Revisiting Bayh-Dole

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The Bayh-Dole Act of 1980 (35 U.S.C. Parts 200-12) has been one of the most important engines of the high technology revolution of the past 30 years. Previously the U.S. government owned the inventions conceived or reduced to practice through research that it funded. Federal civil servants with no interest in this vast body of intellectual property (IP) had little or no motivation or capability to manage it in the interests of the public that paid for it. This inhibited the development of useful products that would benefit society. Bayh-Dole gave the institution or organization at which IP was created the right to ownership, subject to some limited rights of reversion (which have been tested only rarely). The "end" that justified this vast transfer of value was that society would benefit from its original investment through the availability of new products and improved international competitiveness and productivity. While much of that benefit has been realized, the "means" spawned an academic bureaucracy of IP management and technology transfer offices that are now widely perceived by industry and inventors alike to be a frustrating barrier to this end (Litan et al., 2007a, Sampat, 2010; Jamieson and Richmond, 2014). The world of academic IP is now a very different place, largely as a result of Bayh-Dole's successes and concurrent trends (Mowery, 2009), so it is time to recall the ends and revisit the means.

<u>Major changes since 1980:</u>

- Academicians used to be reviled by their colleagues for showing an interest in commercialization of their scholarly work; now they are lionized.
- It used to be difficult for non-scholars to find academic research in obscure journals and proceedings; now anyone can find anything and anyone via internet search engine.
- The scope of a patent used to be defined by the claims of the inventors and certified by the patent office; now that is merely the first step in a contentious, lengthy and expensive process that regularly leads to the courts for IP of any value.
- The size and duration of the investment required to secure IP and convert it into profitable products has generally increased substantially, particularly for regulated and/or reimbursed medical products.
- The volume of potential IP generated by the average university far exceeds the ability and resources of its academic IP office to evaluate, file and prosecute utility patents, whose value may require years of additional legal and technical effort to appreciate.
- A recent report from The National Academies on how US universities have managed IP since the implementation of the Bayh-Doyle Act, reminded universities that their main goal is NOT raising

money, but rather to disseminate new knowledge and technologies as widely as possible (Merril and Maza, 2010).

Problems and Disincentives:

Academic IP offices have become an end in themselves, even as most of them actually lose money for their institutions. These offices and the IP that they manage are NOT a fundamental function of the university or its fiduciary responsibility to manage its assets. The IP now held by the university is simply a creation of Bayh-Dole. It may or may not be valuable; much of it involves basic discoveries that need substantial further investment and development (Rai and Eisenberg, 2003). If there is already competitive interest in the IP, then institutional ownership is an unnecessary obstacle to the original goal of motivating commercial development of IP. If there is not even potential interest, then the institutions should not be wasting resources and tying up IP in meaningless patents. If interest must be developed by promoting the potential of the IP, then this should be turned over to the inventors themselves, who are likely to be highly motivated to see it incorporated into products. Professors no longer need motivation or tools to seek fame and fortune through such commercialization. Their specialized technical knowledge makes them much better at understanding and contributing to the process than the generalists in the academic IP office. In a recent New England Journal of Medicine paper entitled "*Biomedical Research and Health Advances",* the authors point out that *"during this decade of growing scrutiny between academic institutions and companies, … academic researchers value their non-financial company ties, with access to technology or research materials, more than personal compensation or support of their laboratories"* (Moses and Martin, 2011). If there are competing interests, then society needs the simplest mechanism that will motivate the inventors to make whatever decisions best serve the public interests. Those interests are largely unchanged but even more compelling since Bayh-Dole was enacted – technology has become the key to national economic competitiveness.

A Modest Proposal

When any paper is published as original research in a refereed journal (i.e. not a review of other people's research), it should enter a pool of potential IP that is available to any commercial entity that might wish to develop any aspect of the invention or discovery. For one year following such publication, any such entity could express its interest in any aspect of the work that it believes constitutes protectable IP. This period would be comparable to the one year grace period now allowed in the US and obtainable anywhere in the world by submitting that same manuscript as a provisional patent application before it is published.

The organization attempting to claim the published IP would have to certify whether it was willing to pursue development and protection of that IP as an exclusive licensee or whether it required only nonexclusive rights. If no one expressed interest in securing exclusive rights during the one year period, the IP inherent in the publication would pass into the public domain (as it does now under the international rules governing provisional patents and the US rules governing the one year grace period). If one and only one party expressed interest in securing exclusive rights, it would be obligated to file a

utility patent application within one year and to prosecute the patent and develop products in a timely manner. This obligation would be subject to a more enforceable version of the "march-in" provision of the current Bayh-Dole Act, which is designed to prevent assignees from sitting on fallow IP that other parties wish to develop.

