both the developed and developing world. Technology development policies can refocus this debate into one that seeks to leverage intellectual property rights for the benefit of society generally.

Naturally, the reasons set forth above in favor of technology transfer policies will be more or less applicable to any specific country depending on

developing nations and international development organizations. Relatively few developing nations to date have implemented comprehensive policies to promote the commercialization of government-funded research. There are some indications, it must be noted, that this is gradually changing. For instance, India, Brazil, and South Africa have each recently adopted policies designed to make it easier for universities and other recipients of public research funds to claim title to and license intellectual property.[15] Yet these initiatives also illustrate the challenges that developing nations face in implementing such policies in an effective manner. Brazil provides a useful case study in this regard.

In 1997, Brazil amended its patent law to provide protection to a broader range of products and processes, and, subsequently, enacted rules allowing research institutes to patent and license technologies created with government funds.[16] Brazil's technology transfer policies, however, have been criticized as inadequate on several grounds, for example, failing to provide sufficiently strong incentives for public research organizations and researchers to identify, patent, and license promising inventions.[17] Commentators also have noted the lack of clear, government-wide technology transfer policies, the absence of technology transfer offices and expertise at most Brazilian universities, and a tradition of offering publicly funded research to the private sector on a nonexclusive, no-cost basis as additional barriers to the successful development of Brazil's technology transfer framework.[18] As the United Nations Conference on Trade and Development observed in a 2000 study, "[t]he concept of publicly-owned technologies does not appear to be appreciated in Brazil due to the fact that research institutions are not concerned with patenting the technologies generated and, when the patent is requested, no attention is given to licensing."[19]

These types of hurdles do not appear to be unique to Brazil. Indeed, to the extent that research in this area exists, it suggests that the adoption of Bayh-Dole-type policies in developing economies generally has been sporadic, and those countries that have begun the process of adopting such policies often face important challenges in successfully implementing these policies.

There are, of course, several possible explanations for this. Because developing economies typically have fewer funds than developed economies to devote to research, they are likely to have correspondingly fewer inventions that would be suitable for commercial development (other things being

patenting and licensing of inventions arising from government-sponsored research to those best situated to make these decisions. Prior to the enactment of the Bayh-Dole Act, officials at the sponsoring agency typically had the principal or sole authority to decide whether and on what terms to patent and license inventions created in the course of government-funded research. Furthermore, most agencies adhered to the policy that title to any inventions arising in the course of a government-sponsored research project automatically resided in the government. The Bayh-Dole Act changed this structure by granting recipient institutions—which are typically more cognizant of private-sector activities in a given field of technology and, thus, better able to assess the commercial potential of inventions—the right to retain title to and license such inventions.

Second, the Bayh-Dole Act adopts a complex set of *market-based incentives* to make patenting and licensing decisions more efficient. Because the act allows universities and individual researchers to share in any royalties generated from inventions arising from government-funded research—but also requires universities to underwrite the costs associated with patenting, marketing, and licensing these inventions—universities have powerful incentives to identify promising inventions (and to invest the funds necessary to support their licensing and ultimate commercial development), and to weed out those inventions that have little commercial potential. Furthermore, because licensing royalties effectively underwrite much of the infrastructure necessary to support this process, there are no added costs to the government.

Third, the Bayh-Dole Act brought *clarity and uniformity* to government procedures in this area. Prior to enactment of the Bayh-Dole Act, the rules governing the patenting and licensing of inventions arising from government-sponsored research varied among agencies, and exclusive licensing was permitted only in exceptional cases. Consequently, firms often perceived the potential returns on commercial development of such inventions to be outweighed by the costs and risks of doing so. The Bayh-Dole Act simplified and clarified rules that permitted universities to claim title to and license such inventions. This made licensing more predictable and transparent, and, therefore, more attractive, to potential licensees. Furthermore, by expressly permitting exclusive licensing, and, thereby, increasing licensees' potential return on their investments, the act made the development of

To date, however, adoption of such technology development policies outside the United States has occurred primarily in developed and newly industrialized economies. While a small number of developing nations have enacted legislation that incorporates elements of the Bayh-Dole framework, and certain others are in the process of evaluating whether to do so, the fact remains that relatively few developing economies have successfully implemented policies specifically designed to promote the licensing and commercial application of inventions arising from government-sponsored research.

