Accountability in patenting of federally funded research

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New data indicating underreporting of federal funding in academic biomedical patents highlight the pressing need for greater transparency under the Bayh-Dole Act.

The 1980 Bayh-Dole Act established a uniform, government-wide policy in favor of allowing academic recipients of federal research funding the right to seek patents on inventions arising from that funding. Although federal funding obviates the usual "incentive to invent" justification for patents, Bayh-Dole's sponsors believed that giving patent ownership to grantees would be the most effective mechanism for further developing university discoveries into the new products and industries necessary for maintaining national competitiveness[1].

Bayh-Dole does not, however, confer entirely unfettered discretion upon grantees. To the contrary, the Act contains accountability safeguards, including requirements for reporting not simply the existence of federally funded patents but also information regarding the licensing, assignment and practical utilization of these patents. The Act also provides the government with an array of retained rights in the work that it funds[2].

At least in theory, these accountability safeguards are a significant policy tool. To the extent that reporting is implemented faithfully, it creates a data set that could be extremely useful for evaluating the impact of government funding and for calibrating how funding should be deployed in the future. Proper reporting also assists the government in determining whether it should exercise its retained rights. These include the right to compel additional licensing in cases where the grantee or its licensee and/or assignee has not achieved "practical application" of an invention[3]. Concerns that federally funded academic patents are being used to hinder development rather than promote it can arise when universities or their licensees and/or assignees assert these patents against independent commercializers[3,4]. They can also arise when universities license or assign federally funded patents to firms that aggregate these patents in mass quantities for purposes of assertion against firms that produce products[5]. Indeed, in the latter case, proper reporting regarding utilization may be the only mechanism by which the government knows how a federally funded patent was deployed. Universities are reluctant to publicize their dealings with aggregators[6], and aggregators typically do not record exclusive licenses with the US Patent and Trademark Office. Even assignments may not be recorded, or are recorded using names of shell companies that are nontransparent[5], with the consequence that assignment data can obscure rather than clarify questions of utilization.

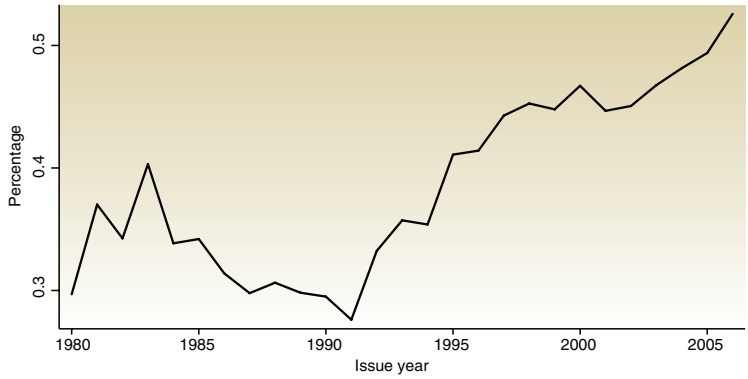

Figure 1 Percentage of academic biomedical patents with government-interest statements

Proper reporting could also reduce taxpayer costs associated with procurement. As the Government Accountability Office (GAO) has pointed out[7], the government has a right under Bayh-Dole to royalty-free practice of patents on federally funded inventions. The importance of Bayh-Dole's accountability provisions has been highlighted by several recent events. In *Stanford v. Roche*[8], a 2011 Supreme Court case addressing the question of whether universities or individual academic scientists should have default ownership under Bayh-Dole, the US government invoked as an argument in favor of default university ownership the claim that such ownership would more readily promote accountability than ownership by individual scientists[9]. A 2010 National Academy of Sciences (NAS) report on Bayh-Dole has several chapters and recommendations that specifically target accountability[10].

Most recently, in the 2011 America Invents Act, universities secured a privileged position for their patents. Unlike all other infringement defendants, defendants charged with infringement of patents that originated in a university will not be able to assert a newly enacted defense of "prior use"[11]. Thus, even in cases where a defendant has successfully commercialized without even being aware of a subsequently issued patent originating in a university, the defendant could be found guilty of infringement. The privileged position universities and their assignees and/or licensees now hold in patent litigation, even against prior, independent commercializers, makes proper information as to whether those patents

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involved federal funding even more important. If universities and their licensees and/or assignees were to assert patents governed by Bayh-Dole's commercialization imperative against prior users, universities would directly contravene the goals of Bayh-Dole.

