Academia, Industry, and the Bayh-Dole Act: An Implied Duty to Commercialize

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I. Introduction

The Bayh-Dole University and Small Business Patent Procedures Act of 1980[1] (the Bayh-Dole Act) fundamentally altered the ownership paradigm of intellectual property developed with federal research dollars, transferring that ownership from the federal government to grant recipients (grantees) and organizations that are parties to government funding agreements (contractors), in an effort to enhance the public's access to technology developed with federal funds. However, moving innovative technology from the laboratory into the public domain is a complex exercise. In the case of medical technology, those who develop new technologies are ill-trained and ill-equipped to perform this function. Only industry, with its ability to manufacturer and distribute medical products with a high degree of precision and quality control, is able to effectively convert promising ideas into effective, widely available products.

The combination of Bayh-Dole's, 1) stated goal of increased public access to federally-funded research, 2) provision for the transfer of intellectual property to grantees/contractors, and 3) identification of the crucial role of industry in transforming ideas into available products and services, create an implied duty on the part of grant recipients and government contractors to partner with industry to commercialize promising federally-funded research. By its nature, this implied duty transforms the academia-industry relationship from the traditional view of disparate entities into a Congressionally-mandated partnership, intended to advance technology and benefit the public. An analysis of this implied duty and its implications on the complex and often controversial relationship between the academic community and industry are the subject of this paper.

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II. A Brief Legislative History

To fully appreciate the Bayh-Dole Act's revolutionary nature and the dramatic effects brought about by its enactment, it is necessary to examine the government-sponsored research environment that existed prior to the Act's introduction and implementation. An examination of these pre-Act policies illustrates the motivation behind Bayh-Dole, providing a valuable perspective on today's academic medical research environment.

Prior to Bayh-Dole, title to scientific inventions arising from federally-funded research typically vested in the government, reflecting the popular rationale that research funded by the public belonged to the public.[2] Though attractive in a theoretical sense, this rationale stifled the transfer of research from the laboratory to the public domain. To begin, the policy left the federal government with the responsibility to develop and commercialize promising technology, functions that it was ill-equipped to perform. Second, the government practice of granting non-exclusive licenses removed valuable industry incentives to invest. Lastly, adding to these fundamental issues, specific details of patent policy were left to the various agencies funding federal research, leading to significant variation in the policy actually applied in individual cases. Overall, this pre-Bayh-Dole paradigm produced an environment where federally-funded research infrequently led to viable products or services. These effects can be seen in the low technology licensure rate prior to enactment of Bayh-Dole: just prior to the Act's passage, the federal government held title to roughly 28,000 patents, only 5% of which were licensed to industry for commercial development.[3] Concerned that the public was not benefiting from its substantial research investment, Congress began exploring options to stimulate innovation and ensure commercialization of promising technology.

In 1945 the National Patent Planning Commission, created four years earlier by President Roosevelt, issued a report on the role of patents in government sponsored research.[4] The document, 1) recognizing the utility of patent protection in stimulating commercial development, and 2) affirming the belief that government-funded research should remain in the public domain, began a national dialogue regarding the effectiveness of the government's policies toward federally-funded inventions. In contrast, a subsequently issued report by the Attorney General supported the then-existing approach, recommending that title to all government-funded inventions vest in the government, with exceptions only in very limited circumstances.[5] Together, these reports formed the basis of a national debate as to the appropriate policy governing ownership rights.

Those who favored government retention of full title to inventions resulting from federally-supported research formed one side of this debate. These organizations and individuals tended to include small businesses and consumer advocates who feared that big business would gain an unfair advantage over smaller competitors if allowed to retain ownership of patent rights, concentrating too much economic power and possibly creating monopolies, higher prices, and anti-competitive behavior.[6] However, licensing policy advocates saw the issue quite differently. Arguing for grantee/contractor retention of title, this group saw both a stimulus to innovation created by the protections afforded with patent ownership, and investment incentives created from such protections.[7]

In the years succeeding these reports, numerous presidential memoranda, policy statements, and commission reports followed as the federal government sought to establish a mechanism for ensuring public access to federally-funded research results, while at the same time, retaining unrestricted rights to use these innovations as needed for the public good.[8] However, inconsistencies in federal patent policy continued as Congress remained divided on the more desirable overall federal mechanism, leaving untouched the considerable discretion individual federal agencies enjoyed in the policies they imposed on the research they funded.[9]

