MANAGING UNIVERSITY INTELLECTUAL PROPERTY

IN THE PUBLIC INTEREST

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

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Committee on Management of University Intellectual Property: Lessons from a Generation of Experience, Research, and Dialogue

Board on Science, Technology, and Economic Policy

Committee on Science, Technology, and Law

Policy and Global Affairs

Stephen A. Merrill and Anne-Marie Mazza, Editors

NATIONAL RESEARCH COUNCIL
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The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

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Preface

This study of the organization, functioning, and effects of university technology transfer activities involving formal intellectual property rights resulted from the deliberations of two standing National Research Council (NRC) committees: the Board on Science, Technology, and Economic Policy (STEP) and the Committee on Science, Technology, and Law (CSTL). Aware of both claims for the success and criticisms of the system that has evolved since passage of P.L. 96-517, the Patent and Trademark Act Amendments of 1980 (the Bayh-Dole Act), members of the two committees concluded that an Academy review was appropriate and that the eve of the Act's 30th anniversary made it timely.

The Academies sought private funding for the project and ten philanthropic institutions responded: the Andrew W. Mellon Foundation, Robertson Foundation, John T. and Catherine D. MacArthur Foundation, Ewing Marion Kauffman Foundation, Burroughs Wellcome Fund, Doris Duke Charitable Fund, High Q Foundation, Myelin Repair Foundation, *FasterCures* Center of the Milken Institute, and one foundation whose grant-making is anonymous. The Academies and the committee assembled to conduct the study are grateful for their support.

The NRC Governing Board Executive Committee presented the committee with the charge to

> conduct a consensus study distilling lessons from research and experience since the Bayh-Dole Act of 1980 for the acquisition, licensing, defense, and sale of intellectual property arising from publicly and privately sponsored research at U.S. academic institutions. The project will involve synthesizing existing research, commissioning a survey of university officials and consulting with private and public research sponsors, holding a national conference, evaluating the various objectives of technology transfer, and

> recommending good practices for research institutions and research sponsors. Those practices will take into account significant differences in the role of intellectual property in different fields of technology, differences in the constraints on and resources of universities, objectives of different research sponsors, and differences among potential commercial licensees of university-owned intellectual property. The incentives that influence the behavior of researchers, administrators, and public policy makers will be examined and related to public goods.

In the course of preparing this report, the committee met five times. At four of the meetings, oral presentations were made by individuals from government, universities, and industry listed in Appendix B. Committee members presided over sessions of a two-day national conference held in Washington on November 20-21, 2008. Invited presenters are listed in Appendix A. The conference also provided an opportunity for interested members of the public to articulate their views. In addition, the committee commissioned an original background paper, Legal Context of University Intellectual Property and Technology Transfer, by Sean O'Connor, University of Washington, Gregory Graff, Colorado State University, and David Winickoff, University of California at Berkeley, that is available on the Academy website at http://sites.nationalacademies.org/PGA/step/ PGA_058712.

The committee also provided partial support for a previously planned survey of university technology transfer personnel, conducted by Professor Maryann Feldman, University of North Carolina at Chapel Hill, and Janet Bercovitz, University of Illinois at Urbana-Champaign. The results made available to the committee can be found under the title "Commissioned Papers" at http://www.nationalacademies.org/step. Other results will be reported in due course. The papers by O'Connor et al. and Feldman and Bercovitz were subject to external review. Finally, the committee received very preliminary results of an examination of invention disclosures filed with technology transfer offices of the University of California system over a five-year period, 1992 to 1997, by Kyriakos Drivas, Zhen Lei, and Brian Wright. See http://www.national academies.org/step. The committee is grateful to all of these important contributors to its understanding of the system and its consequences.

The report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Academies' Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process.

We wish to thank the following individuals for their review of this report: Robert Blackburn, DNAlex.com; Michael G. Borrus, X/Seed Capital Management; Wylie Burke, University of Washington; Joseph DeSimone, University of North Carolina at Chapel Hill; Maria Freire, The Albert and Mary Lasker Foundation; Rebecca Henderson, Harvard University; Krisztina Holly, University of Southern California; Trevor Jones, ElectroSonics Medical; Richard Nelson, Columbia University; Marvin Parnes, University of Michigan; Lori Pressman, Harris & Harris Group; Luis Proenza, University of Akron; Tim Quigg, University of North Carolina at Chapel Hill; John Raubitschek, U.S. Department of Commerce (retired); and Catherine Woteki, Mars, Inc.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by Johanna Dwyer, Tufts University, and Joseph Cecil, The Federal Judicial Center. Appointed by the National Academies, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

The committee's work was ably assisted by staff of both the STEP Board and the CSTL. We wish to thank Stephen Merrill, Executive Director, STEP, and Anne-Marie Mazza, Director, CSTL, who served as study directors, and their colleagues Steven Kendall, Daniel Mullins, and several Academy science and technology policy fellows.

