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ARTICLE *in* THE ANATOMICAL RECORD PART B THE NEW ANATOMIST · MARCH 2004

DOI: 10.1002/ar.b.20008 · Source: PubMed

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COMMENTARY

Intellectual Property Conundrum for the Biological Sciences

JAMES L. OLDS

Policy regarding academically generated biomedical intellectual property (IP) has been shaped by two important events: the Vannevar Bush report to then President Roosevelt in 1945 and the Bayh-Dole Act of 1980. This policy, which vests the intellectual property produced from federally funded biomedical research from the government to the academic institution, was designed to promote technology transfer and thus promote the health of the U.S. economy. However, the policy has led to significant challenges, particularly in implementation. Here it is argued that the difficulties are due to differences in the structure of motivations between biomedical scientists, institutional officials, and private sector entrepreneurs. Understanding these differences may lead to a review of policy with the goal of enhancing technology transfer for the future. ***Anat Rec (Part B: New Anat) 277B:5–9, 2004.*** **© 2004 Wiley-Liss, Inc.**

KEY WORDS: biomedical research; education; government; intellectual property; research and development; public policy

INTRODUCTION

> *It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development.*
> *—Bayh-Dole Act*

Intellectual property (IP) can be defined as any useful creation of the human mind that can be potentially commercialized. In the biosciences, intellectual property might be a new drug, diagnostic kit, or even a genetically modified mouse. Within the framework of American academic biomedical research, IP was not of urgent importance until the passage of the Bayh-Dole Act in 1980. Since that time, a cottage industry has grown up within the academic research community ostensibly to promote the spirit of the Act, although many working scientists view such efforts with some degree of skepticism.

This commentary will deal with a major challenge facing institutional technology transfer officers and academic administrators in the biosciences, namely, how to comply with Congressional intentions, yet do so in a way that does not conflict with the basic culture of biomedical research. It is the thesis of this article that the challenge arises because working scientists often have different incentive structures from institutional officials who have still different incentive structures from typical licensees in the private sector. Scientific productivity is often potentially at conflict with academic technology transfer, even if remunerative for an institution or an academic inventor. Hence, the risk is either science lags or no technology transfer.

Post-1945, but prior to Bayh-Dole, most biomedical research in the U.S. academic setting was conducted without reference to the notion of intellectual property.

HISTORICAL BACKGROUND

Any policy analysis of modern American science policy usually begins with Vannevar Bush. In his 1945 report to President Roosevelt, *Science: The Endless Frontier*, Bush laid out a blueprint for the future of federal Republican and Democrat spending (Bush, 1945). The report described the critical link between the payoff from wartime investments in military-related basic research (e.g., the Manhattan Project) and future societal payoffs from federal investments in biomedical research. He postulated that such peace-dividend federal investments would translate into better health for the average American. While federal investment in research was a crucial part of Bush's vision, it was inseparable from another component: the notion of such federal investments enhancing the American economy. According to Bush's report, "A nation which de-

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DOI 10.1002/ar.b.20008
Published online in Wiley InterScience (www.interscience.wiley.com).

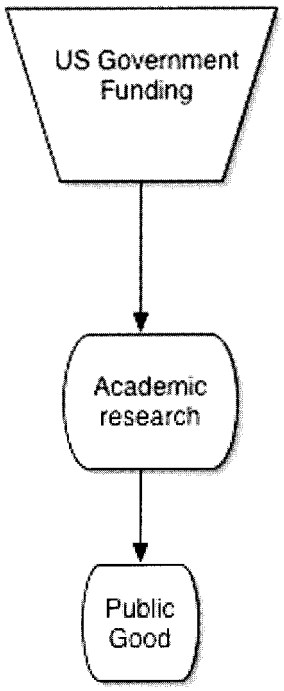

Figure 1. Institutional view of government-funded basic biomedical research prior to Bayh-Dole. Note that intellectual property as a concept is absent from the diagram.

pends upon others for its new basic scientific knowledge will be slow in its industrial progress and weak in its competitive position in world trade, regardless of its mechanical skill" (Bush, 1945). The mechanism for the competitive enhancement would be the transfer of technology from the academic sector to the private sector. It is this notion of technology transfer that became the driving motivation behind the Bayh-Dole Act.

