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January 7, 2010

Mr. Tobin Smith  
Associate Vice President for Federal Relations  
The Association of American Universities  
1200 New York Ave, NW, Suite 550  
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Re: CFR Encourages to Discuss Kauffman Proposal on Technology Transfer with Campus  
Officials

Dear Toby:

Per your request for our comments regarding the article by the Kauffman Foundation in the January-February issue of the Harvard Business Review (HBR), following is our response:

### **Response to HBR “Idea” of Letting Academic Researchers Choose Licensing Agents**

In its 2010 list of “Breakthrough Ideas,” the Harvard Business Review includes a proposal by Robert E. Litan and Lesa Mitchell that they claim would accelerate commercialization of university inventions. Specifically, Litan and Mitchell argue that academic inventors should be free to choose any licensing agent, “just as anyone in business can now choose his or her own lawyer,” rather than being limited to a university’s tech transfer office. In support of this argument, they compare the growth rates of NIH funding to the number of drugs approved by the FDA. We believe Litan and Mitchell’s proposal is misguided and flawed.

Most importantly, Litan and Mitchell’s proposal rests on a false premise; it assumes that universities are merely part of an industrial supply chain whose role is to facilitate conversion of research funds into commercial products. In fact, although tech transfer has become increasingly important, it is not a university’s only responsibility (or even most important one). Universities must also promote the dissemination of knowledge through publication, education, basic/non-commercial innovation, healthcare, non-scientific scholarship, and more. Because Litan and Mitchell’s proposal ignores the complex interplay between universities’ non-commercial responsibilities and tech transfer efforts, it threatens to harm the public interest rather than benefit it.

Further, it is not clear, as argued by Litan and Mitchell, that universities manage technology transfer inefficiently or that private licensing agents would at all facilitate commercialization of

university inventions. Litan and Mitchell's evidence about the supposed inefficiency of university tech transfer operations is simply inadequate to support their thesis. The number of "FDA-approved" new drugs is a poor proxy for tech transfer efficiency, because it ignores the role of the FDA itself in the fluctuating rate of drug approvals. As has been reported in the New York Times (*see* September 2, 2006, "New Sense of Caution at the FDA"), during the years referenced in Litan and Mitchell's proposal, the FDA became far more cautious in approving applications for new drugs in response to criticism about the FDA's safety record. Further, Litan and Mitchell's data itself shows that FDA drug approvals spiked up to record levels in 1996, 16 years after passage of Bayh-Dole, and there is no evidence that university tech transfer offices have become less (rather than more) efficient since that time.

In addition, in a 2006 report entitled "Research and Development in the Pharmaceutical Industry" ("CBO Report"), the Congressional Budget Office explains that the spike in drug approvals in 1996 and subsequent decline may simply reflect a sudden increase in the FDA budget that allowed it to clear a backlog of drug-approval applications:

Some analysts have concluded that the spike in total NME [i.e., new molecular entity] approvals may have been partly caused by a federal law designed to hasten the review process, the Prescription Drug User Fee Act of 1992. The law imposed a large increase in the filing fee for new-drug applications submitted for FDA approval; that increase funded additional FDA staff to review applications. As a result, the median FDA review time fell by nearly one-half, from 22 months in 1992 to 12 months in 1999. That change suggests that if a backlog of applications existed when the law was enacted, faster processing could have contributed to the record number of NME approvals in 1996. A backlog may have accumulated in the early 1990s, because the annual number of applications was rising at that time, while FDA approvals were falling. The decline in NME approvals in the late 1990s would be consistent with a decrease in the backlog, although NME applications were also in decline at that time. (CBO Report, at 12.)

In short, the relationship between university tech transfer efficiency and drug approval is simply too attenuated to allow for any meaningful conclusions. In any event, the proposal is seriously flawed in several respects.

First, Litan and Mitchell's proposal would undermine the ability of universities to comply with numerous federal and state laws governing not-for-profit academic and research institutions. Failure to comply with such laws could, in turn, destroy university exemptions from taxes and regulations that are essential to beneficial university activities.

For example, state laws governing not-for-profit organizations require university assets to be used for proper charitable (or public) purposes only and impose fiduciary duties on university employees and agents to preserve such assets and assure their proper use. There is no question that inventions subject to Bayh-Dole are university assets subject to such laws—a fact that Litan and Mitchell ignore. Universities provide the laboratories, administration, and infrastructures that enable solicitation of government research grants, processing of the grants, and performance of many of the tasks necessary to make or demonstrate an invention. Universities also employ the principle investigators responsible for inventions under a grant. To turn decisions regarding the disposition of university assets over to individual faculty members, therefore, would not only be unenforceable, but also violate state not-for-profit laws.

