Bayh-Dole: if we knew then what we know now

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More than 25 years after the US Bayh-Dole Act was passed to encourage technology transfer from universities, is it time to reexamine and revamp this key legislation?

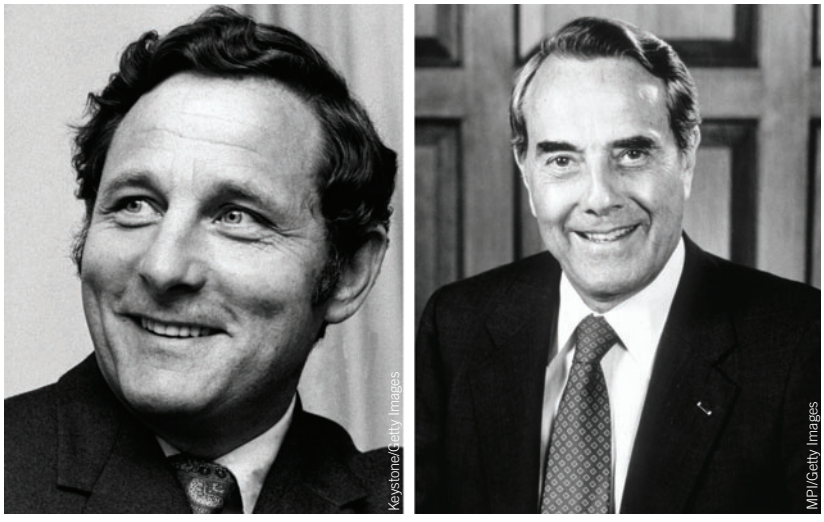
The controversies surrounding the US Bayh-Dole Act[1], enacted 25 years ago, are a frequent topic of scholarly articles and conferences, as well as the topic of regular legislative forays designed to modify the Act's terms to achieve a variety of social or economic goals[2]. In addition to its importance as a component of the US innovation system, Bayh-Dole-like legislation is being adopted in other countries[3], providing an impetus to ask the question: If we were to write similar legislation today, what issues would be addressed differently, given our experience with the Bayh-Dole Act over the past quarter century?

The track record

The range of immediate answers to the above question would likely reflect the now entrenched camps of opposing opinions. Supporters believe Bayh-Dole's nationally uniform framework is critical for the successful transfer of technology from university to industry, and that it serves as a catalyst for economic growth[4]. Critics argue that the Act has brought about deleterious consequences for the US innovation system and altered the nature of the public research enterprise[5]. A third camp in the debate believes that Bayh-Dole has had little impact, viewing the upswing in university technology transfer as the result of other, concurrent events, such as US Supreme Court decisions permitting the patenting of novel organisms, increased government investment in biomedical research and the emergence of research-intensive companies in information technology and life sciences that could exploit university inventions[6].

Fundamentally, Bayh-Dole shifted the incentive structure that governed the research and development path of federally funded inventions by allowing institutions to own inventions resulting from federally sponsored research and to exclusively license those inventions. The Act also requires the institution to establish patent policies for its employees, to actively seek patent protection and to encourage the development of their inventions. Beyond these basic requirements, the legislation leaves a great deal of discretion to the institutions. This flexibility has been both a source of strength for Bayh-Dole and a weakness. Many of the issues that are identified today as negative consequences of Bayh-Dole can be traced to the institutional policies structured to optimize institutional benefits and income, rather than to the Act itself.

Over time, universities have come to a more subtle understanding of the benefits and the limitations of technology transfer. Collectively, university technology transfer offices (TTOs) have learned that patent portfolios are difficult and expensive to manage, they take a long time to mature to the point where they will deliver revenue, results are widely variable and the investment required represents a long-term commitment. As a result, expectations have changed with the primary focus of technology transfer shifting from one that is narrowly based on institutional revenue to one encompassing impacts on the broader local economy, industry-university relations, the formation of new companies and the development of industry clusters. However, changing the metrics by which a TTO is evaluated, and thus indirectly changing the incentive system affecting those making patenting and licensing decisions, has been a slow and evolving process.



US Senators Birch Bayh, left, and Bob Dole, who sponsored a small amendment (P.L.96-517) to the Patent and Trademark Act in January 1980. Little did they know how important their act would be for the growth of the fledgling biotech industry.