That the Bayh-Dole Act has not attracted greater attention from developing nations and international development organizations is a cause for concern. The Bayh-Dole Act's combination of market incentives and procedural safeguards should, at a policy level, be of equal interest to both developed and developing economies. Indeed, there is a persuasive argument to be made that carefully tailored technology development policies along the lines of the Bayh-Dole Act would enable at least some developing countries—specifically, those that invest significant government funds into basic research conducted at universities and other public research organizations and that have the necessary legal and institutional framework to enforce intellectual property rights—to exploit more effectively their own intellectual resources. In doing so, such countries could become more fully integrated into the "innovation economy" of the twenty-first century.

This article examines the potential benefits to developing countries of adopting policies modeled on the Bayh-Dole Act. After a brief discussion of the act's effects in the United States, the article analyzes three components of the act that have been instrumental to its success and discusses a survey of other nations that have adopted similar policies. It then assesses the potential value of the Bayh-Dole framework for economically more-advanced developing nations and recommends actions that U.S. officials and universities might undertake to support such efforts.

Bayh-Dole: The U.S. Experience

Congress's primary goals in enacting the Bayh-Dole Act were to promote the dissemination and commercial development of inventions arising from government-supported research and to foster greater collaboration between universities and industry.[3] America's experience under the Bayh-Dole Act since 1980 demonstrates that these goals have largely been met. Recent data

The *AUTM Journal's* editors and Editorial Advisory Board appreciate and solicit suggestions and comments regarding the *AUTM Journal.* Please send your comments to us via e-mail at autm@autm.net.

I also want to take this opportunity to thank everyone who has contributed to the successes of the *AUTM Journal* over the past few years as I near the end of my term as editor. We had a very special foundation upon which to build, and you all deserve to be very proud of what we have created. It has been a delight to work with all of you, and I am very grateful for your efforts and contributions. Effective July 1, 2005, Kirsten Leute of Stanford University will become editor of the *AUTM Journal,* and I wish Kirsten all the best as she continues to enhance and improve this publication for our readership.

Thank you.

Leona C. Fitzmaurice, Ph.D.
Editor

1. "Innovation's Golden Goose," *The Economist,* Dec. 14, 2002,3.

provide possible explanations. They conclude their article with recommendations for the United States government and universities that encourage specific outreach efforts in developing countries.

The second article, "The Bayh-Dole Act at Twenty-Five Years: Looking Back, Taking Stock, and Acting for the Future," was written by Michael J. Remington, JD, a partner in the Washington, DC, office of Drinker Biddle & Reath LLP, where he represents the Wisconsin Alumni Research Foundation among other clients. Remington's perspective is a political one, and his article is not only a celebration of the successes of the Bayh-Dole Act over the past 25 years, but also a call to action to defend the act against current and future challenges.

The author contends that the Bayh-Dole Act has been a success but notes that it is subjected to review every five years by the comptroller general of the United States, it falls within the purview of congressional oversight and may be amended at any time, and it is subject to the court of public opinion. Remington then catalogs current challenges to the Bayh-Dole Act including decreases in federal funding of scientific research, concerns about the efficacy and quality of the U.S. patent system, requests that the federal government exercise march-in rights, attempts by federal agencies to avoid the provisions of the Bayh-Dole Act, creation of controversy over common law experimental use and research exemptions, and the ever-present possibility of legislative reform. The author also reviews challenges to the Bayh-Dole Act inherent in pricing proposals for drugs that are being presented in Congress as well as public administration proposals for modifications to the act. Remington concludes with a call to action: "After twenty-five years, it is time for the proponents to step forward and assist in a realistic appraisal of the act."

The third article, "Losing Patent Rights for Failing to Comply with the Bayh-Dole Act: The Implications of *Campbell Plastics* on Federally Funded University Research," was written by Scott D. Locke, JD, a partner with Kalow & Springut LLP, in New York, and Eric W. Guttag, a partner with Jagtiani + Guttag, Fairfax, Virginia. Locke and Guttag describe the Bayh-Dole Act as a "two-edged sword." As they discuss, the Bayh-Dole Act allows universities and other recipients of federal funding to retain title to patent rights created during the conduct of federally funded research, but it also provides means whereby the federal government can require the funding

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