

University Licensing and the Bayh-Dole Act

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The Bayh-Dole Act of 1980 allows universities to patent and exclusively license federally funded inventions. With dramatic growth in university licensing, the

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Act has become controversial and the subject of policy review.

For the 84 U.S. institutions responding to

the Association of University Technology Managers' (AUTM) 1991 and 2000 surveys, inventions disclosed increased by 84%, new patent applications by 238%, license agreements by 161%, and royalties by more than 520% (1). Bayh-Dole advocates argue that in its absence many results from federally funded research would remain in the laboratory; critics say exclusive licenses are not needed for technology transfer and universities are chasing profits (2). Amid the rhetoric, what are the issues and evidence?

Would technologies be transferred in the absence of Bayh-Dole? Technology can be, and obviously is, transferred to industry without patents or licenses. Historically, publications, meetings, and consulting were the primary ways for industry to learn about academic research, and recent evidence suggests they remain so (3–5).

If and when exclusive licensing is needed to augment these channels is an important issue. Exclusive licensing may be needed when inventions require further development before use (6). A survey of 62 U.S. universities suggests that much university research fits this profile, with 45% of inventions no more than a "proof of concept" and only 12% "ready for practical use" at the time of license (7, 8). The failure rate for these inventions is high, 46% for all inventions and 72% for those that are only a proof of concept (9). Exclusive patent rights provide an incentive for firms to invest in costly development, but only to the extent that patents are effective in protecting intellectual property (IP), which varies by industry (10, 11).

Many university inventions are research tools, in which case exclusivity may limit use

by future researchers. Although Bayh-Dole permits exclusive license, it does not require it, and surveys show many licenses are nonexclusive (AUTM reports half) (2, 12). How often research tools are exclusively licensed is not known, but known examples, such as the OncoMouse, have exacerbated the controversy. Restricted use of such tools is more detrimental the broader their patent claims (13). Regardless, NIH guidelines for sharing research tools are helpful (14).

Are technology transfer offices "profit centers"? In the 2000 AUTM survey, 156 U.S. respondents reported \$1.24 billion in income from royalties and cashed-in equity net of unreimbursed legal fees (1, 15). This income was about 4.7% of their research expenditure. For every dollar of income, there is about \$0.20 in sponsored research tied to a license. The average income per active license is \$66,465, but only 43% earned royalties and 0.56% earned more than \$1 million in 2000.

Although average income per respondent was about \$8 million, 79% earned less than \$5 million, and half reported income less than \$824,000. On average, technology transfer offices below the median had four employees, which made it likely that many spent more than they received in income. While more offices have become profitable over time and this trend may continue, the current picture suggests that profits are not the sole goal of licensing. Survey research highlights the complexity of university goals, which also include sponsored research and Bayh-Dole's mandate to commercialize federally funded research (8, 16). Further, many in the university community recognize the need to balance IP rights and the public good (17).

Does licensing restrict dissemination of academic research? A survey of industry licensing executives shows 27% of their university licenses include clauses that allow deletion of information from papers before submission, and 44% ask for publication delay (3.9 months on average) (18). Life science faculty involved in commercial activity often deny requests by other scientists for research results, although multiple factors are involved (19, 20). This problem is more likely related to research that is company sponsored rather

than federally funded, because companies can protect IP with secrecy, whereas Bayh-Dole requires eventual disclosure through patents.

Have financial incentives from licensing diverted faculty from basic to more applied research? Evidence on the direction of faculty research is limited, but suggests that the answer is no. A survey of firms that license from universities indicates that the prime reason for increasing their collaboration with universities was receptivity to licensing rather than a change in faculty research (18). Studies of technology transfer from the University of California, Stanford, and Columbia find little evidence of either changes in research direction or financial return as a major motive for the research (6, 21). Our study of over 3400 faculty at six research universities from 1983 to 1999 suggests that the portion of research that was basic has not changed even though licensing increased by a factor greater than 10 (5).

There is evidence to suggest that university licensing facilitates technology transfer with minimal effects on the research environment, but the issues are complex and there are unknowns. Further study is needed, particularly as to whether faculty involvement in licensing complements or substitutes for open publication. The environment is also evolving. The explosive growth of licensing cannot continue forever—the final equilibrium, however, remains to be seen.

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