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Among the impacts of Bayh-Dole that have been widely deliberated and criticized, four main issues stand out that warrant consideration in any future revision or national emulation of Bayh-Dole: first, the need for a practical research exemption to permit the ongoing use of technologies developed with public funds for noncommercial research; second, the lack of a systemic approach to provide broad access to publicly funded upstream inventions and research tools; third, the need for reform to address the 'anticommons' effects that result from fragmented ownership of publicly funded research inventions; and fourth, access to patented, publicly funded technologies for humanitarian purposes. Indicative of the significance of these four issues, *ad hoc* measures have been proposed and implemented to address each issue at some level. Even so, the scale and complexity of the problems demand, instead, a uniform and consistent framework of public policy designed to optimize innovation within the public research system.

Evidence that adjustments to Bayh-Dole are warranted comes from several perspectives. Requests for march-in rights have become more vocal and there have been proposed amendments to the legislation. Some have argued that the administrative hurdles required to initiate march-in rights petitions be significantly reduced to allow greater public opportunity to contest university licensing practices and influence the way in which publicly funded research results are transferred to the public[7]. This underscores an increasingly articulated view that universities are not managing intellectual property (IP) to provide the greatest public benefit. Below, we discuss in more detail the four areas that lie at the root of these problems.

A research exemption/reservation of research rights

Until recently, many university researchers incorrectly believed that the research exemption codified in patent law extended to fundamental research in general and that they could freely use IP in their research without regard to infringement. The *Madey v. Duke University* (307 F.3d 1351) ruling, however, argued that any university research may be viewed as advancing the business interests of the institution and thus of a fundamentally commercial, rather than philosophical, nature. This ruling effectively narrowed the research exemption for university research beyond any practical use[8].

The Bayh-Dole Act requires the grant of a nonexclusive license to the government and so provides an effective research exemption for federal government entities to practice the invention, but this license does not extend to universities or nonprofit research institutions. The lack of a research exemption has created the unusual situation where a university invention, if licensed exclusively, may be unavailable for use in fundamental, noncommercial research, even in the very laboratory where it was made. Universities' vulnerability to infringement suits highlighted by *Madey v. Duke* and the increasing trend in requests for universities to take licenses indicate that it may only be a matter of time before the US university system is forced to face a difficult problem. In the meantime, the current situation creates uncertainty and confusion that can have a negative influence on public research. As an example, the University of Iowa (Ames, IA) conducted an investigation to determine the ownership of IP used in a single laboratory. This single study involved contacting 71 different entities, and an expenditure of $24,000 to conduct background checks and to send inquiries to patent owners[9].

Many universities in their exclusive license agreements now reserve rights for the use of inventions within their own institution and within all academic or nonprofit research institutions, effectively creating a research exemption to use publicly funded technologies for noncommercial research applications in other publicly funded research. For example, the University of California routinely incorporates the following clause into its exclusive license agreements:

"Nothing in this Agreement will be deemed to limit the right of The Regents (the University)…to make and use the Invention…and associated technology and allow other educational and nonprofit institutions to do so for educational and research purposes."

Broad adoption of similar language would effectively create a research exemption to use publicly funded research results for noncommercial research in academic and nonprofit research environments, but this broad adoption has not yet occurred. This issue could be readily addressed through a legislative amendment to the Act because the exemption could be clearly articulated and questions of adherence are relatively straightforward. Although commercial firms that exclusively license technologies resulting from federal funding may object to a legislatively mandated reservation of rights for noncommercial research purposes, such an addition to the Bayh-Dole Act would ensure that the Act supports, rather than blocks, the advancement of fundamental science within the public research community.

Access to research tools

Research tools have been defined by the US National Institutes of Health (NIH) as inventions whose primary usefulness is in discovery rather than as a product in itself. This definition can also be extended to include broad enabling technologies, such as recombinant DNA technologies or gene transfer methods—methods that are essential for producing a wide range of new inventions and new products and that may enable entire new industries. Broad access to research tools and enabling technologies is necessary to advance both noncommercial and commercial research. Lack of access to these so-called 'upstream' technologies can block innovation across broad areas of applications and this has raised significant public policy issues, particularly with regard to exclusive licensing. A prominent example is the Cohen-Boyer 'recombinant DNA' patent[10], which was licensed nonexclusively by Stanford University and enabled the development of a robust industry during the 1980s. Imagine the world today if the patent had instead been licensed exclusively to a single biotech company.

A research tools policy, modeled after the NIH policy, governing all federally funded research is needed to clarify public policy and to ensure that federally sponsored research results are deployed in ways that will support broad innovation.