Post-1945, but prior to Bayh-Dole, most biomedical research in the U.S. academic setting was conducted without reference to the notion of intellectual property, at least as the term is generally used today (Figure 1). Such research typically took place within the confines of teaching hospitals (academic medical centers) or large research universities and the coin of the realm was pretty much exclusively scientific discovery—as measured by peer-reviewed publication. Individual researchers were rewarded largely on the basis of their scientific productivity, and institutions invested in such biomedical research activities because they found that basic research provided stable revenue streams with concomitant prestige. Note that a key part of the original Vannevar Bush vision was missing from the equation, namely, technology transfer.

The problem for policy makers was that with the exception of a very few institutions, the IP generated by federally funded research and development was not being systematically transferred from academia to the private sector, where it could enhance the economy. According to a University of California report (2001), in 1980 the U.S. government owned 28,000 patents yet fewer than 5% of those were licensed to industry for development of commercial products (www.ucop.edu/ott/bayh.html#introduction). This issue became more salient during the late 1970s and early 1980s, when the competitiveness of American manufactured products began to be called into question.

The intention of Congress in passing Bayh-Dole was explicitly to instruct federal agencies to allow IP to vest with the universities and, crucially for the academic institutions, to protect and facilitate the private sector's development of intellectual property derived from federally sponsored research. This notion became known as technology transfer. The purpose of the Act was squarely within the overarching vision of Vannevar Bush, namely, boosting the economy by exploiting the intellectual products of American academic science (Figure 2).

BIOMEDICAL-SPECIFIC ISSUES

Biomedical research and development funding has been somewhat distinct from other areas of federally supported research since Vannevar Bush's report. In part, this has been due to the rapid growth of the National Institutes of Health (the budget of the NIH has nearly doubled in the past 5 years, from $15 billion to $27 billion) and the concomitant expansion of the investigator-initiated research grant award as a mechanism for supporting biomedical research in academia [research project grants accounted for nearly 56% of the NIH budget in fiscal year 2003; see Ad Hoc Group for Medical Research Funding (2003)]. Such awards are awarded to an individual biomedical researcher. The investigator submits a (generally unsolicited) proposal that is subsequently subjected to scientific peer review. The NIH extramural funding effort has, over the years, resulted in the development of a "principal investigator" (PI) culture. The culture has manifested as small science, in contrast to the historical large-team approaches in other disciplines such as astronomy or physics.

While PI culture has retained many of its defining characteristics (close-knit laboratory meetings, authorship issues, and grantsmanship), post-Bayh-Dole it has been forced to evolve with respect to awareness of the private sector and more specifically with regards to the concept of intellectual property. Thus, until recently, individual investigators were somewhat isolated from institutional concerns, especially those concerning enterprise relationships (i.e., relationships with private sector for-profit companies). More specifically, PIs tended to run their own laboratories as independent fiefdoms where the primary concerns were scientific discovery, publication, and developing continuing grant support. Noticeably absent among those priorities was the concept of intellectual property, particularly such property as an asset.

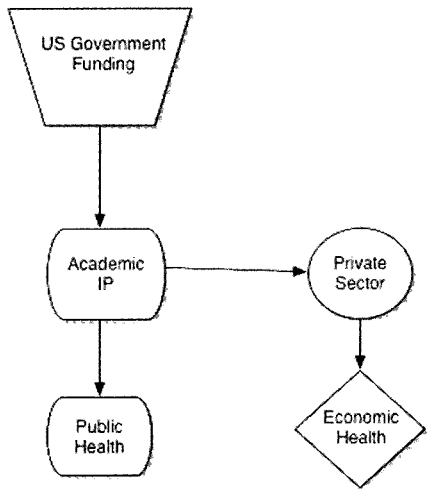

Figure 2. Diagram of Bayh-Dole vision for government-funded biomedical research. Government-funded academic biosciences research results in the development of intellectual property that is owned by the institution. This intellectual property leads directly to improvements in public health through peer-reviewed publication, but also is licensed to the private sector where it can contribute to the overall economy. This echoes the vision of Vannevar Bush.