As major recipients of federal research funding, universities were especially affected by the patent debate and wide variation of funding agency policies. Exacerbating the problem was a report issued to Congress by the Commission on Government Procurement on the issues surrounding patent rights in federally-supported research.[10] This report, proposing an approach whereby title would be granted to contractors subject to the government's right to intervene (quite similar to Bayh-Dole's eventual provisions), explicitly excluded educational and other non-profit organizations due to concerns regarding these institutions' ability to promote inventions "in a manner consistent with the objectives of utilization and maintenance of competition."[11]

However, as the debate on a uniform patent policy continued, the environment changed. In 1979, then President Carter took issue with the Commission's report, publicly advocating full title retention for

universities and small businesses. With regard to large business, Carter proposed permitting exclusive licenses, with the government retaining the right to exercise a non-exclusive license and the right to intervene.[12] Predictably, President Carter's position generated substantial opposition from large business contractors and industry trade groups who lobbied against any restrictions on large business contractors, resulting in a new wave of heightened debate.

Introduced by Senators Birch Bayh and Robert Dole, the Bayh-Dole bill began moving through Congress in 1980. Notably, its provisions were not at all novel, containing many elements similar to previously proposed recommendations and policies. However, with its limited applicability to small businesses and nonprofit organizations, and its exclusion of large business interests, the bill avoided serious opposition from consumer advocates and antitrust lawyers and became law in December, 1980, with an effective date of July 1, 1981.[13]

The Bayh-Dole Act applies to all research performed under a federal funding agreement, whether funded in whole or in part by the government.[14] The Act requires a written agreement between the federal agency and the grantee/contractor which contains the terms upon which federal funding will be provided.[15] Among the sections of the Bayh-Dole Act delineating funding terms are two key provisions, one governing the rights and responsibilities of government grantees/contractors and the other, the rights and responsibilities of the government and government agencies.

Specifically, Bayh-Dole allows contractors to choose to retain title to federally-funded inventions, an option that, if exercised, is accompanied by various responsibilities.[16] For example, non-profit contractors electing title, including academic institutions, are required to file a patent application in the United States and grant the government a non-exclusive, non-transferable, paid-up right to practice the invention in the U.S. and throughout the world.[17] In addition, the Act mandates that contractors take necessary steps to commercialize any discoveries or inventions resulting from federally-funded research, with the right to grant non-exclusive, partially exclusive, or exclusive licenses.[18] The Act also requires contractors to favor U.S. industry for the manufacture of inventions, and small businesses for the granting of exclusive licenses. Contractors must report to the funding agency periodically, share royalties or income generated from inventions with the inventor(s), and apply the balance of income toward additional research or educational endeavors.[19]

In the event the grantee/contractor breaches its agreement with the government, Bayh-Dole includes provisions providing for the government to assume the failed commercialization efforts. These provisions allow the government to "march-in" and assume ownership rights of intellectual property when specific provisions of the Act have not been fulfilled, particularly, failure to take necessary steps to achieve practical application of the subject invention.[20] In addition to this right, the government also has a responsibility under a separate provision to ensure that licensing agreements governing government-owned inventions are granted in accordance with the objectives of the Act, responsibilities very similar to those applicable to grantees/contractors.

The provisions of Bayh-Dole, while addressing the national debate on government patent policy, responded to university and small business frustration with the unpredictable and ever-changing patent policies of the Health, Education and Welfare agency as well as the Department of Defense. In contrast to the previous environment, Bayh-Dole provided clear, predictable grantee/contractor retention of patent rights for non-profit and small business concerns. This shift allowed these individuals and entities to plan technology transfer activities earlier in the development process, ultimately facilitating their success.

In the next few years immediately following enactment of Bayh-Dole, large business contractors continued to operate under the varying agency policies. While occasionally able to gain patent rights to federally-funded inventions under the various agency regulations, they still lacked a predictable uniform policy. In 1983, Bayh-Dole's scope was expanded through a Memorandum to the Heads of Executive Departments and Agencies to include large businesses.[21] In the memorandum, President Reagan directed agencies to treat all inventions resulting from federally-funded research in the manner prescribed under the Bayh-Dole Act, an action which was later endorsed by Congress in a 1984 housekeeping provision.[22] Thus, through Executive Order, President Reagan allowed for the application of a uniform patent policy applicable to all government contractors of federally-supported research.

III. Bayh-Dole's Implied Duty to Commercialize

The Bayh-Dole Act can be seen to impose a duty on the part of all researchers who contract with the government, referred to as grantees or contractors, to pursue the commercialization of government-funded scientific inventions. The duty to commercialize is not explicitly stated within the Act, but is formed through the interplay of two key provisions. The result is a "use it or lose it" policy, whereby government contractors must take steps to reach "practical application" of their inventions and comply with all requirements under the Act, or be subject to the government's right to intervene and assume ownership.