Unfortunately, as the 2010 NAS report notes, much of the actual data on compliance with reporting are incomplete and quite stale. The last quantitative study on compliance dates back to the 1990s[12]. This prior research, largely conducted by the GAO, also does not attempt to determine trends over time. Here we present fresh data, quantitative and qualitative, on academic biomedical patents, focusing on the period from 1980 to 2007. These data suggest underreporting throughout the period, albeit with some improvement over time.

However, because of the nearly complete secrecy associated with relevant government databases, our research can shed light only on one aspect of the accountability puzzle—whether the existence of patents was properly reported. We cannot investigate completeness of reporting regarding licensing and/or assignment and utilization. This level of secrecy is unnecessary and counterproductive. We argue that, through modest tweaks in relevant Bayh-Dole regulations, the government could foster much greater transparency and accountability, including on the fundamental question of how the current Bayh-Dole regime is fostering—or failing to foster—innovation and competitiveness.

Bayh-Dole's accountability provisions

Under Section 202(c) of Bayh-Dole, a grantee must report to the US agency from which it received funding any patent application the grantee files. The section also allows agencies to require "periodic reporting" on utilization or efforts at achieving utilization. Most agencies require such reporting. Subsequent judicial cases interpreting Bayh-Dole have held that failure to report inventions to the funding agency allows the agency to assert title over the patent[13].

Additionally, as the legislative history of the Bayh-Dole Act emphasizes[1], some of the Act's reporting requirements create an opportunity for third parties to supplement the oversight efforts of resource-strapped funding agencies. For example, Section 202(c) requires not only reporting to funding agencies but also a statement in the public patent document itself regarding the existence of federal funding and the fact that the government retains certain rights because of this funding. This "government interest" statement alerts third parties negatively affected by improper use of a patent of their ability to petition the funding agency to exercise these retained rights[1]. Specifically, based on third-party complaints regarding a grantee's inability to "achieve practical application" of an invention or to use the invention "to alleviate health and safety needs," an agency may choose to require additional licensing by a grantee or its licensee[14].

Although funding agencies have, thus far, refrained from actually exercising this retained right, it has provided important leverage in fostering voluntary moves towards more commercialization-friendly licensing by universities, including in such important cases as the foundational stem cell patents held by the University of Wisconsin[15]. Moreover, to the extent reporting is incomplete, better reporting might well foster greater awareness of the need to exercise retained rights.

Prior research regarding compliance with reporting

As noted, recent empirical data on compliance with reporting requirements are sparse. Relevant information on reporting to agencies resides in Interagency Edison (iEdison), which incorporates information by grantees provided to the 29 funding agencies[16]. Nongovernmental researchers are, however, denied any direct access to the iEdison database. GAO has occasionally investigated completeness of reporting to iEdison, but the last study containing actual data was conducted in 1999 (ref. 11). A follow-up report issued in 2003 (ref. 7) simply examined whether the agencies studied in 1999 had made procedural efforts to improve compliance. The 2003 study did not determine whether compliance had in fact improved.

The lack of recent empirical data is particularly worrisome because the 1999 GAO report found that, out of a sample of 633 medically related patents issued to 12 academic grantees, 143 had most likely arisen from US National Institutes of Health (NIH) funding but had neither been reported to iEdison nor contained government-interest statements.

Academic biomedical patents

In our research, we also focused on academic biomedical patents. Using a definition of "academic" developed by one of us in prior work[17], we obtained information on all academic patents issued from 1980 to 2007. About 40% of all academic patents issued during this period mapped to six biomedical patent classes (435, 514, 424, 530, 536 and 600).

Overall, 43% of these patents had government-interest statements. This share has shifted substantially over time, rising from 30% to 40% in the early 1980s before reaching a nadir of 28% around 1991 (**Fig. 1**). Since 1991, the percentage has gone up steadily, reaching 53% in 2006. By contrast, the federal share of total biomedical funding *decreased* somewhat in both the early 1980s and the mid to late 1990s (**Fig. 2**). Thus, reporting trends are unlikely to reflect changes in the composition of research funding. Moreover, because about 60% of academic biomedical research was federally funded in the period between 1980 and 2007 (**Fig. 2**), the overall 43% incidence of government-interest statements provides *prima facie* evidence of underdisclosure.