Mark S. Wrighton, *Chair*
Committee on Management of University
Intellectual Property: Lessons from a Generation
of Experience, Research, and Dialogue

Contents

Summary

Discovery, learning, and societal engagement are mutually supportive core missions of the research university. Transfer of knowledge to those in society who can make use of it for the general good contributes to each of these missions. These transfers occur through publications, training and education of students, employment of graduates, conferences, consultations, and collaboration as well as by obtaining rights to inventions and discoveries that qualify for patent protection (intellectual property, or IP) and licensing them to private enterprises. All of these means of knowledge sharing have contributed to a long history of mutually beneficial relations among U.S. public and private universities, the private sector, and society at large.

Several of these mechanisms undoubtedly exceed intellectual property-based licensing in economic and social impact. However, patenting and licensing of IP by universities is more closely regulated by national policies emanating from the dominant role of the federal government in funding academic research. Thirty years ago federal policy underwent a major change through the Bayh-Dole Act of 1980 (P.L. 96-517, the Patent and Trademark Act Amendments of 1980), which fostered greater uniformity in the way research agencies treat inventions arising from the work they sponsor, allowing universities to take title in most circumstances, and as a result accelerating patenting and licensing activity. Universities have generally applied the same policies and practices to self-supported and privately sponsored research whose output is not regulated. Although the system created by the Bayh-Dole Act has remained stable, it has nevertheless generated a good deal of debate about whether it is as effective as it could be and whether it has produced unintended effects that are adverse to other modes of technology transfer and even to the norms of the university community.

On the eve of the 30th anniversary of the Act, the National Research Council's Board on Science, Technology, and Economic Policy and Committee on Science, Technology, and Law, with the support of ten private foundations, convened a committee of experts from universities, industry, and foundations, and similar organizations, as well as scholars of the subject, to review experience and evidence of the technology transfer system's effects and recommend improvements. The committee held a series of open meetings with a variety of presenters, including a two-day public conference with invited experts addressing questions on six topics identified by the committee. It also commissioned original research on the activities and organization of university technology transfer offices and on the legal context of technology transfer. The following summarizes the committee's principal findings and recommendations.

PRINCIPAL FINDINGS AND RECOMMENDATIONS

THE UNIVERSITY AND THE TRANSFER OF TECHNOLOGY

Finding 1: The first goal of university technology transfer involving IP is the expeditious and wide dissemination of university-generated technology for the public good. The public good might include inputs into further research; new products and processes addressing societal needs; and generation of employment opportunities for the production, distribution, and use of new products. Although the transfer methods will vary from institution to institution depending on the history, location, and composition of the institution's research portfolio, the goal of expeditious and wide dissemination of discoveries and inventions places IP-based technology transfer squarely within the research university's core missions of discovery, learning, and the promotion of social well-being.

Finding 2: The transition of knowledge into practice takes place through a variety of mechanisms, including but not limited to

1. movement of highly skilled students (with technical and business skills) from training to private and public employment;
2. publication of research results in the open academic literature that is read by scientists, engineers, and researchers in all sectors;
3. personal interaction between creators and users of new knowledge (e.g., through professional meetings, conferences, seminars, industrial liaison programs, and other venues);
4. firm sponsored (contract) research projects involving firm-institution agreements;
5. multi firm arrangements such as university-industry cooperative research centers;
6. personal individual faculty and student consulting arrangements with individual private firms;
7. entrepreneurial activity of faculty and students occurring outside the university without involving university-owned IP; and
8. licensing of IP to established firms or to new start-up companies.

All eight mechanisms, often operating in a complementary fashion, offer significant contributions to the economy. The licensing of IP, although not the most important of these mechanisms, is more often discussed, measured, quantified, and debated than all other mechanisms combined and is the subject of our findings and recommendations.