Recognizing an implied duty to commercialize under Bayh-Dole begins with the Act's enumerated objectives, contained in Section 200. Directly implicating utilization of the patent system for the purpose of effectuating its goals, Congress identifies seven objectives which form the basis of its policy promoting commercialization, three of which are of particular importance in outlining a duty to commercialize. The first of these relevant objectives, "to promote the utilization of inventions arising from federally-supported research or development," indicates the intent of Congress to ensure that promising research results are put to productive use.[23] The second objective, "to protect the public against nonuse or unreasonable use of inventions," supports the first objective and further demonstrates Congress's intent to ensure that publicly-funded inventions reach the public. Furthermore, it reflects the government's right to enforce the commercialization provisions of Bayh-Dole.[24] The third key objective, "to promote collaboration between commercial concerns and nonprofit organizations, including universities," explicitly partners academia and industry, providing a pathway for academic interests to comply with the Act's duty and ultimately effectuate the Act's goals.[25]

Section 202, entitled Disposition of Rights, is the first substantive provision embodying Bayh-Dole's implied duty to commercialize, and sets forth the rights and responsibilities of government grantees/contractors.[26] Under Section 202, all grantees/contractors are allowed to "elect to retain title to any subject invention."[27] A subject invention is defined as "any invention...conceived or first actually reduced to practice in the performance of work under a funding agreement...."[28] Thus, contracts, grants, or cooperative agreements between a federal agency and an individual or institution for the "performance of experimental, developmental, or research work" that is funded in whole or in part by the federal government, allows for the option to retain title.[29]

Exercising the option to retain title to a subject invention triggers various requirements and responsibilities, ultimately included in the government's funding agreement with each contractor. A key requirement supporting an implied duty to commercialize is the requirement to file a patent application in the United States. Section 202(c) provides that contractors who elect title to a subject invention "agree to file a patent application prior to any statutory bar date."[30] Furthermore, failure to file a patent application within the statutory timeframe may result in title forfeiture to the federal government and loss of ownership rights.

In addition to the patent-filing requirement, Section 202(c) requires reporting to the funding federal agency. Specifically, contractors must periodically report on the "utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees."[31] Thus, merely filing a patent application in the United States in compliance with Section 202(c) is not enough to satisfy the federal government's goal of ensuring public availability and use of subject inventions. Contractors must also report on efforts to obtain utilization of the invention, with associated consequences for failing to promote utilization, as found in the subsequent section of the Act.

A second key Bayh-Dole provision supporting the implied duty to commercialize sets forth the rights retained by the government. Section 203, entitled March-In Rights, allows federal funding agencies to assume ownership rights to subject inventions, including the right to require the contractor to grant a non-exclusive, partially exclusive, or exclusive license to a responsible applicant.[32] Such actions are permitted when the contractor has failed to take "effective steps to achieve practical application of the subject invention," among three other enumerated circumstances.[33] Under the statute, practical application means "to manufacture...to practice...or to operate...under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."[34] Accordingly, when the federal government determines that a contractor has not taken and is not expected to take effective steps to ensure public use of an invention, a federal agency may "march-in" and require the licensing of the invention. Furthermore,

if the contractor refuses to license the technology, an agency may grant the license itself.[35]

Together, the practical effect of Sections 202 and 203 is that contractors to federal funding agreements must actively pursue commercialization, through the development and eventual public availability of inventions to which they have elected to retain title. Incorporated into the requirements and responsibilities attached to title retention are specific retained government rights, applicable should a contractor fail to actively pursue public utilization or commercial development. These provisions effectively establish contractor responsibility to effectuate the Act's objectives, with government intervention as a built-in safeguard to ensure the Act's objectives are carried out.

These provisions of Bayh-Dole are clearly designed to ensure that the ultimate goal of Congress is achieved: federally funded inventions are made available to the public, for the public's benefit. Sections 202 and 203, and the implied duty imposed upon contractors are the main provisions supporting this goal. However, a related provision of the Act also lends support to Congress's principal purpose, and by extension, to the implied duty to commercialize.

