Do Universities Have a New Mission?

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Bayh-Dole Act, ability of education centers to manage technology transfer, and other factors are fueling major changes

Research emerged as an important part of the academic endeavor in America toward the end of the 19th century, when the mission of the university shifted by adding the function of creating knowledge through the exercise of reason to their traditional role of transmitting cultural values (1,2). During the first half of the 20th century about 15 U.S. institutions could be characterized as research universities. Today there are more than 200.

Are we at a similar junction? Are we in the process of structural change by adding another mission to academia?[1] Events during the past two decades have brought technology transfer to the forefront of academic activities, with a positive flavor — increased interaction with industry, support on the part of the upper management of academic centers, and a notable cashflow. In some circles this new function appears to be taken for granted. There are recent articles on technology transfer at universities that include, without hesitation, creation and transfer of technology as one of the fundamental missions of the university, together with teaching and doing research.

The early academic research-generated inventions from which a few inventors took commercial advantage on behalf of their universities. For example, Research Corporation was born in 1907 to manage F.G. Cottrell's (University of California) electrostatic precipitator patents, and the Wisconsin Alumni Research Foundation (WARF) was created in 1925 to manage H. Steenbock's (University of Wisconsin) patents on vitamin D. These inventions were licensed and earned royalties.

The success of scientific-military projects such as the Manhattan Project and radar development, which were carried out with significant academic participation, helped lead to the funding of basic university research by the U.S. government following World War II(3). The National Science Foundation was created and the National Institutes of Health were expanded. Central to increased federal support was the expectation that researchers would publish their results in scientific journals and that industry would use this free information to create new products and processes. These new developments would then benefit society.

Substantial federal funding started in the early 1960s and has been increasing since then. This government support fueled the rapid increase in the number of research universities(4).

While inventions generated from federal support during the 1960s and 1970s were freely published in scientific journals, little transfer of technology to industry occurred. The model proved to be inefficient for academia- or government-to-industry technology transfer. Companies would rarely invest essential funds — often large amounts — to develop early-stage inventions into final products or processes absent the exclusivity that patents provide and that enable recovery of investment. And even when patents were available — some researchers had such foresight — they were not easily accessible. Before 1980, the government owned and managed these inventions and offered only nonexclusive licenses. Even these were difficult to obtain, bogged down by cumbersome bureaucratic procedures. Since university-owned inventions were few until the early 1980s, only a small number of research universities engaged in technology transfer.

Since then, however, there has been an explosion of interest prompting a commensurate activity in intellectual property and technology transfer in academia. This occurred due to the passing of the Bayh-Dole Act (96-517 Law of 1980). Among its provisions, the Act allows universities to own and therefore manage inventions obtained in the course of research funded by government sponsors. The change enabled and encouraged universities to protect their inventions and transfer them to industry for development and marketing of end products. Presently, over 250 academic centers engage in technology transfer activities and, in 1997, they collectively generated almost $700 million in royalties(5).

TECHNOLOGY TRANSFER IN ACADEMIC CENTERS

U.S. academic centers today manage the full spectrum of intellectual property matters, including evaluation of inventions disclosed by faculty, their protection through patent applications, copyright or trademark as warranted, negotiation of license agreements with industry, creation of start-up companies, ownership of equity in companies using their technologies, defense of their intellectual property against infringe-

1. In this paper, "academia" or "academic centers" include universities and related institutions such as medical centers.

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ment, and sponsorship of further research with royalty income. A few universities have participated in writing business plans, and even occupying seats on the board directors of start-up companies(6).

Much learning and sophistication in technology transfer has been accomplished by academia since the passing of the Bayh-Dole Act. Technology transfer has become more homogeneous as industry and academia have learned what to expect from each other in negotiations. Also, common activities have been simplified. For example, many institutions and companies now utilize a uniform document for the transfer of biological materials, and a similar document is in the works for interinstitutional agreements on the management of jointly owned inventions.

Concurrently, technology transfer in academia has grown more complex, eclipsing the scope of patentable or patented inventions to encompass copyright trademarks, mask works for semiconductor chips, and even unpublished scientific data. It also spans property not considered "intellectual," such as laboratory materials (cell cultures, plasmids, chemical preparations, etc.), giving rise to the broader term "work product" in lieu of "intellectual property." An increasing number of license agreements involve equity in addition to royalties. Some inventions are jointly owned by two or more academic centers, and/or are licensed in a limited exclusive form to a small number of licensees. Technology packages, assembled from different owners, are offered to venture capital groups or companies.