THE BAYH-DOLE SYSTEM AND ALTERNATIVES

> **Finding 3:** The system put in place by the Bayh-Dole Act, that is, university ownership of inventions from publicly funded research and latitude in exercising associated IP rights subject to certain conditions and limitations, is unquestionably more effective than its predecessor system—government ownership subject to waiver in circumstances that varied from agency to agency—in making research advances available to the public.

In the pre-1980 system of government ownership (albeit with the possibility of waivers in some circumstances), incentives to pursue commercialization and capacity to do so were limited. When research performers had only the possibility to persuade agencies to transfer rights to them uncertainty and complexity were high. Most institutions had no reason to hire personnel to handle these matters. The Bayh-Dole Act removed the inconsistencies with regard to performer rights and was followed by a surge in patenting and licensing activity as well as growth in university's capacity to undertake this activity.

The only proposal for an alternative system to attract interest among observers and critics of the status quo is one giving university faculty much greater autonomy in managing their inventions, either by assuming ownership or by having freedom to pursue licensing opportunities through outside service providers, although the home institution might retain ownership.

> **Finding 4:** The Bayh-Dole legal framework and the practices of universities have not seriously undermined academic norms of uninhibited inquiry, open communication, or faculty advancement based on scholarly merit. There is little evidence that IP considerations interfere with other important avenues of transferring research results to development and commercial use.

> **Finding 5:** A persuasive case has not been made for converting to an inventor ownership or "free agency" system in which inventors are able to dispose their inventions without university administration approval. If evidence is developed suggesting that either approach would be more effective than the current system, other significant practical consequences and policy issues would have to be considered, such as the potential for conflicts of interest and adverse effects on public accountability.

> **Finding 6:** Nevertheless, proposals to empower faculty and other university-based inventors by giving them ownership or rights to market their inventions independent of university oversight reflect a feeling in some quarters that in the current system of university management, inventor initiative is not sufficiently valued and encouraged. In fact, successful commercialization often depends on active inventor engagement and, in some cases, inventors playing a lead role.

IMPROVING THE SYSTEM OF UNIVERSITY IP MANAGEMENT

It is essential that universities give a clear policy mandate to their technology transfer offices and acknowledge the tensions among frequently stated goals: knowledge dissemination, regional economic development, service to faculty, generation of revenue for the institution, and, more recently, addressing humanitarian needs.

Recommendation 1: The leadership of each institution—president, provost, and board of trustees—should articulate a clear mission for the unit responsible for IP management, convey the mission to internal and external stakeholders, and evaluate effort accordingly. The mission statement should embrace and articulate the university's foundational responsibility to support smooth and efficient processes to encourage the widest dissemination of university-generated technology for the public good. Whether the primary emphasis is on global, national, regional, or local benefits is likely to depend significantly on the nature of the IP and vary with the type of institution (public or private), its history, research intensity, primary sources of financial support, and educational characteristics. This places IP-based technology transfer squarely within the university's core mission to advance discovery and learning and to contribute to the well-being of society while recognizing institutional differences.

Patenting and licensing practices should not be predicated on the goal of raising significant revenue for the institution. The likelihood of success is small, the probability of disappointed expectations high, and the risk of distorting and narrowing dissemination efforts great. Nonetheless, in the rare case where significant revenue is generated, universities should have a plan in place for handling and distributing such gains.

Successful technology transfer requires involvement of a variety of stakeholders, such as faculty inventors, students (who may also be inventors), representatives of other parts of the institution and community involved in economic development, and the relevant business and investment communities. All can contribute to the development of appropriate strategies and practices and the identification of new opportunities. Inevitably, disagreements will arise among participants in the process and the university administration may need advice on how to resolve disputes.

Recommendation 2: Universities with sizable research portfolios should consider creating a standing advisory committee composed of members of the faculty and administration; representatives of other business development units in or affiliated with the institution such as business incubators, research parks, proof-of-concept centers, and entrepreneurial education programs; members of the relevant business and investment communities; and, if appropriate, local economic development officials.

The committee should meet regularly to help the technology licensing unit elaborate practices consistent with the institution's goals and policies, consider how best to exploit inventions where the path to wide availability and broad public benefit is not clear, and identify new opportunities.

