



ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS®

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January 6, 2010

Ms. Esther Lee
Department of Commerce
OSEC/OPSP
1401 Constitution Ave., NW
Washington, DC 20230

RE: Bayh-Dole and University Technology Transfer
Effectiveness

Dear Ms. Lee:

I write to you on behalf of the Board of Trustees for the Association of University Technology Managers (AUTM) to express our concerns regarding the memorandum to you from Bob Litan and Lesa Mitchell of the Kauffman Foundation dated August 17, 2009, which only recently became available to AUTM, as well as a recent article in the *Harvard Business Review* (January – February 2010) in which Litan and Mitchell make some additional “suggestions.”

While we appreciate their interest in improving the effectiveness of technology transfer in the United States, their proposed “solutions” suffer from a fundamental error in assumptions about academic research and technology transfer. The Kauffman Foundation has often stated that there is not enough commercialization of university research. They observe the amount of federal funding for basic research and the volume of invention disclosures resulting from such funding, and, without substantial and verifiable data, jump to the conclusions that: 1) much more research should be commercialized; those innovations that are commercialized do not reach the marketplace fast enough; 2) technology transfer offices are ineffective and fragmented and therefore a bottleneck for this process; and 3) only the inventors are capable of making the right decisions regarding commercialization. The AUTM Board of Trustees believes that an informed perspective is missing from these proposals.

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1. Commercialization of research innovations

Litan and Mitchell state that "...although funding from NIH has mounted over the years... the output of new FDA approved drugs has been falling." They also state that "the pace and amount of commercialization is still sub-optimal." These statements demonstrate a significant misunderstanding of the primary missions of universities. Drawing a connection between increased NIH funding and decreased drug approvals and then attributing it to a failure of technology transfer is a naive explanation of the technology transfer, commercialization and regulatory processes.

Universities are not developers, manufacturers or marketers of commercial products. Commercialization of university research takes place in the private sector under licenses with existing or startup companies. Resources dedicated by industry and regulatory processes largely determine the speed at which products reach the market. Litan and Mitchell suggest that the non-profit activities associated with evaluating and protecting an invention and negotiating a licensing agreement for commercial use constitute the most important, most time-consuming aspect of commercialization. They do not. The most time-consuming aspect of commercialization occurs after the license is signed, in particular for therapeutic products requiring clinical trials for approval. Industry and regulatory agencies set the pace.

2. Ineffective and fragmented technology transfer

Litan and Mitchell state that the majority of university technology licensing offices (TLOs) actually "lose money" and that they vary widely in their effectiveness. This is true, but it is important to note that university TLOs do not exist to generate revenue, and most retain little if any of the revenue generated by their function, such that "losing money" is a meaningless statistic. While covering costs, providing revenue incentives to inventors and revenue for re-investment in research is a desired outcome, TLOs exist to ensure that results of research are translated into useful products that benefit society. Differences in effectiveness can be attributed to a number of factors including research expenditures of the university, age of the TLO, tenure of its staff, resources allocated by the university to support technology transfer, and external resources and infrastructure that support entrepreneurial and business development activities. Absent careful research, it is irresponsible to claim that certain universities are successful and other schools are unsuccessful only because of their TLOs. One would have to take into account the varied missions of the universities as well as the TLOs, with the primary understanding that the research at certain institutions may be more applicable to commercialization as a route of dissemination than others.

Litan and Mitchell also state that the "market of technology licensing agents is highly fragmented and inefficiently organized." It is true that there are over 200 U.S. research institutions with TLOs. However, sheer numbers don't necessarily infer fragmentation or inefficient organization. TLOs differ because research institutions differ. Each TLO reflects its local and regional needs. In particular, they reflect the diverse cultures and priorities of their institution and faculty. Truly, this is diversity at its finest. To advocate for consolidation of TLOs or creation of a "centralized office" is to create an entity that is unlikely to reflect the wants and the needs of the institution or region. Along Litan and Mitchell's line of reasoning, one would advocate that all biotechnology or high technology companies should utilize one standardized in-licensing office because they all in-license technologies from universities and each other. This

simply does not make sense because any such centralized mechanism cannot take advantage of the regional resources.