COMPANY CREATION AND EQUITY

While academia focused on establishing technology transfer offices during the 1980s, in the 1990s attention has shifted to starting new companies or securing equity participation for the academic owner (and for the inventors). Of 3,328 license or option agreements signed in 1997, 333 were start-ups while 251 licenses had an equity component. The cumulative value of equity holdings relating to licensing activity for 1997, was estimated to be $271 million (5). What fueled the interest in equity participation was the perception that a much higher yield and a much faster pay-off is possible with equity than with licenses with straight royalties, given the success of some well-known biotech companies such as Biogen, Genentech, Genetic Institute and others, some of which used university-based technologies.

However, the popularity of start-ups and/or equity stakes raises potentially thorny issues, which require careful attention. One of the most important is conflicts of interest. Can one ethically perform research on the subject of an invention — especially involving students — while being shareholder of the licensee or holding a position as director or manager in the interested company? Does conflict arise when the equity-holding institution acts as the site of research on the same subject, or even more worrisome, the site of clinical studies of a drug licensed to the company in which it holds equity? Would there not be an inclination to make the data appear better than they are, potentially harming patients? Could there be the appearance of conflict that might undermine the public confidence in the academic center? Is the public interest protected by federal agencies that sponsor research and clinical trials or that oversee the drug approval process?

Until recently, conflict-of-interest policies of many academic centers did not contemplate this type of situation. Others totally banned carrying out any official activity through the academic center with companies in which the academic employee had equity or for which he/she was a consultant. Sponsored research, and very specially clinical trials, could not be done with those companies. Some placed quantitative limits that governed to conflicts of interest. An example was owning more of 5% of the total equity of a company.

In 1994, the NIH and the NSF proposed restrictive rules requiring recipient instutitions to manage conflicts of interest. After a strong response by academia, the NIH and NSF softened the norms, but required all recipients to have and to enforce a conflict-of-interest policy (7). The academic centers delivered. Those without policies wrote them, and many rewrote existing codes. The new wave of policies, however, proved more liberal than the older ones. They emphasize control rather than prohibition of conflicts of interest. With the exception of flagrant cases, the policies typically dictate that internal committees be formed to supervise the work or the performance of a colleague who may have, or appears to have, a conflict of interest. The committee ensures that the project abides by the norms of academic research, particularly in reference to student involvement.

Academica also evaluated its own institutional conflicts of interest. Formerly, some academic centers flatly prohibited or limited the amount of equity that could be accepted in a technology transfer negotiation, sometimes 5% or for the equivalent of up-front payments. Primarily this concerned protecting the image of the academic center from the appearance of a conflict of interest. The smaller the equity, the smaller the probability of a conflict, or the appearance of one. Again, the clearest example is with the clinical trials.

◄ Conflicts No Problem ►

However, after this process of introspection, the universities concluded that institutional conflicts of interest do not pose a problem. On the one hand, activities that could generate this type of problem are so minute in relation to the whole of the center's activities that they would be almost imperceptible. On the other hand, the conflict, if it existed, would be easily discovered and controlled.

For example, to obtain FDA approval, new therapeutics must be proved non-toxic and effective. The last phase of this study is normally performed in multi-center clinical trials. Consequently, if an institution that owns technology presents more favorable data on its own product than other medical centers,

these data simply are rejected. Last February the FDA enacted final regulations regarding financial disclosure by clinical investigators. It recognizes the development of beneficial therapeutic products through clinical research led by the inventor, or by whoever was compensated for these studies with equity in the contracting company (8). Therefore, FDA does not prohibit, nor does it discard the possibility of using these data as the basis for product approval. The FDA nevertheless, intends "to give such studies particularly close scrutiny and evaluation."

Although concerns remain (9), faculty's reluctance to interact with private industry such as consulting and sponsored research is a thing of the past. It is now closer to being a status symbol. But we have gone much farther. With the blessings — and supervision — of employers, there exists full-time faculty and researchers with inventions licensed to companies in which they hold equity, and simultaneously do research and clinical trials on their invention, now bankrolled by the licensee, consult, or have management or directors positions with the licensee.