A separate committee of faculty, employee, and administration representatives (who may or may not also serve on the advisory committee) should be charged with advising on university policy regarding technology transfer and hearing and helping to resolve disputes between inventors and the technology transfer office with respect to the protection and commercialization of inventions. Both the full advisory committee and the internal committee should make recommendations to the provost or other executives of the university.

Because of the wide variability among institutions in their resources, the scale and focus of their research efforts, their experience in technology licensing, and not least their missions, there cannot be a single template for technology transfer that all institutions should attempt to model. Moreover, there are technological fields such as information technology, in which aggregation of IP can increase utility and value. As a result, this organizational guidance is general rather than highly prescriptive.

Recommendation 3: There is a strong theoretical case and some empirical evidence that the technology licensing unit is more effective when exposed to broader issues in the financing and conduct of research. That objective is best served by locating the technology transfer office in proximity and making it accountable to the university's research management, for example, reporting to the provost or vice provost for research and allied or integrated with the office of sponsored research.

Recommendation 4: Smaller institutions and those with less experience should consider the following options for technology transfer policies and practices:

1. permitting greater outreach by faculty and others who have the experience and inclination to pursue entrepreneurial development of their ideas;
2. inter-institutional agreements—collaborating with larger institutions in the same region or in fields with complementary research strengths or engaged in research collaborations; or
3. outsourcing certain functions to private entities with appropriate skills and contacts, perhaps focused on particular technology fields or markets.

The latter practices may also be appropriate for larger institutions with IP portfolios in fields such as information technology, where aggregations of patents are often necessary to achieve value.

Patenting, licensing, and enforcement practices, too, can vary depending not only on the technology but also on circumstances peculiar to the invention, business opportunity, licensee, and institution. As a general matter, however,

Recommendation 5: Universities should pursue patenting and licensing practices that, to the greatest extent practicable, maximize the further development, use, and beneficial social impact of their technologies.

More specifically, the committee supports an informal, evolving set of good practices originally articulated by several university leaders and endorsed by the Association of University Technology Managers.

Recommendation 6: This committee reviewed the "Nine Points to Consider in Licensing University Technology" and endorses the guidelines most closely related to its charge:[1]

- Universities should reserve the right to practice licensed inventions and to allow other nonprofit and government organizations to do so. In most cases this should not require a negotiated licensing agreement, although notice of intent to use the invention and awareness of any terms and limitations on use may be required through use of an online click-through license or other simple mechanism.
- Universities should also endeavor to structure licenses, especially exclusive licenses, in ways that promote investment, diligent development, and use, with milestone criteria to back up such requirements.
- Universities should strive to minimize the licensing of "future improvements."
- Universities should try to ensure broad access to research tools.
- Universities should anticipate and do their best to eliminate conflicts of interest associated with technology transfer.
- In cases where there is a market for the sale of unlicensed patents, universities should try to ensure that purchasers operate under a business model that allows for commercialization rather than a model based on threats of patent infringement litigation to generate revenue.
- Universities should be careful to avoid working with private patent aggregators whose business model is limited to asserting patents

[1] Unlike the drafters of the "Nine Points," this committee did not consider the relationship between licensing patents and compliance with national security export controls.

against established firms rather than seeking to promote further development and commercial application of the technology.
- Universities should try to anticipate which technologies may have applications that address important unmet social needs unlikely to be served by terms appropriate for commercial markets and to structure agreements to allow for these applications. The principal examples are technologies suited to meeting the agricultural, medical, and food needs of developing countries.

Enforcement of IP rights against suspected infringers should be approached carefully to protect the institution's resources and reputation.

Recommendation 7: A university's decision to initiate legal action against an infringer should reflect its reasons for obtaining and licensing patents in the first instance. Examples include

- contractual or ethical obligations to protect the rights of existing licensees to enjoy the benefits conferred by the licenses;
- disregard by infringer of scientific or professional norms and standards, such as use of medical technologies outside standards of care or professional guidelines; and
- disregard by an infringer of the institution's legitimate rights, for example, as evidenced by a refusal to negotiate a license on reasonable terms.

One burden in technology transfer efforts stems from difficulties in accessing proprietary research materials, whether patented or unpatented—difficulties that seem likely to be related to scientific as well as commercial competition. Concern over the flow of research materials—which may be critical inputs for the success of a research project—is not new; nor has it gone unaddressed. The research tool guidelines developed and published by the National Institutes of Health (NIH) address the process of materials exchanges, and NIH also has developed model Material Transfer Agreements (MTAs). However, facilitating voluntary exchanges of materials among researchers requires further attention and effort on the part of research sponsors and universities.