What best described PI culture? In her book *At the Helm: A Laboratory Navigator*, Kathy Barker (2002) quotes Nobel Laureate Arthur Kornberg: "There are no pre-employment drug screens, dress codes or strict notebook protocols. With the labs active days, nights and weekends, with equipment operated in crowded hallways, with daily seminars and discussion groups, and with a constant torrent of publications, the atmosphere reflects a work ethic driven by ambitious individuals rather than by an organization, academic or industrial" (Barker, 2002).

In this quote, the reference to "strict notebook protocols" is in contrast to the practices of large pharmaceutical companies, where complicated documentation is necessary to substantiate the creation of new intellectual property.

RELATIVE INCENTIVES IN PI CULTURE

The concept of a "work ethic driven by ambitious individuals" is clearly important in the PI culture. Socially learned motivations are characteristic of complex human interactions such as those that take place in a research laboratory. In PI culture, such incentive structures typically begin to be acquired during graduate school, but the process can extend into early professional life (e.g., assistant professorship).

A very important motivator within PI culture (as operationally defined within the biomedical setting) is the notion of having a profession that has the potential to improve public health and welfare profoundly. The recent epigram of "from bench to bedside" has its origins in the idea that a researcher conducting a basic-sciences experiment at the bench may one day see his or her result translate into a cure for some dread disease or condition. This "science for the public good" motivator is also extremely important in PI culture and it often subserves the passion that researchers bring to their work. Interestingly, it also echoes the idealism of Vannevar Bush.

Among the memes that take hold during training are the prohibitions against scientific misconduct. But also prevalent is an almost puritanical work ethic, where hours at the bench have intrinsic character-building value above and beyond their leading to scientific discovery. Within the milieu of this PI culture work ethic is a system of rewards that is almost entirely based on peer approval. At the front end of the process, peer approval regulates availability of collaborators both within and outside the laboratory. At the back end, peer approval regulates scientific publication and grant success, both of which are crucial to professional advancement within the culture.

In contrast to the private sector (at least early on during professional development) is the noticeable deemphasis of overt reward systems relating financial compensation to professional advancement. (This is not to say that academics don't want raises, only that within PI culture they have a reduced relative importance to other rewards.) Often during the training phase, personal poverty is almost worn as a badge of honor. As with the monastic orders, poverty comes to symbolize a single-minded focus on understanding Nature rather than building personal material wealth. While this tendency does become less salient as an investigator becomes more senior, it never completely disappears. Thus, as I shall argue below, PI culture creates over a lifetime an individual with an incentive system highly distinct from that of institutional officials and decision makers within the private sector.

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INCENTIVE STRUCTURES OF INSTITUTIONAL OFFICIALS: INHERENT CONTRADICTIONS BETWEEN PI CULTURE AND PRIVATE SECTOR

Institutional officials are, of course, diverse. They range from technology transfer officers (with extensive understanding of intellectual property law and relevant regulations) to deans, provost's staff, and university presidents. Yet within academia they all tend to share a common viewpoint, namely, to maximize the financial return to the institution from academically generated intellectual property while at the same time maintain top scientific quality.

Institutional officials, particularly technology transfer officers, are in fact the agents of the Bayh-Dole Act. Their institutional affiliation, however, puts them in potential conflict with entrepreneurs in the private sector and PI culture. This occurs on three levels.