The NIH addressed this issue with guidelines for preserving access to research tools[11,12]. These guidelines suggest that research tools developed under NIH funding be licensed nonexclusively and made widely available. The NIH successfully promoted voluntary adoption of the guidelines and later integrated them into their sponsored research agreements. In spite of the remaining ambiguity over the definition of a 'research tool,' the NIH policy is working well to facilitate broad access to publicly funded upstream technologies. So if the policy is working for NIH-sponsored research, why not for the rest of the federal agencies? A research tools policy, modeled after the NIH policy, governing all federally funded research is needed to clarify public policy and to ensure that federally sponsored research results are deployed in ways that will support broad innovation.

Anticommons effects

The 'anticommons' is a term coined by Heller and Eisenberg[13] to describe how technologies owned by multiple parties may impose daunting transaction costs and delays in accessing research inputs, which ultimately may lead to an underutilization of proprietary technologies. Bayh-Dole contributed to the creation of an anticommons by establishing incentives for universities to develop independent technology transfer programs and to manage IP in a highly individualized and even competitive framework, with respect to other universities. As a result, it is often difficult to aggregate a range of IP rights required to develop a product. Although Walsh *et al.*[14] found that fragmented proprietary rights rarely precluded the pursuit of worthwhile projects, this conclusion may have limited relevance if 'worthwhile projects' are equated with research that has sufficient commercial potential to overcome the high transaction costs characteristic of the anticommons. Projects with limited profitability but of high social or humanitarian value, on the other hand, are likely to suffer disproportionately from anticommons problems. Anticommons problems associated with neglected diseases were exemplified in early development of a malaria vaccine where the major mitogen-activated protein kinase MPS1 antigen was found to be covered by 39 patent families describing and claiming the antigen, which added a degree of complexity and cost in identifying strategies for vaccine design[15].

In discussing the stifling effect of the anticommons on innovation, Benkler[16] suggested voluntary actions, such as peer production and publicly minded licensing, as two alternatives to legal reform. The Bayh-Dole Act allows institutions the discretion to create internal policies that support the types of alternative management of IP discussed by Benkler and indeed several exist. For example, publicly minded licensing is a concept illustrated by the Public Intellectual Property Resource for Agriculture (PIPRA; http://www.pipra.org) developed in response to concerns about IP impediments to research and development in subsistence crops for the developing world. Recognizing that the patent system provides an important tool to promote commercialization of technology, PIPRA has created a mechanism for its members to collaboratively manage their agricultural IP with goals that focus on both individual universities' interests as well as public interests. Another approach to the anticommons issue is Biological Innovation for Open Society (BiOS), which is modeled on the open source paradigm in software. BiOS provides access to platforms of patented enabling technologies through an 'open source' license[17] that protects the BiOS technologies from private appropriation and begins to build a 'commons' of IP through a grant-back provision that expands the initial technology pool and prevents the development of blocking patents on improvements[18].

The *ad hoc* measures exemplified by PIPRA and BiOS are beginning to show signs of progress in addressing anticommons problems, particularly in agriculture. However, such public interest efforts are unlikely to arise broadly from the existing incentive structure because they deliver public, not private, benefits. PIPRA's framework was successfully adopted by so many universities in part because the financial stakes in agriculture are relatively low and Land Grant Universities have a long history of publicly minded technology transfer in this sector. Whether the incentives exist for universities to support such a framework in a technology sector with higher stakes, such as the biomedical sciences, is uncertain.

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The problem of public interests being underserved by private incentives illustrates the need for national policy guidance on these issues for the management of IP developed within the US public research system and for the many technology sectors where there are no *ad hoc* measures in place to alleviate anticommons effects. There is no easy solution to this issue, which at its core requires the development of collaborative IP management strategies across multiple publicly funded research institutions. Having said that, we believe that the trajectory of scientific research is toward large-scale, multidisciplinary and multi-institutional projects, and these projects will demand the development of collaborative approaches to manage their IP outputs.

There is no readily apparent amendment to the Bayh-Dole Act that might provide incentives for such approaches. However, a starting point may be to require, as a condition of some of these large-scale research projects, the development of multi-institutional strategies of IP management that go beyond the normal acknowledgement of joint inventorship. In addition, there should be a role for federal agencies in expanding the utility of databases that are an essential tool in understanding the set of inventions that comprise the publicly funded IP portfolio. The data gathering infrastructure for federally funded inventions already exists in the iEdison system. The iEdison system[19]—which was created in 1997 to facilitate NIH compliance with Bayh-Dole's reporting requirements and has since expanded to track invention and patent information for inventions supported by eighteen federal agencies. If iEdison were modified, it could provide valuable insight into the public IP portfolio. Finally, individual agencies should begin to pay greater attention to the management of research outputs and to fund the development of IP clearinghouses in technology sectors where publicly funded research is perceived to be building an anticommons of IP.