In light of the success of technology transfer activities and with an eye toward the potential income such operations could generate for academic centers in times of scarce research funds, the attitudes of faculty and the upper management of academic centers, as well as the federal government, have shifted significantly toward greater tolerance of scenarios that in the past would have been deemed unacceptable. Situations that before were impossible or very difficult, now are "managed."

As a consequence of this *laissez fair*, academic centers have negotiated equity deals well over 5% ownership, up to 100% (Boston University's Marathon Biopharmaceuticals). The Memorial Sloan-Kettering Cancer Center, which until two years ago did not accept equity in technology negotiations, today is owner of 50% of the company Genos Biosciences, Inc., created to discover genes related to cancer. ARCH Development Corp. (Argonne National Laboratories and the University of Chicago) owned 40% equity in Everyday Learning when it was sold in 1994.

CONCLUSION

The Bayh-Dole Act has been successful. The impact of technology transfer activities by academic institutions on the American economy was estimated at $29 billion in 1997, adding more than 245,000 jobs. The growth of technology transfer activities, including the number of invention disclosures, patents filed, patents issued, new licenses, the expansion of its results in terms of royalty income, and new products and services, have been strong. Royalty income, for example, has grown at almost a 25% per year during the last five years. Growth is expected to continue, and may even accelerate in the near term as more than half of the technologies licensed each year are in the development process toward final products. In the case of health products, regulatory requirements lengthen development time to 5-10 years or longer. Products made with technologies licensed by academic centers in the last few years will continuously mature into products that will reach the market, generating royalties.

At the same time, academic institutions have been able to manage the conflicts and other issues generated by technology transfer in academia well. There have been relatively few mishaps (10,11,12). Important academic centers have strengthened their technology transfer offices by supplying them with adequate resources, giving them more flexibility, and by giving them appropriate administrative backing.

As a consequence, the relative importance of technology transfer in academia is taking hold. In a few cases, income due to technology transfer has become very important for the institution's research effort. New York Blood Center's royalty income is more than double the amount of sponsored research expenditures, City of Hope Medical Center's royalty income covers 66.5% of its sponsored research expenditures, Memorial Sloan-Kettering Cancer Center 46.3%, Florida State University is at 29.2%, and Columbia University, 20.6%. The aggregate royalty income from technology transfer as compared to the aggregate research budget of academic centers has grown at a pace of more than 10% a year during the last six years, and now it stands at close to 3% of the total research budget. Although the number in itself appears to be small, it is measurable, and its impact on the foundations of the university is much greater than it seems.

The demonstrated ability of academic centers to manage technology transfer, the changes of attitude toward interaction with industry, and its economic impact since the passing of the Bayh-Dole Act may be changing the very nature of academic institutions. Just like the fundamental change initiated a hundred years ago with the introduction of basic research, universities seem to be adding to their mission of preparing able professionals and creating knowledge through research, the new function of creating technology and transferring it for social benefit.

REFERENCES

1. Christopher J. Lucas, "American Higher Education: A History" St. Martin's Press, New York, 1995, and John S. Brubaker, "On the Philosophy of Higher Education" Washington D.C. Jossey-Bass Publishers (1982).
2. Gary Matkin, "Technology Transfer and the university," Macmillan, New York, 1990.
3. Vannevar Bush, "Science — The Endless Frontier," National Science Foundation, 1980.
4. Science and Engineering Indicators, 1998, National Science Foundation, 1998.
5. AUTM Licensing Survey: FY 1996," Association of University Technology Managers, Inc. 1998.
6. "Go Team, GO!" Lisa Piercey, Signals, 6/23/98. (www.Signalsmag.com/Signalsmag.nsf/O/F36B6BBADD5E78825662000D5D750C.
7. NIH Guide, Volume 24, Number 25, July 14, 1995.
8. 63 FR 5233, February 2, 1998.
9. R. Florida, L. Randazzese, and J. Walsh, in "Challenge to the Research University (1998), as found at www.nsf.gov/sbe/srs-/seind98/c5/c5s1.htm#c5s111b.
10. *Gibson-Stephens Neuropharmaceuticals Inc. v. University of Arizona* (Case Number 290280).
11. *Kucharczyk v. The Regents of the University of California* (Case Number C-94-3886 EFL) and *Singer v. The Regents of the University of California* (Case Number 950381).
12. *Platzer v. Sloan-Kettering Institute for Cancer Research* (Case Number 91 Clv. 6578).