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To Whom it May Concern:

I write in response to the RFI on Commercialization of University Research issued jointly by the Office of Science and Technology Policy and the National Economic Council in Federal Register 75:57. pp. 14476-8. I write as a practitioner, a consultant in technology-based economic development who has been active in the field since 1986.[1] My comments are undifferentiated with respect to Parts I and II of the RFI.

To understand what works and where help is still needed, one must begin with what already works. For nearly three decades, the Bayh-Dole Act has provided the legal and policy stability necessary for American universities to design, launch, and sustain the offices that protect discoveries made by faculty in the course of federally financed research. These offices also negotiate licenses with firms willing to undertake the development of commercial products based on that intellectual property.

There is nothing organically wrong with the Bayh-Dole framework. It has been adapted in countless ways to local circumstance, without compromising the essential principle of the control of intellectual property by the work-performing institution, including the unambiguous authority to execute exclusive licenses. These features have proved spectacularly successful in giving companies the comfort necessary to invest in licensing and commercializing at least some federally financed discoveries. As documented amply by others, these rules have brought many innovations into the commercial marketplace, and the taxpayers have seen many benefits in return for their generous financial support of research institutions. Among these benefits have been improvements in technologies (including but not limited to biomedical) that make a big difference in daily lives, and also the generation of new commercial activity that creates jobs and pays taxes to all levels of government.

[1] I am a former senior staff member in a New Jersey government agency for science- and technology-based economic development, have more than a decade of service in a national consulting practice in this same area, and currently direct a New York State association of business incubators, many of which are university-affiliated. However my opinions are my own and not those of any of my past or present employers or clients. For more information or to contact me for follow up, please see http://tbed.org.

The licensing model for technology commercialization seems to work best in cases where the handoff between discovery and commercialization is straightforward and not inordinately risky, where projected market sizes and profitability meet the internal project "hurdle" criteria of major corporations, and where the ongoing involvement of the faculty inventor is not necessary to the commercialization process. Examples include licensing the rights to a novel therapeutic use of a molecule to a pharmaceutical company that is prepared to invest in its approval by the FDA and its marketing and distribution. Successes in this realm have yielded blockbuster products, and for some universities, these have returned flow of royalty payments more than sufficient to underwrite and even expand the technology transfer offices. Royalties shared with faculty inventors under Bayh-Dole requirements have also made some of them rich, an incentive designed into the Act.

Success is less assured, but still attainable, in cases where a complex property is at issue – perhaps comprising a broad "platform" rather than a single discovery. For example, in the case of biotechnology-derived products, it is often small, venture-capital-backed companies that can most cheaply raise and deploy the capital necessary to conduct the painstaking additional work needed to turn discovery into commercial product. Therefore the university issues a license to a startup company financed for this specific purpose. Indeed, the pharma industry has come to rely on such university-launched ventures as targets for future joint ventures or acquisitions, a way of keeping the long-term product pipeline well stocked. In such cases, Bayh-Dole again provides the certainty – in this case to the venture partnerships and *their* backers – that commitment of what could be up to 15 years of time, effort, and capital is a prudent business investment. These cases, too, have produced a fair measure of product success and wealth. Similar dynamics are at work in nanotech.

Less success is seen in those far more numerous cases where the discovery does not meet obvious corporate or venture-capital criteria for investment *at the stage where it currently rests*. Before such a discovery can attract capital, more work must be done, either in the laboratory to demonstrate feasibility or acquire surrounding intellectual property, or in the form of early-stage business planning, in order to assess whether there is a market value to the discovery and to de-risk private investment in further commercialization. When faced with a gap of this kind, most university licensing offices grind to a halt, often even abandoning provisional patent applications if there is no obvious external partner willing to finance a full application in exchange for rights. What one sees is a pattern of institutions deferring to the decisions made by others, rather than taking charge of their own destinies and driving the commercialization process themselves.

Many licensing offices have now hired "commercialization officers" whose job is to cultivate, sense, and respond to VC interest, but even these people have limited capacity to deal with cases that are not yet ready (or will never be appropriate) for venture-capital backing. Therefore, it is not uncommonly left to the faculty inventor to form the company, find pre-seed-stage financing, and somehow advance the project. This represents a poor default definition of "spin-off" and a serious mismatch between needs and skills. The commercialization officer can be sympathetic and even helpful, but without resources cannot really influence the outcome.