Section 209, entitled Restrictions on Licensing of Federally Owned Inventions, imposes on federal agencies duties similar to those imposed on contractors by Section 202, building on the Act's push for successful commercialization.[36] Under its provisions, Federal agencies may only license inventions to those requestors who can provide a concrete plan for invention development and marketing.[37] In addition, federal agencies licensing a federally-owned invention must include provisions detailing "periodic reporting on the utilization or efforts at obtaining utilization," and provide for license termination when the licensee fails to take effective steps to achieve practical application within a reasonable time.[38] These requirements, mirroring those applicable to contractors, are designed to further ensure successful commercialization and public availability of government-funded innovations.

IV. Technology Transfer: Academia's Mechanism for Fulfilling Bayh-Dole's Duty

While Bayh-Dole created an implied duty for government grantees/contractors, including academic medical institutions, to commercialize subject inventions and explicitly encouraged academia-industry collaboration in this pursuit, the Act does not provide specific mechanisms to achieve commercialization and the public access it requires. This effectively leaves the mechanism of accomplishing this duty to the discretion of each grantee or contractor. Academic medical centers, while superb at performing medical research, are not structured to transfer their discoveries into broadly usable technologies through effective commercialization, even where this technology is promising enough to obtain a patent as provided for under Bayh-Dole. For example, even very early clinical trials of a promising new device-based medical technology demand that the product be manufactured to exacting specifications, typically while maintaining sterility. This is very difficult to achieve, even on a very small scale, outside of an industrial setting. Furthermore, if the data from these trials is intended to support eventual marketing approval or clearance for the product, the trials must take place under a U.S. Food and Drug Administration (FDA)-sanctioned Investigational Device Exemption (IDE). In practice, it is extremely difficult and costly for an academic institution to maintain labs that meet FDA requirements to fashion the product, as well as support the significant administrative burden inherent in conducting IDE-covered trials.

The difficulty of pursuing commercialization within the academic medical setting has led centers to turn to industry to move technology from the laboratory to the patient care setting. Technology transfer, effectively moving patented academic discoveries and innovations to the commercial setting, has become the mechanism enabling broader development of research discoveries. Often taking the form of licensure agreements that provide private industry with access to academic research, such transfers are facilitated by the Bayh-Dole patent paradigm: academic patent holders have an incentive to obtain resources via technology transfer agreements and industry gains access to academic technology with patent protection. This arrangement fulfills Bayh-Dole's implied duty to commercialize, with the added benefit of providing an income stream to the academic patent holder that is then required to be reinvested in the academic mission and used to fund further research.[39]

V. In the Wake of Bayh-Dole

A. Technology Transfer Activity Flourishes at Academic Centers

The academic research environment changed dramatically following passage of the Bayh-Dole Act, as evidenced by numerous objective measures. At academic research institutions in particular, technology transfer has become a fundamental part of research activity since the Act's introduction, with an eight-fold increase in the number of universities engaged in transferring academic research to the private sector.[40] The number of patents issued by the United States Patent and Trademark Office to universities alone has skyrocketed, from approximately 250 patents per year prior to the Act to about 1600 by 1993.[41] This trend continues to accelerate, with a recent survey by the Association of University Technology Managers (AUTM) reporting over 3,000 U.S. patents issued to universities in 2000.[42]

Licensing activity, the main vehicle for technology transfer at academic institutions, mirrors the trend seen with patents. In fiscal year 1999, AUTM reported close to 4,000 new licensing agreements executed.[43] The following year saw an 11% rise in agreements to approximately 4,300 in 2000.[44] In addition, new companies and start-ups formed around federally-funded scientific inventions has increased dramatically: about 450 companies were founded in the year 2000 alone, with approximately 2,200 new companies formed since 1980.[45]

With the dramatic increase in patents issued, new companies formed, licensing agreements executed, and incoming royalties and licensing fees to academic institutions, universities have greatly benefited from the Bayh-Dole paradigm. The public has experienced significant benefits as well. Technology transfer activities have resulted in the creation of additional jobs and generated substantial economic activity, adding an estimated $40 billion into the U.S. economy.[46] More importantly, the flow of innovative products resulting from federally-funded research reaching the public has become faster and more efficient, with over 1000 products based on federally-funded academic discoveries reaching the market since its inception.[47] In the case of patient care, Bayh-Dole's impact has translated into a wide variety of medical products to diagnose and treat disease, almost certainly providing patients with beneficial healthcare technology that may not have reached clinical application without Bayh-Dole.[48]

B. Criticism of Academia-Industry Partnerships

While the success of Bayh-Dole in transferring government-supported research to the public is substantial, there are those who are uncomfortable with academia-industry partnerships that have made public access through commercialization possible. Historically, academia's mission has been focused on education and research, with the expectation that research results would be shared throughout the academic community and beyond. Academic medicine operates under the same guiding principles, along with a third mission, patient care. The pursuit of commercialization, as implied under Bayh-Dole, does not exist within the traditional missions of the academic institution, and is seen by some as counter to the basic academic mission.