Recommendation 8: To facilitate the exchange of scientific materials among investigators, especially those engaged in nonprofit sector research, research sponsors should explicitly encourage and monitor compliance with requests for materials. Also, industry research sponsors should explicitly allow requests by other academic scientists for materials developed in the course of studies they have sponsored at a university. Moreover, technology transfer offices should in the future either

- cease requiring use of Material Transfer Agreements when their investigators and colleagues at other nonprofit research institutions are exchanging non-hazardous or non-human biological material for in vitro research, or
- use only the Uniform Biological Material Transfer Agreement (UBMTA) or the Simple Letter Agreement (SLA) recommended by the National Institutes of Health.

NIH should reiterate its support of these options, monitor the actions of grantees and contractors with regard to material sharing, and, if necessary, require compliance with this policy. Industry sponsors should follow similar practices, encouraging material exchanges and refraining from demanding overly restrictive conditions. University technology transfer and sponsored research offices should discourage investigators from entering into sponsored research agreements where the terms governing material exchanges between nonprofit institutions deviate from this policy.

Launching a stand-alone firm may be the best option for commercializing a new technology, particularly when its use would displace existing methods, but the conditions for success in this endeavor extend well beyond securing and licensing IP rights to include reasonable assurance that the technology addresses a market need, developing a viable business plan, and attracting investment capital and managerial talent.

Recommendation 9: Universities engaged in licensing technologies to a new enterprise should ensure that a process is in place not only for securing IP protection but also for evaluating whether the technology is more appropriate for development and commercialization by a start-up rather than an established firm and for determining that the requisite assets for the start-up's viability are in place or in process. These assets generally include a clear conception of market need, a vetted business plan, investment capital, and management with appropriate skills. In some universities, diverse units might contribute to creating some of these assets. In other cases, they are largely handled externally. Regardless of the extent of the university's involvement, the technology transfer office is usually only one source of the expertise needed to make these judgments, and it should be prepared to collaborate with others. To the extent possible, the university administration should try to ensure that the key inputs are available and coordinated.

The technology transfer office can enhance the cooperation of faculty, staff, and student researchers and contribute to entrepreneurial success by streamlining the licensing of new ventures.

Recommendation 10: Universities seeking to encourage entrepreneurship should consider instituting an expedited procedure and more standardized terms for licensing university-generated technology to start-up enterprises formed by faculty, staff, or students of the institution. The decision to extend such a license should depend on the existence of a vetted business plan, absence of conflicts of interest, and evidence that the principals, per Recommendation 9, have sought out competent managerial and other expertise to enhance the enterprise's commercial viability. There may be circumstances justifying the university's departure from the standardized, expedited procedure for specific inventions or inventors. However, both the conditions and the grounds for discrimination should be articulated *ex ante* to avoid arbitrariness in the process, align expectations, and make the process as efficient as possible. With respect to a university's equity stake and/or royalty rates, these terms are likely to vary from institution to institution and from one technology field to another, but they should reflect sensitivity to the exigencies facing start-up enterprises in their earliest phases, and they should provide for predictability and simplicity with a view toward reducing transaction costs that may be especially burdensome for prospective entrepreneurs with limited time and resources.

This recommendation is intended to support venture creation as a principal vehicle for technology transfer for social good and, to this end, is also intended to encourage staff cooperation with the technology transfer office, facilitate cooperation among elements of the support structure for entrepreneurship, and result in more accurate reporting of entrepreneurial activity.

Finally, negotiating the terms of IP arrangements with private sponsors often has been perceived by observers to be accompanied by friction and delays. This has not been systematically documented, but it has been the subject of ongoing discussion in various university-industry forums. There are now some exceptions to the norm of university ownership and licensing for a fee that should be evaluated in operation but that in the meantime merit consideration to facilitate private-sector investment in university research. Examples include the following:

- Corporations offer and universities accept a percentage premium on research contracts in lieu of negotiating future royalty terms.
- For work that does not represent leading-edge, knowledge-enhancing research, some universities give corporate sponsors title to results.
- Universities grant corporate sponsors royalty-free nonexclusive licenses to research results where the company pays the full cost of the research in question.