To provide another perspective on the reporting question, we looked at correspondence over time between reporting of patents to the NIH and statements of government interest in the patent document itself. As noted, nongovernment researchers do not have direct access to iEdison. However, the NIH RePORTER database, unveiled in 2010 to provide information on NIH grants in general, imports data on patents reported to NIH from iEdison and thus provides a small window into that otherwise secret database. The RePORTER website appropriately cautions that "[n]ot all recipients are compliant with the iEdison reporting requirements"[16].

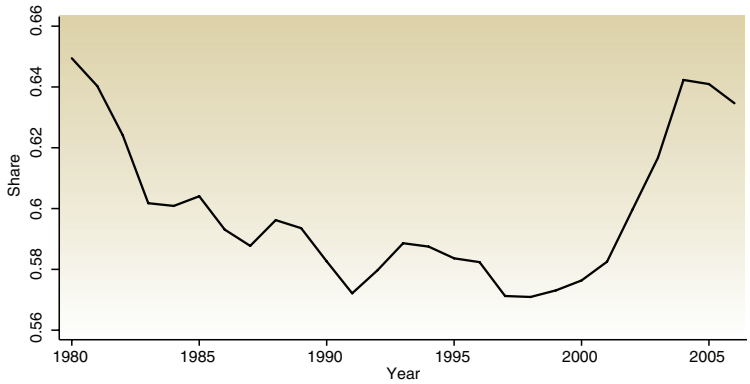

Figure 2 Percentage of academic life sciences research federally funded by year. Calculations based on data from NSF WebCASPAR database.

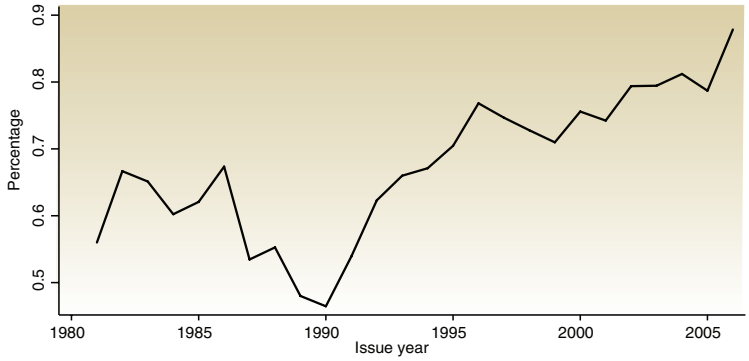

Figure 3 Percentage of RePORTER patents with government-interest statements.

Even so, the RePORTER data can be used to determine if institutions that reported patents to iEdison also complied with the Bayh-Dole requirement that the public patent document itself acknowledge that the invention had emerged from federal funding. Simply put, *all* patents disclosed in RePORTER should have a government-interest statement in the patent document itself.

Figure 3 shows that the share of RePORTER patents that have a government-interest statement has generally increased over time, with the inflection point coming in 1990, at about the same time that the overall percentage of government-interest statements in academic biomedical patents began to increase. However, the incidence of government-interest statements has generally hovered between 60% and 80% (**Fig. 3**). For RePORTER patents, the incidence of government-interest statements should always be 100%. Even as of 2007, the incidence rate was less than 90%.

FDA-approved drugs

We also examined these reporting issues qualitatively for patents on FDA-approved small-molecule drugs. Biomedical therapeutics like drugs are directly important for healthcare, including healthcare purchased by the US government[7], and thus are particularly likely to raise concerns about lack of accountability. A prior study by one of us[18] contains a *prima facie* suggestion of noncompliance with reporting obligations. That study aimed to assess the role of the public sector in the development of drugs approved by the US Food and Drug Administration (FDA) between 1988 and 2005. It did so by examining government-interest statements in the patents on those drugs. However, to examine the robustness of results to alternate indicators of government influence, the study also examined all drugs where academic institutions held patents. Comparing the two measures, of the 48 drugs with academic patents identified in that study, 21 (44%) had no government-interest statement in their patents. In addition to these drugs (where none of the patents acknowledged government support), seven other drugs were associated with some academic patents that acknowledged government support, but others that did not.

Following up on this initial finding, we determined that a total of 43 patents without government-interest statements were associated with the 28 drugs. Consistent with the lack of full correspondence between RePORTER and government-interest statements noted above, 7 of the 43 patents were listed in the NIH RePORTER database. The remaining 36 patents (associated with 22 drugs) did not acknowledge government funding in any way.