If more than one party expressed interest in securing exclusive rights, the authors of the paper (i.e. inventors of the IP) would decide which party should receive that right and the obligations that go with it, subject to binding arbitration if there were multiple inventors and they could not agree on the selection. The bidders in this process would be free to offer any inducements that would be attractive to the inventors, including equity, royalties, consulting agreements or grants and contracts to further their research. Their employers could use their terms of employment to tax or prohibit any such benefits. Non-profit employers would be prohibited from requiring their employees to assign their right to make the actual decision, but they could (and should) make the exercise of those rights subject to existing mechanisms for dealing with conflicts of interest. For-profit employers would have the option to make such a pre-assignment a condition of employment.

The goal of this new policy is to disintermediate academic IP offices while preserving the incentives for inventors to invent, for universities to employ them and for industry to invest in the development and commercialization of IP. Importantly, it recognizes that the real IP of value is not just what is contained in the original publication but rather what is between the ears of the inventors. At present, developers of products are fearful of any consultation or collaboration with academic researchers because of the potential for their academic employers to assert ownership of new IP that may arise through such activities. This deprives society of the benefit of this "know-how" even more perniciously than the government ownership of patented IP that Bayh-Dole largely eliminated.

The policy described above provides a mechanism for IP to be sorted automatically among the various alternatives to university ownership that have been considered, including inventor-ownership, non-exclusive licensure and consignment to the public domain (Kenney and Patton, 2009). Each of those has advantages and disadvantages whose relevance depends on the nature of the IP and the economics and business practices of the specific industry. In the proposed policy, the publication process (in which academia is highly invested) would be coupled to the patenting process and to an informal "silent auction" process that would motivate all interested parties to come forward in a timely manner so that the appropriate path can be determined.

<u>Some Scenarios</u>

The obvious question that arises from eliminating the IP development office is how will decisions be made when interest in IP is contested? Let us consider who the contesting parties might be:

1. Existing corporations that intend to develop products expeditiously.
2. Existing corporations that intend to suppress the IP because it is disruptive to an existing business.
3. Start-up businesses formed to develop the IP, in which the inventor(s) typically have a financial interest and, thereby, a potential conflict of interest.

4. Patent trolls who do not develop IP or products but rather amass a portfolio of IP in the hope of securing windfalls from licensing if and when a commercial application arises.

All except the first type seem to raise problems that might require exactly the intermediary structure that we propose to eliminate, so we need to imagine how the IP landscape would eventually be transformed by the proposed policy. As we shall see, most of these problems tend to evaporate with competition and transparency, both of which would be facilitated by the proposed policy:

- Problem 2 – **licensees suppressing IP** – exists under the present system. One strategy for addressing it is to increase the number of bidders for IP to make it more expensive for a licensee to do this. Academic IP development offices try to do this by "shopping" IP to potential licensees, but this has been criticized as cheapening the value of the IP by making it difficult for serious developers to acquire the IP without tipping their hands to the rest of the industry. Another mechanism is to give inventors a more active role in the decision; no one has a greater interest in seeing a baby thrive than its mother. Most important would be licensing agreements with firm milestones and reversion rights, something that academic IP offices have been slow to impose even when they can.
- Problem 3 – **self-dealing the IP to the commercial interests of the inventor** – is a problem only if there was a more promising alternative. Again, the answer starts with increasing the number of bidders. If self-dealing were suspected, the conflict-of-interest committee should be empowered to force the decision to binding arbitration, in which impartial outsiders would consider what is best for society. At present, similar decisions are being made by the academic IP offices, but they have an obvious conflict of interest as owners of the IP. The avowed interest of such offices is to earn money for the university, not to benefit the public (Litan et al., 2007a). In practice, however, IP offices are run by bureaucrats whose interest is their own survival, which makes them excessively cautious. They will not be criticized for products that never appear; they will be criticized for "giving away the store" when products enjoy unexpected commercial success.
- Problem 4 – **the patent troll** – is, in fact, the academic IP office itself. The university has not paid for the development of the IP, it has no intent or mechanism to develop products itself and it hopes to secure windfall profits from licensing. Eliminating the academic IP office would effectively privatize its business model. External patent trolls would have to compete openly for the IP instead of letting the academic patent troll enjoy and abuse its Bayh-Dole monopoly. Or the academic IP office could emulate the successful model of the Wisconsin Alumni Research Foundation, a technology transfer office that faculty tend to use because they want to, not because they have to (Litan et al., 2007a). Inevitably, the private trolls would have to provide services that cost them money in order to win such competitions. They would probably start specializing in sectors where they could function as effective and profitable intermediaries, obviating the generalist problem that plagues the academic trolls. Their existence would motivate Desirable Party #1 – **product-making corporations** – to search and compete avidly for such IP to keep it out of the hands of any trolls. And that was the whole point of the original Bayh-Dole Act.