Recommendation 11: University technology licensing and sponsored research offices should explore arrangements with private research sponsors that promise to obviate the often protracted process of negotiating licensing terms, the principal source of friction and delay in reaching agreement.

ENSURING EVALUATION AND ACCOUNTABILITY

At the institutional level, there should be a process in place for evaluating the technology transfer function. The process should involve consultation with key stakeholders and use of performance measures that include, for example, the length of time to negotiate contracts, the number of technologies being promoted at any one time, and the number of contacts made in the process of marketing them.

> **Recommendation 12:** Universities should periodically review the operations of their technology transfer office in a manner similar to the evaluation of academic and administrative units. This could involve the formation of a visiting committee with members drawn from other institutions' technology transfer offices generally recognized as high performing; members of the relevant business and investment communities; and representatives of research sponsors, faculty, and economic development organizations.

At the national level, data collection should focus on placing IP-based transactions in the context of knowledge dissemination broadly defined and attempt to capture the social and economic impacts of technology transfer.

> **Recommendation 13:** Principal university and professional organizations and federal science agencies should coordinate efforts to develop a more balanced set of measures of total university knowledge exchange with the private sector to improve understanding of the process and its performance. This should result in a manageable set of questions incorporated in the National Science Foundation's annual survey of higher education institutions' expenditures on research and development and in other private surveys. To the extent possible, the responses should be capable of being linked to other data sets on research outputs, new business creation, and industrial performance.

Although the Bayh-Dole Act is effective in its primary purpose, its implementers have failed to establish a stable, effective framework for government oversight. By statute and in practice the role of the Department of Commerce has been limited to developing implementation regulations, reporting to Congress, hosting an interagency working group, and encouraging some consistency in practice, and even these functions have been moved around the Department from time to time. Recently, they were assigned to the National Institute of Standards and Technology (NIST).

> **Recommendation 14:** There should be a clear assignment of federal government oversight responsibilities, perhaps by Executive Order, including

- ensuring consistent implementation of federal technology transfer laws by all agencies;
- reviewing agency diligence and actions with respect to Determinations of Exceptional Circumstances, government use rights, and exercise of march-in rights;
- revisiting the Department of Commerce regulations implementing several provisions of the Bayh-Dole Act, including the conditions for access to and use of data gathered about inventions;
- heading an interagency committee on technology transfer that would, for example, evaluate and develop a government-wide position on proposed changes to the Act or system; and
- reviewing with other agencies and with representatives of research universities and relevant professional groups the data that should be collected from universities.

To play an effective role, the oversight unit needs to extend its outreach not only to other federal research agencies but also to the university research community.

Effective oversight relies on the availability of relevant data, for which the NIH iEdison database services as a central repository, but institutional reporting has been judged by the Government Accountability Office to be incomplete and access to the data is severely restricted.

Recommendation 15: Federal research agencies should reinvigorate the requirement that institutions reliably and consistently provide data to iEdison on the utilization of federally funded inventions, including licensing agreements and efforts to obtain such utilization. Such data should be available for analysis by qualified researchers who agree not to disclose the parties to or terms of particular agreements.

1

The Growth of University Technology Transfer

INTRODUCTION

By most accounts, the Bayh-Dole Act of 1980 (P.L. 96-517, the Patent and Trademark Act Amendments of 1980) together with a number of important changes in the patent system[2] has stimulated extensive patenting and licensing activity among research universities in the United States. Although a substantial amount of research has centered on this means of transferring technology developed by university scientists and engineers, there is a lack of consensus about the intended and unintended effects of university management of technology transfer and the lessons learned from more than three decades of experience. In response to these issues, the Board on Science, Technology, and Economic Policy and the Committee on Science, Technology, and Law of the National Research Council conducted a consensus study to distill lessons from both research and experience regarding the acquisition, licensing, defense, and sale of intellectual property (IP) arising from publicly and privately sponsored research at U.S. academic institutions.

The committee's work was informed by commissioned papers synthesizing existing research, a commissioned survey of university technology managers, and a series of open sessions featuring presentations from diverse participants. Armed with this background information, the committee conducted a series of deliberations focused on evaluating the various objectives of technology transfer and recommending good practices for research institutions and research sponsors (public and private). The results of those deliberations are presented in this report. This first chapter provides a background to the report by placing IP-based university technology transfer in the context of the many ways that knowledge from academic research is disseminated to and used in the private sector and by discussing the forms of technology transfer that involve IP transactions.