3. Inventors' rights to own intellectual property and use any technology licensing "agent"

Litan and Mitchell suggest that faculty and inventors should have the right to own the intellectual property and determine which TLO to use. They state that being "obligated to use the Technology Licensing Office (TLO)" of their institution is a disadvantage, and that faculty would much rather use a "successful" TLO at another university. They further propose that this flexibility will lead to greater commercialization. This is a stretch that assumes faculty, and their host institutions, industry, and venture capitalists would want such a system. And it ignores evidence that technology transfer works best when faculty has a strong, ongoing relationship with their university technology transfer office. Other than anecdotes based on a sample that is, at best, a small fraction of the faculty that engage in technology transfer activities, Litan and Mitchell have no data to support their position.

What Litan and Mitchell fail to recognize is that such a system would add a new layer of bureaucracy to the technology transfer process, including the need for agreements between the patent assignee and the licensing agent which would add time to the technology transfer process, as well as potentially reducing the inventor's share of royalties through management fees assessed by the licensing agent. Additionally, many university inventions involve several faculty members and, increasingly, several institutions thanks to increased inter-institutional collaboration. Such a change would potentially pit faculty co-inventors against each other as they strive to select a licensing agent and has the potential to reduce faculty and institutional collaboration, and potentially increase conflicts-of-interest. If the most successful inventors went somewhere else, this would deprive access to new inventors, as universities use the limited successes they have to dedicate resources to help those faculty that are engaging in entrepreneurial activities for the first time.

Finally, with a reduced stake in the process, universities would have less incentive to allocate money for patent protection or gap funding (which neither companies nor venture capital provides) to those technologies that have promising applications. As you may know, there has been tremendous growth in institutional and regional gap funding programs. These programs provide critical early stage research and development funds to promising technologies, enabling them to meet certain milestones that increase commercial viability. Without those funds many university technologies would not develop to the point of licensability. Beyond the practical hurdles associated with this proposal, it serves to limit the ability of universities to fulfill the intent of Bayh-Dole which is to disseminate research for public benefit through commercialization.

In conclusion

Litan and Mitchell suggest "Certain TLOs will believe they cannot survive in a more competitive environment" and that they and AUTM will "oppose rule changes aimed at generating more competition." This is an uninformed and unsupported claim and can only be construed as disrespect to the technology transfer profession and a blatant attempt to pre-empt reasonable comment and critique by the people who work every day to find industry partners willing to invest large sums of money in early stage technology that will benefit our nation's economy,

global health, universities and their inventors. The process of identifying, protecting and licensing discoveries made at such an early stage is among the most challenging of disciplines. It involves a highly complex intersection and interaction of technology, law and business, not to mention individual, regional and organizational needs, expectations, and personalities. To overlay this challenge with “competition” as suggested by Kauffman would substantially hinder the ability of TLO professionals to do their job.

Universities should expect and insist on high quality, effective service by their TLOs whether profitable or not and, in fact, they already compete for the best licensing professionals. Adding a false “competition” among universities for inventors as a consideration in the highly complex function is a poorly conceived idea that fails to recognize the disparity in funding at the various universities. Ultimately, TLOs and AUTM are not concerned about competition. Rather, they are concerned with the collegiality and cooperation of the members of the university sector. Most, if not all, of Kauffman’s proposals are impractical and unworkable. If implemented, these changes would obstruct the conducive and enabling environment crucial to carrying out the difficult, complex and risky endeavors of the technology transfer office.

As stated above, AUTM does not believe that inefficiencies in the technology transfer process are slowing the pace of innovation in America. To the contrary, since the passing of Bayh-Dole, university innovation has done nothing but increase. We also do not believe that academic technology transfer is fragmented or inefficiently organized. Academic technology transfer is diverse and relies on local and regional strengths and needs as well as successful practices that are promoted through the efforts of AUTM to deliver consistent professional development. Finally we do not believe that a licensing agent system would do anything other than create confusion and slow the technology transfer process.

We believe the Litan and Mitchell proposal would turn the clock back, undermining years of progress. Is there room for improvement? Of course. However, before any changes in legislation are made, or new mandates, regulations, or untested practices are put into place, they should be well thought out and based on verifiable facts, not the opinions of critics, who may be uninformed or may be utilizing anecdotal information as a basis for their criticism or have an agenda that is not constructive.

AUTM would be pleased to elaborate on any of the above points, to provide you with access to our wealth of data and, of course, to engage in a constructive dialog on how we can all work together to enhance the technology transfer process. We look forward to the opportunity to have that dialog.

Sincerely,



Arundeeep S. Pradhan
President

Cc: Gary Locke, U.S. Secretary of Commerce