As severe as they are, these problems do *not* represent flaws in the legal structure or operational deployment of the Bayh-Dole regime on intellectual property management and disposition. Rather, the problems flow from the inadequate and unstable availability of funding for the purposes of post-discovery/pre-launch activities. Almost without exception, the "pre-commercialization" work necessary to advance such cases is ineligible for support through projects funded by the federal sciences agencies, as either direct or indirect costs. Nor are there federal grant programs in the economic-development function that reliably cover the needed expenditures.[2] Finally, very few university technology transfer offices are staffed, empowered, or budgeted from internal sources (including royalty returns) to perform these pre-commercialization functions.

In summary, the problems in commercializing discoveries that are not yet "ripe" for investor-driven exploitation represent a hole in American *industrial* policy, *not* intellectual-property policy. In response to the central question of the RFI, there certainly do exist "promising models" for addressing these gaps, at the level of individual universities and regional collaborations.

As the RFI anticipates, these are sometimes called "proof of concept centers" such as those privately endowed at MIT or USC. Another name that has come to prominence in recent years is the publicly financed "venture lab" modeled by the Georgia Research Alliance and now also in service at the University of Central Florida and the University of Texas. Others models that eschew either name include the CONNECT (UCSD) or Northeast Ohio JumpStart programs. All these have in common several important features:

[2] Support for technology incubators or research parks through EDA never includes operational funding for these activities. The SBIR program is often cited as a form of pseudo- or pre-venture capital, but only indirectly. Its primary mission is to support the research needs of federal agencies. The NIST TIP is not aimed at university-owned discoveries. And the NSF Partnership for Innovation while appropriate in theory is not large enough or reliably available enough for such uses.

First, these successful programs break the bad habit – especially common among smaller universities that have had limited success at spinning off venture-capital-backed startups – of thinking of the spin-off as a choice driven by the faculty inventor, the last available option if all other commercialization strategies fail. A great deal of effort around the nation is now placed on educating faculty members on how to become entrepreneurs, and one certainly hopes that more scientists will become more entrepreneurial in orientation and more knowledgeable about the commercialization process, but it is far from clear that this represents the most efficient uses of societal resources.

Some faculty members find they want to be entrepreneurs and decide to leave the academy, but most are ill-suited to a simultaneous double role. Even if there is a generous temporary-leave policy, it is usually in society's interest that they remain in the laboratory where they can do what others cannot. Moreover, there are also structural inhibitions (such as the requirements of the SBIR program for full-time principal investigators or the conflict-of-interest rules in place at the science agencies) that make it quite awkward for a faculty member to exercise control at both a spin-off and their own faculty laboratory.

If the underlying discovery is in fact venture-ready, it is actually the venture investors who will drive the spin-off formation, retaining the active participation of the inventor as Chief Technical Officer but not usually relying on him or her as its CEO. If the discovery is *not* venture-ready, the faculty member is usually the wrong choice to rely on as CEO. Either way, *the faculty inventor should not drive the process*. To complete the commercialization process really requires the involvement of an entrepreneur (who in symmetry should be at least technically qualified). These may be drawn from the ranks of graduate or postdoctoral students who choose not to follow the academic career path, or from a university's professional schools of business or law, or from a surrounding community of technical entrepreneurs who have done it before.

In summary, successful POCCs or venture labs think of the spin-off as a decision that the institution drives itself, with the *help* of the faculty member and the regional entrepreneurial community, and only *after* the necessary additional work and planning.

Second, successful POCC or venture lab programs are budgeted independently from the university technology transfer office, whose core functions do not extend to pre-commercialization research or planning.

Some POCCs are endowed or otherwise funded by alumni who became wealthy as entrepreneurs who have commercialized a university-based discovery or hired its students. Others are financed by state-level programs for technology-based economic development, which have been the federal government's de facto partner in the research-to-commercialization spectrum since the 1980s. Some may be funded by local governments or by state-assisted regional business partnerships for innovation-based economic development, or even by philanthropic foundations.