[2] Among other changes, various federal court decisions expanded the scope of patentable subject matter to include engineered organisms and isolated, purified nucleic acid sequences, computer software, and business methods. Patent appellate jurisdiction was consolidated in the U.S. Court of Appeals for the Federal Circuit, generally considered more favorable to patent holders than several of the circuit courts of appeals. In addition, international protection of intellectual property was strengthened by multilateral and bilateral agreements, including the 1994 World Trade Organization agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

UNIVERSITY MANAGEMENT OF TECHNOLOGY TRANSFER IN PERSPECTIVE

Universities have a lengthy track record of providing dynamic environments for generating new ideas and spurring innovation, and for moving advances in knowledge and technology into the commercial stream where they can be put to work for the public good; these endeavors collectively are referred to as "technology transfer." Given that public investment in research has been an explicit national priority for more than six decades, and given the level of that investment, universities arguably have an obligation to organize themselves effectively to facilitate the transition of knowledge into practice. This transition takes place through a variety of mechanisms,[3] including but not limited to

1. movement of highly skilled students (with technical and business skills) from training to private and public employment;[4]
2. publication of research results in the open academic literature that is read by scientists and engineers in all sectors;[5]
3. personal interaction between generators and users of new knowledge (e.g., through professional meetings, conferences, seminars, industrial liaison programs, and other venues);
4. firm-sponsored (contract) research projects involving firm-institution agreements;
5. multi-firm arrangements such as university-industry cooperative research centers; and
6. personal individual faculty and student consulting arrangements with individual private firms
7. entrepreneurial activity of faculty and students occurring outside the university without involving university-owned IP, and
8. licensing of IP to established firms or to new start-up companies.

Many industries critical to the U.S. economy have relied on basic and applied academic research in the past century, including agriculture, biotechnology, chemicals, pharmaceuticals, software, microelectronics,

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[3] For a discussion of these mechanisms, see W.M. Cohen, R.R. Nelson, and J.P. Walsh. 2002. Links and impacts: The influence of public research on industrial R&D. *Management Science* 48:1-23; L. Branstetter and K.H. Ug. 2004. The restructuring of Japanese research and development: The increasing impact of science on Japanese R&D. *RIETI Discussion Paper Series* 04-E-021; and R.K. Lester. 2005. Universities, innovation, and the competitiveness of local economies. *MIT Industrial Performance Center Working Paper* MIT-IPC-05-0101.

[4] See, e.g., National Academy of Engineering. 2003. *The Impact of Academic Research on Industrial Performance*. Washington, D.C.: National Academies Press. Also, the Kauffman Foundation's survey of Massachusetts Institute of Technology (MIT) alumni found that an estimated 6,900 MIT alumni companies with worldwide sales of approximately $164 billion are located in Massachusetts alone and represent 26 percent of the sales of all Massachusetts companies, and 4,100 MIT alumni-founded firms are based in California and generate an estimated $134 billion in worldwide sales. Kauffman Foundation. 2009. *Entrepreneurial Impact: The Role of MIT*. Available at: http://www.kauffman.org/uploadedFiles/MIT_impact_full_report.pdf.

[5] R. Lester, op. cit.

computers, telecommunications, and aerospace. In 2008, U.S. companies spent $2.5 billion out of their total $219.6 billion R&D investment at U.S. colleges and universities, representing 5 percent of university R&D spending.[6] Directly sponsored research is just a small part of the web of intricate academic-industrial interaction that characterizes the U.S. innovation system.

Of the eight mechanisms of technology transfer listed above, the first seven offer significant contributions to the economy, yet it is the eighth (licensing of IP[7]) that is more often discussed, measured, quantified, and debated than the other mechanisms combined.[8] There are several reasons for this. First, patenting and licensing activities by universities are easier to observe and measure than several of the other mechanisms, for example, movement of students and consulting arrangements. Second, in contrast with scholarly publications and most professional interactions, patenting and licensing activities are characterized by readily apparent economic value or distinct potential revenue streams for businesses, universities, and faculty inventors. Third, there has been a dramatic upsurge in patenting and licensing since 1980, which is primarily associated with a change in federal policy brought about by passage of the Bayh-Dole Act. Although the economic value of licensing is readily apparent, the social value of licensing activities (i.e., the net societal benefit of commercialization of a particular IP) is more difficult to estimate and is expected to be larger than the economic value recorded.