First, institutional officials are bureaucrats. Such individuals tend to focus much attention on the enforcement and development of regulations and rules. This mindset is not entirely compatible with the entrepreneurialism needed to transfer technology from academia to the private sector efficiently. This mismatch manifests especially when institutional officials are faced with the private sector's need for timely decisions. Under such stress, institutional officials display a natural tendency to play it by the book. By the time all of the ramifications are considered, the entrepreneur may have moved on to other deals.

The second level has to do with the structure of motivations for such officials. Ultimately, from an institutional standpoint, intellectual property is a potential revenue source. By leveraging the revenue generated from intellectual property, institutional officials gain potential budget relief. Often that budget relief is largely unrestricted and therefore can be leveraged further. Thus, because institutional financial health is a primary concern of institutional officials, they are strongly motivated to push PIs toward lucrative licensing arrangements with the private sector, potentially at a cost to science. Specifically, an institutional official may exert unintentional pressure for a PI to move forward with an invention disclosure at a moment that would be premature from a scientific standpoint. While such a premature disclosure might protect the interests of the institution, it might also be based on

erroneous scientific conclusions—conclusions that might be proven false by further experiments.

Finally, the development of new intellectual property (prior to filing a provisional patent application) is an inherently proprietary process. This closeted context is directly contradictory with PI culture's need for open scientific discussions (even between competitors).

INCENTIVE STRUCTURES RELATED TO ACADEMIC BIOMEDICAL RESEARCH: PRIVATE SECTOR

Prior to Bayh-Dole, linkages between the private sector and academic biomedical research were traditionally limited to consulting agreements between individual PIs and large companies. Since the passage of the Act and in parallel with the development of the biotech industry, these linkages have become increasingly diverse and ubiquitous. They range from cooperative research and development agreements to spin-off entities based on IP ownership and include many other types of arrangements in between.

With the notable exception of philanthropic organizations, private sector entities ultimately have one primary motivation: the financial bottom line. From the standpoint of academic biomedical research (and within the context of Bayh-Dole), this means licensing IP from academic institutions and developing from that IP a product that can subsequently be marketed. If the above is not achieved in a profitable manner, then, in general, private sector entities have no inherent interest in IP generated from the academic sector.

From a business standpoint, the meaning of the term *profit* really depends on a delineation of temporal domain to be associated with it. Profit in some contexts is over the short run (e.g., less than 18 months) while in others over the long haul (e.g., 5 years). Thus, in the latter case, a company may invest in IP (paying a large up-front licensing fee) as an investment to be covered by future profits. In the former case, a business may still license IP from an academic institution, all with the notion of immediately relicensing the same IP to a third party at a short-term profit. Still, the raison d'être for private sector players is to generate a profitable return for the owners/shareholders. Only within this framework can the relationship to academically generated biomedical IP be understood.

How does this profit motive run potentially counter to PI culture? At the idealistic level, PI culture seems almost contradictory to the business framework: biomedical research is generally conducted to improve the public health and for the sheer satisfaction of acquiring new knowledge about life as a physical process. At this level, PI culture does not address profits in the same sense that a business does. Additionally, as mentioned earlier, PI culture tends to revere the notion of monastic other-worldliness in a way that simply would not make sense to the average MBA degree-holder.

A business entrepreneur has no inherent interest in academically derived intellectual property becoming part of the peer-reviewed literature, while for a PI this is a sine qua non.

At a more concrete level, while a PI does not require a scientific discovery to become intellectual property for success, a business entrepreneur generally does. Conversely, a business entrepreneur has no inherent interest in academically derived intellectual property becoming part of the peer-reviewed literature, while for a PI this is a sine qua non. Hence, the motivations for the private sector are potentially mismatched to those of PI culture.

The private sector profit motive is also potentially at conflict with institutional officials. Here the difficulty is less one of content (both institutional officials and business entrepreneurs are interested in financial issues) than of process. As mentioned earlier, institutional officials by their very nature tend to be cautious. Before a deal is signed, all the potential ramifications in terms of relevant regulations must be explored. The tolerance for risk among such officials tends to be low. Yet for the entrepreneur, risk tolerance is necessarily high. Furthermore, private sector entities often have very intense time constraints as a function of the need to generate profit. For the above reasons, licensing as a process tends to get bogged down in spite of the best intentions between the private sector and institutional officials.