It will be argued that professors and graduate students will not have the sophistication to decide among competing claims and offers, that they will fall out among themselves, and they will fall victim to the sharp practices of the industry. Unfortunately, much the same has been said about the academic IP offices themselves. They are rarely staffed by sophisticated players with successful experience in the industry; such players do much better for themselves on the industry side. At least the inventors have some "skin in the game". Nothing would prevent the academic institution from providing the inventors with advice and nothing would prevent the inventors from seeking outside advice or even delegating their decision-making authority to the university if they so chose. Many universities have schools of law and business whose faculty should be able to provide useful advice.

Making This Happen

This modest proposal seems certain to raise the opposition of academic institutions, who collectively control a lot of political power. Universities in the United States have moved towards an IP development model by which they intend to obtain the types of financial returns that a **privately** funded company would expect from their innovations. However, US Universities are using mostly **public** money to fund these innovations, so they can hardly take the fiduciary high ground. The question is whether the current situation is actually in their financial interests at all. The perceived profitability of academic IP offices reflects the occasional "homerun" (e.g. Genentech, Gatorade, UC-Davis strawberry cultivars) rather than steady profitability. The rare university earns a great deal of money while most actually take a net loss after expenses (REFERENCE). The academic IP office is under huge pressure by its star faculty to write and prosecute patents and to find and secure industrial licensees because that office controls the only outlet. This simultaneously drives up the university's costs while generating animosity and the loss of star faculty, who feel they must leave academia to realize the commercial potential of their inventions. The largest and most reliable source of non-tuition income for universities is what they discreetly call "development" – the philanthropic donations of their successful alumni, at least those who have fond memories of the institution (Litan et al., 2007b). Obstructing entrepreneurial faculty and students is a very bad business model for a university.

Interestingly, nothing would prevent a private university from unilaterally adopting virtually all of the policy proposed here. As the legal owner of the IP under Bayh-Dole, the university could simply change its internal policy to give the IP back to the inventors (Stanford University actually had such a policy from 1970 to 1994; Mowery et al., 2001). The Patent Act already empowers the inventors and only the inventors to seek a patent; they now assign that right to the university as a contractual condition of their employment. A university that rewrote those contracts might immediately enjoy several benefits. Its faculty would applaud enthusiastically. It could close its loss-making technology transfer office forthwith. It would be much easier for its faculty to participate in collaborative research with other universities and industry. Research dollars in the form of grants and contracts from industry would likely increase, generating revenue from indirect costs. It would possess a huge advantage for recruiting and retaining star faculty and students.

Of course, much of what would make this policy really effective relies on the mass effect of shifting the industry from avoiding academia whenever possible to actively seeking IP and inventors in the published

literature from universities. But suppose just one university did this and found it to be advantageous. Another would soon copy it, then another and another. As Arlo Guthrie sang, “Soon, folks, you would have a movement.”

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Survey methods were used to explore the expectations and recommendations of senior business development professionals with respect to the roles, activities, and interactions with US universities in the development of new medical products. This target group was chosen because it was judged to be most likely to interact with university faculty and technology transfer services and seek and acquire university assets. The survey instrument was first reviewed by a focus group of individuals with experience both in technology transfer and in academic or industry policy, then distributed to a selected subset of 80 business development professionals, of whom 72 responded. Serious concerns were expressed over the current mechanisms for technology transfer and university support of commercialization. When asked if they believed that there is a need for a change in the way that universities interact with industry in the US, 86% of the respondents replied that they either strongly agreed or agreed that there was, indeed, a need for change. Among several areas that might be improved, the availability of proof-of-concept facilities and funds for early-stage feasibility studies were most often identified as important.

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