Litan and Mitchell's proposal would also contradict state and federal tax-exemption rules. Private contributions and bonds relied upon by universities are tax-exempt because they promote charitable purposes and public benefits. In addition to supporting the infrastructure and resources necessary for innovation and new IP, tax-exempt funds properly support education, non-commercial scientific research, non-scientific scholarship, healthcare, and more. To award control over university inventions to individual faculty members would effectively transfer the benefit of such charitable funds from universities to private individuals in contravention of numerous long-standing tax laws and regulations.<sup>1</sup>

Likewise, Litan and Mitchell's proposal could preclude exemptions from export regulations for "fundamental" research that allow universities to include foreign students and faculty members in research and learning. Publication and dissemination of research results are hallmarks of fundamental research that distinguish it from commercial (and highly regulated) research. If granted control over university IP, faculty members might have more incentive to commercialize ideas than to publish them. Resulting restrictions on international exchanges could have a devastating effect on U.S. universities and divert academic leadership abroad.

Second, while calling university tech transfer offices a "monopolistic model," Litan and Mitchell ignore important countervailing facts. Universities compete for faculty—and especially faculty who can bring a large portfolio of grants. Any university would be at a significant competitive disadvantage if it were especially bad at commercializing faculty inventions.

More importantly, Litan and Mitchell fail to explain why any university would tolerate an inefficient tech transfer office in view of the potential for royalty revenue. If independent agents were more efficient than internal offices, then universities would have every incentive to outsource administration of technology transfer, but they have not done so. Litan and Mitchell offer no explanation as to why universities would act contrary to their own economic interests.

Third, Litan and Mitchell ignore the fact that universities, their tech transfer offices, and their faculty members are not, in fact, like "anyone in business." Many, if not most, University faculty members have substantially less experience with the legal and commercial aspects of intellectual property than business executives or university technology transfer offices. Regardless of any outside licensing agents, university faculty would still need advice from experienced university technology transfer professionals, which would reduce the hypothesized savings from the use of outside agents.

Moreover, universities and their faculty members have different incentives and obligations than private businesses. Unlike commercial firms, universities are not free to bet their assets on any invention or group of inventions, to forego future research in return for near term revenue, to license inventions for the purpose of blocking competition, to license to the highest bidder regardless of the positive or negative implications to society or the community, to guarantee performance, or to otherwise accept common commercial risks. As a result, universities must balance competing, and sometimes conflicting, obligations and fiduciary obligations in licensing

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<sup>1</sup> Notably, in a prior publication, Litan and Mitchell have proposed to grant full ownership of faculty-created IP to the inventors, which would unambiguously transfer charitable assets to private individuals. See Robert E. Litan, Lesa Mitchell, and E.J. Reedy, *Commercializing University Innovations: A Better Way*, Working Paper (National Bureau of Economic Research, April 2007).

new technologies. By contrast, private businesses and independent licensing agents can focus on the bottom line only.

Because independent agents would not share a university's interests, any technology transfer deal under Litan and Mitchell's proposal would require potentially extensive negotiations between the university and the outside licensing agent. Worse, in most instances universities would need to negotiate with multiple outside agents to transfer IP (and those outside agents would, in turn, need to negotiate among themselves). Most university IP is created by multiple inventors and commercialization increasingly requires universities to offer "bundles" of IP. Further, a lack of university standards for managing inventions would invite internal conflicts among faculty members. As a result, Litan and Mitchell's proposal would severely reduce the efficiency of university tech transfer and possibly paralyze it, because it would require layers of costly and time-consuming internal and external negotiations.

Fourth, other than noting that an outside technology licensing office would charge fees that reduce royalties to universities, the Litan and Mitchell proposal fails to address the implications of such fees. Notwithstanding every inventor's belief that he or she has invented the next "better-mousetrap," many university inventions have limited, if any, commercial value. Litan and Mitchell fail to explain how the costs of failed licensing efforts would be addressed, and who would pay for them. The long odds against commercial success for most inventions makes it unlikely that contingent fee arrangements would be embraced by outside licensing agents. On the other hand, the risk of failure would make it difficult to fund fixed-fee arrangements. The net result would be that only inventions with readily apparent and significant commercial value would be commercialized, which would reduce overall commercialization rates and prospects for unexpected successes.

In sum, Litan and Mitchell's proposal to grant control over university inventions to individual faculty members is misguided and fails to appreciate the nature and importance of university technology transfer operations. The premise of the proposal is not supported by meaningful data, the proposal would impose unnecessary and counterproductive costs on the tech transfer process, it contradicts long-standing principles that govern intellectual property, and it would undermine essential public benefits of research universities.