FIXING THE CONUNDRUM: A ROAD MAP

In spite of the best efforts, the transfer of technology from the academic biomedical research community to the private sector is currently hampered. Far too frequently, intellectual property developed at the academic laboratory bench lays fallow. The proposed double benefit of government funding of basic bioresearch that was the hallmark of Vannevar Bush's report—improving public health and the economy as a whole—is unfulfilled.

As noted previously, one of the major reasons for these difficulties is related to the different motivational frameworks within the three cultures: PI, institutional, and private sector. Because technology transfer depends critically on an interaction between PI, academic technology transfer officer, and private sector licensee, a mismatch, particularly in how incentives are perceived by either of the other two parties, can lead to difficulty. I propose here a threefold approach to ameliorating this problem.

Education

It would be useful for decision makers in each of the three cultures to have a deeper understanding of the others within the framework of Bayh-Dole. Just as science writers visit laboratories at the Marine Biological Laboratory in Woods Hole to gain a better understanding of the process of conducting biological research, it would be similarly productive to invite business entrepreneurs and institutional technology transfer officials to visit real laboratories or, alternatively, to

read one of the many books that describe PI culture in some detail.

At the same time, it would be useful to include lectures or courses on intellectual property as part of the modern graduate school curriculum for a PhD in the biosciences. As with training in ethics and grantsmanship, there are areas of learning outside of the traditional scientific disciplines that are necessary for success in PI culture. One might imagine a seminar-style semester-long course that would include content and case studies. The content would focus on the reason for technology transfer and the mechanisms by which it should take place. The case studies might include both routine and more controversial examples of academic IP.

Communication

When disparate organizations find the need to agree on common standards, they often form consortia that serve as standards-setting bodies. These committees are often venues for tough negotiations because the organizational consequences of such agreements can be enormous. An example of this type of standards-setting body is the committee that determines top-level domain names on the Internet (Internet Corporation for Assigned Names and Numbers). While standards may or may not need to be negotiated in the world of academic technology transfer, clearly the process of bringing together decision makers from the three cultures in addition to other stakeholders (government officials, patent lawyers, etc.) to discuss improving the Bayh-Dole process would be useful. The agenda for such a consortium organization might include such topics as innovating better incentive structures for academic inventors and streamlining the institutional process for connecting academic IP to potential licensees. But most importantly, such a committee could serve as a think tank to consider Bayh-Dole in a cross-cutting manner rather than from the silos from which most individuals approach these issues currently. This was the perspective of Vannevar Bush and it should be the perspective also for such a potential organization.

Regulation

It may well be that certain aspects of Bayh-Dole need to be revisited in order to facilitate Congress' intention of technology transfer from academia to the private sector. While such a review is beyond the scope of this commentary, the precedent for such legislative rewriting is ample. As with a scientific manuscript, revision can be a very positive process. It is also possible that the rules and regulations that represent the implementation of Bayh-Dole at the level of government agency and/or academic institution may warrant some type of review to access how well they serve the intention of Congress. This would be particularly useful in terms of addressing concerns from the private sector regarding temporal sensitivity.

CONCLUSIONS

The transfer of technology from the academic biomedical research arena to the private sector is both a public good (in terms of public health and the economy) and a legal obligation (since Bayh-Dole). Nevertheless, institutions often find this process challenging. This commentary argues that the difficulties often arise because of inherent differences in the structure of motivations between the three cultures: PI, institutional, and business. Because these cultures must by definition be involved in technology transfer, it would be useful to facilitate a dialogue among them, particularly as far as incentives and process are concerned. It is proposed that this dialog include education, communications, and regulation components with the goal of facilitating the technology transfer process for the future.

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