Should the 36 patents have been reported? Under the Bayh-Dole Act, an invention is a "subject invention" governed by reporting obligations and retained government rights if it was "conceived of or first actually reduced to practice in the performance of work under a funding agreement"[19]. In practice, as many decades of expensive patent litigation over "conception" and "reduction to practice" has shown, these legal terms of art are hardly a model of clarity. In the case of Bayh-Dole, moreover, one has to determine whether conception or first reduction to practice occurred while the scientist was performing work under the funding agreement.

These caveats aside, one can examine the extent to which inventors on the 36 patents at issue were receiving federal grants covering the same inventive territory as the patent before the patent application was filed. In some cases, one can also link publications to grants and thereby further rely on the relationship between information disclosed in the publication and the patent document. For our qualitative study, we used all publicly available scientific information contained in inventors' grants and publications at relevant times.

For our analysis, we used a conservative definition of "subject invention." For example, when a patent had many inventors and only a few of the inventors appear to have been supported by federal grants covering similar territory during the time of the relevant research, we deemed the situation "unclear." We also deemed "unclear" situations where the federally funded research appeared to cover compounds closely related to the patented drug, but we could not resolve the precise question of overlap. Based on this lack of clarity, we excluded five drugs and five associated patents. Even with these exclusions, we determined that 15 patents (and 8 associated drugs) raised substantial questions about appropriate reporting.

Discussion

Overall, the data suggest that universities are improving their compliance with reporting obligations. That said, reporting is incomplete and could be improved further. Reporting is incomplete even for inventions such as FDA-approved drugs that presumably should be high on the radar screen of university technology transfer offices. Moreover, the fact that reporting regarding the mere existence of patents is incomplete does not bode well for reporting on actual utilization.

Although the burden of accurate reporting should be relatively small, incomplete reporting has many important consequences. Where no patent information whatsoever is reported, the consequence is uncertainty about the federal government's "march in" rights and understatement of the public sector role in innovation. In cases where patents are reported, but reporting on utilization is incomplete, university success in achieving commercialization of federally funded research cannot be assessed comprehensively.

Notably, the lack of transparency surrounding iEdison makes assessment of compliance difficult. Lack of transparency is especially acute outside the biomedical field—in biomedicine, the NIH RePORTER database has at least made indirect access to a small portion of iEdison available. Greater transparency would not only facilitate better assessment of compliance but would itself improve compliance. Universities that knew compliance was going to be monitored, not only by funding agencies but also by third-party firms, academics and public-interest groups would presumably be motivated to improve compliance.

More fundamentally, and across all fields, lack of transparency makes systematic analysis of Bayh-Dole's overall success difficult. Although reports on utilization of patented inventions are contemplated by Bayh-Dole, and are required by many agencies, third parties do not have access to information regarding report completeness or to underlying specific information, presumably contained at least in

reports that are complete, about exactly who universities are transacting with and whether university intellectual property management has facilitated commercialization. Such lack of access is unfortunate, as third parties could substantially supplement the analytic efforts of government researchers.

The Bayh-Dole Act does not require this level of secrecy. To the contrary, the requirements regarding government-interest statements in public patent documents and march-in contemplate active participation by third parties. The Act does contain a provision stating that utilization information provided by grantees "shall be treated" by the federal funding agency as exempt from mandatory disclosure under the Freedom of Information Act (FOIA)[20]. The Commerce Department, which administers Bayh-Dole, currently reads this statutory language as requiring the agency to refrain from disclosing "such information to persons outside the government without permission of the contractor"[21].

Contrary to the Commerce Department interpretation, however, the Supreme Court has clearly held that agencies have discretion to disclose information that Congress has exempted from mandatory disclosure under FOIA. Specifically, in *Chrysler v. Brown*[22], the Court determined that so long as information disclosed by an agency did not encompass trade secrets traceable to a specific entity or individual, such disclosure was permissible. The Commerce Department could work with funding agencies to devise mechanisms for information release consistent with the *Chrysler v. Brown* standard, particularly in cases where the passage of time has diminished the trade secret value of relevant information.

An advantage of the accountability safeguards embedded in Bayh-Dole is that they should produce a wealth of data. But these data are currently shrouded in secrecy, so their robustness cannot be assessed, and policy lessons cannot be drawn from them. Although our research sheds some light, federal agencies could, within the limits imposed by law and sound policy, shed much more.

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COMPETING FINANCIAL INTERESTS

The authors declare no competing financial interests.

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