Sincerely,



Mark E. Coticchia

JANUARY–FEBRUARY 2010

The HBR List: Breakthrough Ideas for 2010

When the business community supports an idea, change can happen fast. HBR's annual ideas collection, compiled in cooperation with the **World Economic Forum**, offers 10 fresh solutions we believe would make the world better. Ranging from productivity boosting to nation building, from health care to hacking, any of the ideas presented in the following pages could go far with broad-based buy-in. Which ones will you get behind?

## **A Faster Path from Lab to Market**

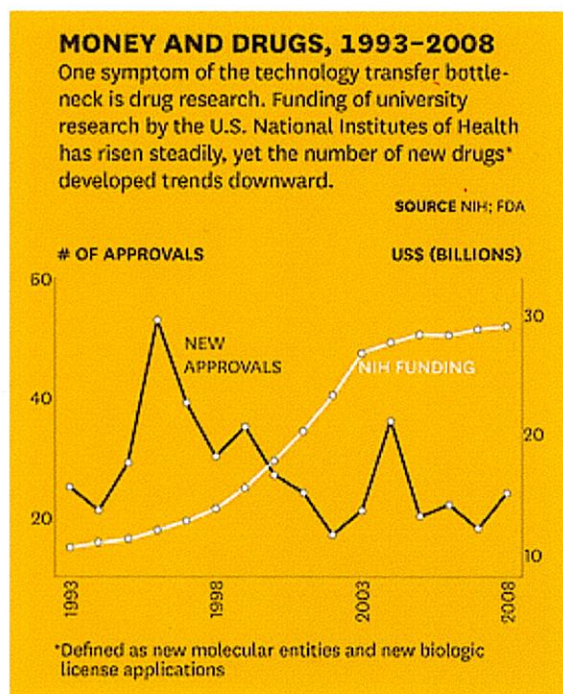
by **Robert E. Litan and Lesa Mitchell**

*Removing the technology licensing obstacle.*

### **The Problem.**

University-based innovators routinely produce breakthrough technologies that, if commercialized by industry, have the power to sustain economic growth. Because their research is largely funded by the U.S. government (much of whose \$150-billion-plus R&D budget is channeled through universities), it is all the more imperative that these innovations find their way to the marketplace and generate benefits for society. But our system today is suboptimal: Many university-developed innovations could reach the marketplace much faster than they do now. The problem, ironically, centers on the very entities designed to facilitate commercialization. Nearly 30 years ago Congress provided a huge incentive for universities to pursue more commercialization of federally funded innovations. Through the **Bayh-Dole Act**, it granted them the rights to the intellectual property. That carrot got immediate results: Virtually every U.S. research university created a technology licensing office (TLO) to organize its commercialization activities and increase revenues from them. These centralized offices require that faculty members disclose their inventions to the TLO and pursue licensing opportunities through it.

Yet like the student who could earn A's but consistently takes home B's, TLOs are underperforming. For example, although funding from the **National Institutes of Health** has mounted over the years (and is now some \$30 billion), the output in terms of new FDA-approved drugs has been falling. As the **Department of Energy** prepares to spend tens of billions of dollars on R&D to replace dirty fossil fuels with alternative sources of energy, it is critical that the disappointing pattern in drug commercialization not be repeated in clean tech.



Perhaps it was not a bad idea at first for universities to centralize their commercialization capabilities and give TLOs control of the process; they gained immediate organizational benefits and economies of scale. But this monopolistic model has since evolved into a major impediment. Inventive faculty members are hostage to their TLO, regardless of its efficiency or contacts. Moreover, because many TLOs are short-staffed, professors must queue up to get proper attention for their inventions.

## The Breakthrough Idea.

So why not free up the market in technology licensing? Let's allow any inventor-professor to choose his or her licensing agent—university-affiliated or not—just as anyone in business can now choose his or her own lawyer. This would be as simple as having the **Commerce Department** amend the rules of Bayh-Dole. (Maybe the **Small Business Administration** would have to revise its rules as well.) Specifically, federal

research dollars should come with a condition attached: University recipients must allow faculty members to choose their licensing agents.

## **The Promise.**

A free and competitive market in technology licensing would disturb neither the legal status of the invention nor the way royalties or license fees are divided between faculty member and university (a subject governed by the standard employment contract). But like other free markets, it would dramatically speed up the commercialization of new technologies, and ultimate consumers—in the U.S. and around the world—would thereby benefit from them much more rapidly. A free market would also most likely lead university TLOs to specialize or turn to outside agents with the appropriate expertise. A university might drop its TLO altogether but continue to earn licensing revenues—less the fees charged by outside TLOs or agents.

Let's stop penalizing professors who come up with new ideas and the universities they work for. Most important, let's not keep the world waiting for new products and services—some of them lifesaving—while valuable ideas languish on university shelves.

*Robert E. Litan is the vice president for research and policy, and Lesa Mitchell is the vice president for advancing innovation, at the **Kauffman Foundation** in Kansas City, Missouri.*