Humanitarian access

The Bayh-Dole Act has a provision to require substantial domestic manufacture of products developed from publicly funded IP. This provision has probably outlived its usefulness because in today's globalized environment, offshore product manufacture may well provide greater net economic benefit to the US economy. The provision is also parochial and could be expanded to recognize that IP should be managed to provide not only a specific domestic economic benefit but also to ensure the broadest global public benefit. In this regard, it is well recognized that patents can increase the cost of product development, which makes investments targeting the needs of small or unprofitable markets difficult for private companies to justify. When IP developed with public funding is licensed exclusively to private companies, the technology is typically unavailable to support product development for low-income markets, even when the commercial licensee has no intention to address those markets. This situation has led to the development of a range of patenting and licensing strategies that explicitly define and reserve rights for humanitarian uses of patented technologies to allow product development for noncommercial markets.

As an example, PIPRA has used its membership base to develop and promote licensing language aimed at the reservation of

rights for humanitarian commercial development that benefits the world's poor and underserved. PIPRA's licensing language uses a territorial division of rights, separating commercial markets in developed countries from humanitarian use and commercial markets in developing countries. There are a range of other options to achieve similar goals and these have been carefully documented by the Science and Intellectual Property in the Public Interest (SIPPI) program[20]. US national public policy guidance is needed to support these *ad hoc* measures and to require that publicly funded research results be managed in a way that preserves the opportunity to mobilize new technologies to meet humanitarian needs of the world's poorest people in addition to meeting the commercial needs of the developed world.

The next 25 years?

In the 25 years since Bayh-Dole became law, there have been moves to amend the legislation. Most of these attempts have been unsuccessful and underscore the interests of universities and companies to maintain the status quo. However, the forays into legislative reform attest to the concerns of public interest groups and elected representatives that public research support is being leveraged to optimize private, rather than public, interests.

Several *ad hoc* measures, such as the promotion of licensing language to preserve research or humanitarian rights and the creation of PIPRA to foster collaborative management of IP in agriculture, have sought to address the most problematic aspects of Bayh-Dole, but they are not sufficient. The question now is whether a coherent national policy can arise among government agencies using these *ad hoc* measures and the flexibility provided by the Act, or whether legislative amendment is necessary to provide a uniform public policy. Because Bayh-Dole has no sunset and no reauthorization requirement, there is no natural forum for an in-depth legislative review of the effects of the Act. Although the expansion of some of the *ad hoc* measures and systematic institutional adoption, across all government funding agencies and their grantees, could be deployed to address issues of a research exemption, anticommons effects, broad access to publicly funded research tools and access to patented, publicly funded technologies for humanitarian purposes in resource-poor countries, this approach seems unlikely to be adopted uniformly or within any reasonable timeframe.

By vesting such comprehensive discretion and flexibility in patenting and licensing with individual institutions, the Bayh-Dole Act provided the nation and the world with a large-scale experiment in how public institutions manage public assets as private goods. The outcomes have been positive on nearly all counts, but the Act inadvertently created a misalignment between the private interests of university technology transfer offices and public interests that benefit the innovation system at large or that enable access to IP for humanitarian purposes. If the vibrancy and strength of the US university-industry interface is to continue, the next 25 years of Bayh-Dole should be characterized by universities paying greater attention to the innovation system overall, by increased access to patented technologies for research, by broad access to research tools, by a much stronger collaborative environment among universities with a corresponding diminution of the anticommons, and greater attention to managing IP in ways that explicitly support humanitarian applications of new technologies.

Although many institutions are individually moving in these directions, systemic and broad-based adoption of these principles requires a realignment of incentives. This can probably only be addressed through legislative amendments to the legal framework that guides the management of the outputs of the nation's public research enterprise—the Bayh-Dole Act. Indeed, 25 years after this Act passed into US law may just be the right time to take stock of where we are and what the technology transfer and public interest communities have learned in a quarter century of patenting university inventions. Such changes are needed to ensure that the public continues to fully benefit from the products of public research.

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