In summary, in any of these cases, *money is available to do what federal funding currently does not*. Moreover, the decision makers and principals can now think patiently about commercial and economic-development outcomes in a way that is not entirely captive to the university's own interest in (usually short-term) revenue maximization.

Third, successful programs use this independent funding to hire highly entrepreneurial technology managers who are trusted equally by the inventing faculty, external investors, and projected end-users or strategic partners for the envisioned application. It is true that pre-commercialization planning sometimes involves additional laboratory work, but other non-scientific tasks that are just as important, and which are not necessarily suited to the faculty member's own skills, are market research, definition of milestones in the spin-off process, and even the nascent business operations of the spinoff corporation.

Successful programs hire people who are variously known as entrepreneurs in residence or zero-stage CEOs in order to manage these affairs, so that the process does not have to rely solely on the inventing faculty member or overburdened licensing officers, or even commercialization officers who spend their time on active VC projects. In effect, POCC-funded consultants *stand in for the interests of investors or licensees yet to be identified* while additional work is under way.

In summary, the POCC thus serves as a "pre-seed" fund, paying the costs of the project until at becomes a formal company and even then for some more time until the decision is made to launch it into the capital markets.

Finally, successful programs open themselves to local entrepreneurial communities, not only as sources of zero-stage executives and managers, but as components of multi-disciplinary planning teams that advise on the progress of the pre-funding venture, and help prepare it for presentation to more formal sources of investment. Early and open engagement with the community outside the university helps pave the way for building an entire entrepreneurial team of a launch CEO and others who have had experience in startup management. This builds the confidence that even seed-stage and informal investors need, if they are to participate in a launch.

In summary, a successful POCC builds a track record that makes more likely an eventually favorable consideration by formal venture-capital funds.

The weaknesses that non-federal programs are addressing in the four main ways described above actually help define the market failure that the federal government is now considering addressing. Following are some suggested principles for effective action:

First, If Washington does act to fill these gaps, it should act with respect for pioneering efforts under way already. New programs should reward early innovators with additional funding for extended activity, analysis, and replication, rather punishing them when "new-money" match requirements actually favor upstart proposals. In her widely distributed and well argued "IMPACT" white paper,[3] Krisztina Holly of USC has described an appealing "pilot" approach. Awards should be made first to entities that *have already raised and invested non-federal funds in commercialization programming*. There are a number of entities prepared to exercise their institutional muscle and leverage new resources if they were made available.

Second, it is important not to act with a heavy hand. A number of the examples given in Part I of the RFI reside in policy domains best left to the discretion of universities and other research institutions themselves. *A federal program should specify desired outcomes but be agnostic if possible with respect to specific processes or policies*.

Third, it is important to leverage and not bypass the agencies and *programs that the states have put in place to extract value from federally financed R&D conducted in their jurisdictions.* State "tbed" agencies and their partners in front-line economic-development departments are closest to the deals that ultimately create new companies and new jobs. They can also take a broader and less self-interested position than universities themselves, or even the venture-capital community (and the latter are not always essential to every economically favorable outcome).

Fourth, before creating new programs to promote commercialization, the federal government should experiment with giving expanded authority, mandate, and flexibility to existing ones. To use one example from Part II of the RFI, the NSF Engineering Research Centers – which have always had commercialization as *one* of their goals – could easily become the heart of future "regional innovation cluster" competitions, playing a role analogous to that played by the DOE "energy innovation hub" in the current E-RIC funding availability. More radically, certain NIH-funded centers – which have *never* had similar expectations placed on them – could also be positioned as the center of future clusters.

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[3] See "IMPACT: Innovation Program for Accelerating the Commercialization of Technologies." available online at http://stevens.usc.edu/docs/IMPACT%20Initiative%20Whitepaper.pdf (accessed 4/11/10).

To make this work effectively, there will need to be cultural transformation not only in the core federal science agency but also in U.S. EDA, U.S. SBA, and others participating in these multi-agency clusters efforts. For example, US EDA has long provided cost-sharing for incubator and science park *construction*, but never provided operating funding that could support a POCC or venture lab. It will be important, when the E-RIC competition is closed, for the White House to debrief both winners and losers on what they found useful and what restrictive about this new approach.