Though effectively paired together by Bayh-Dole, industry and academia have disparate goals and motivations, and operate in distinct environments (see Table 1). Industry is governed by business ethic, and operates in an environment based on competition and motivated by financial concerns. The primary responsibility of business leaders is to their investors and shareholders, where the ultimate success is increased profits. Academic institutions however, are governed by a professional ethic, with research conducted in a collegial environment motivated by the quest for knowledge for the sake of knowledge. The primary responsibility of academic research, and by logical extension academic researchers, is to society as a whole, not investors.

The inherent tension of the academia-industry relationship, and in particular, the role of patenting, has been the focus of significant analyses and discussion, particularly within the academic community.[49] To some in that community, the purity of the academic mission is a key issue. Through technology transfer activities and collaborative endeavors with private, for-profit industry, motivations underlying academic research have become less clear. Academic centers now have the potential to generate substantial revenue from technology transfer activities. Similarly, individual researchers have the opportunity to profit financially from their work. These economic incentives raise concerning questions as to why research with the potential for financial gain is undertaken and potentially calls into question the results of that research.

Table 1
Fundamental Differences Between
Academic Research Institutions and Industry

	Industry	Academia
Governing Ethic	Business	Professional
Basis	Commerce	Oath
Responsibility to...	Investors	Humankind
Mode of operation	Competition	Collegial
Motivation/Goal	Financial	Knowledge

C. Financial Conflicts of Interest

Compounding the fundamental questions surrounding academia's association with industry are particular problems that have emerged from this relationship, specifically, individual and institutional financial conflicts of interest. Through the pursuit and receipt of patent royalties, licensing agreements, equity holdings, and ownership interests, investigators and academic institutions are presented with financial opportunities with the potential to influence decisions and affect research results. Of particular concern is research involving human subjects, where financial conflicts may jeopardize patient safety. Financial conflicts of interest also threaten to undermine the integrity of academic research and perhaps most importantly, the public's trust of academic research.

VI. Bayh-Dole and Recognizing the Academia-Industry Partnership

The relationship between academia and industry will always be a complex one, combining a culture with a tradition of knowledge for knowledge's sake with an environment that emphasizes increased financial returns. While the tension is real, the cultural differences between the two environments are not an insurmountable barrier to productive collaboration, nor does such collaboration by itself mean that either culture must sacrifice its values. Rather, it is for society to decide how and on what terms academia and industry interact for benefit of all concerned.

The Bayh-Dole Act is just such a societal statement. By transferring ownership of intellectual property developed with federal funds to the grantee or contractor and imposing conditions designed to transfer that research to those who can develop it for broad application, the Act establishes an implied duty to commercialize promising federally-funded research. It recognizes the strength of the academic community in building knowledge, as well as the strength of industry in transforming that knowledge into widely available products. As a practical matter, this implied duty mandates a partnership between academia and industry, providing an effective and definitive answer to those critics who contend that academia and industry should remain arbitrarily separate entities.

Bayh-Dole's implied duty to commercialize, while an important legal and societal statement on the desirability of productive collaboration between academia and industry, is not the only evidence that society encourages this type of interaction. For example, the Association of American Medical Colleges (AAMC) sees the traditional academic medical missions of education, research, and patient care occurring "within the context of service to local, regional, and national communities."[50] This position may be interpreted as establishing community service as a fourth mission of academic medicine, a goal that closely parallels Bayh-Dole's emphasis on realizing the maximum societal benefit from government-funded research. In this light, the AAMC's

community service mission implicitly supports the broadest possible application of new medical technology so as to benefit broader society, something only possible through an active collaboration between the academic medical community and industry.

Associations between individuals and entities entail risks as well as benefits, though it is important to realize that the risk involved in the academia-industry collaboration established by Bayh-Dole is, in effect, a product of the Act's implied duty to commercialize. The inevitable existence of such risks, such as financial conflict-of-interest, should not distract society from the larger benefit derived from academia-industry collaboration, nor should it be allowed to defeat the strong societal statement made by Bayh-Dole. Rather, their existence should serve as a reminder to academia, government and industry to identify and mitigate risks associated with commercialization of academic research, so as to maximize the benefit to society from government-funded research. By doing so, academia and industry will continue to fulfill the vision that is Bayh-Dole, and continue the impressive record of achievement that has provided so much benefit to society.

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