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[6] National Science Board. 2008. *Science and Engineering Indicators*. See Table 4-1, U.S. R&D expenditures, by funding and performing sectors: 2006. Available at: http://www.nsf.gov/statistics/seind08/c4/tt04-01.htm.

[7] See Cohen et al., op. cit., which surveys U.S. manufacturing firms and finds that patents and licensing are relatively unimportant as mechanisms of knowledge transfer. These authors' survey data were collected in 1994 and confined to manufacturing firms. The growing importance of service sector firms and changes in the use of mechanisms since 1994 may affect the interpretation of these results. See also A. Agrawal and R. Henderson. 2002. Putting patents in context: Exploring knowledge transfer from MIT. *Management Science* 48:44-60, which reports results of qualitative interviews with MIT professors in mechanical engineering, electrical engineering, and computer science and finds similarly low relative importance of patents and licensing as channels of knowledge transmission. The Agrawal and Henderson data were collected in 2000 and are confined to two specific engineering fields.

[8] The use of mechanisms apart from patenting and licensing have been documented using (1) survey responses from manufacturing firms (see Cohen et al., op. cit.); (2) survey responses from university scientists and engineers (see A.N. Link, D.S. Siegel, and B. Bozeman. 2007. An empirical analysis of the propensity of academics to engage in informal university technology transfer. *Industrial and Corporate Change* 16(4):641-655); (3) structured interviews with academics, technology transfer officers, administrators, and managers (see D.S. Siegel, D. Waldman, D.L. Atwater, and A.N. Link. 2004. Toward a model of the effective transfer of scientific knowledge from academicians to practitioners: Qualitative evidence from the commercialization of university technologies. *Journal of Engineering and Technology Management* 21:115-142); and (4) industry-specific case studies (see National Academy of Engineering. 2003. *The Impact of Academic Research on Industrial Performance*. Washington, D.C.: National Academies Press). Cohen et al. and the National Academy of Engineering studied the effect of academic research on industrial R&D, although using distinctly different methods (survey responses and industry-specific case studies, respectively).

THE BAYH-DOLE ACT

The Act established a uniform patent policy among federal agencies funding research conducted by small businesses and nonprofit organizations (including universities) largely enabling them to retain title to inventions made under federally funded research programs. For universities, the legislation shifted the incentive structure for commercialization by clarifying that taking ownership of inventions arising from federally funded research and licensing those inventions on terms enabling their commercial development could be standard practice for academic institutions.

Prior to passage of Bayh-Dole, the U.S. government had accumulated 30,000 patents, of which only approximately 5 percent were commercially licensed.[9] As federal funding to support research in military, defense, and medical technologies increased following World War II, the government did not have a unified patent policy. Starting with the Kennedy administration, attempts were made to develop a consistent government-wide policy, but the policies put forth directed title to the agencies and not to the public.

Nonprofit organizations, led by the University of Wisconsin–Madison, sought even more favorable policies and successfully entered into Institutional Patent Agreements (IPA), which, among other things, allowed universities and nonprofits with approved patent policies to retain title to their inventions. While an improvement over the practice at the time, the IPA only applied to federally funded inventions supported by the National Institutes of Health (NIH) and the National Science Foundation (NSF). With all other agencies, universities would need specific approval or approval on a case-by-case basis.

With agencies disagreeing on a uniform technology transfer policy, no simple consistent mechanism existed for universities to move academic research to the marketplace. Agencies varied widely in whether they allowed university ownership of inventions and in the speed with which they handled requests to transfer title to inventions. Consequently, very little federally funded research was commercialized prior to 1980. As Senator Birch Bayh noted at the time, “What sense does it make to spend billions of dollars each year on government-supported research and then prevent new developments from benefitting the American people because of dumb bureaucratic red tape?”[10]

One purpose of the Act was to provide consistency within federal agencies with respect to inventions developed with federally funded research. The broader purpose of the Act was to ensure that publicly funded inventions should, whenever possible, enhance the public welfare through commercialization of technology to contribute to public health, government missions, job creation, international competitiveness, economic growth, and other public goods.

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[9] Federal Council for Science and Technology 1978. *Annual Report on Government Patent Policy* (0565-5102). Washington, D.C.: Government Printing Office.

[10] Senator Birch Bayh, statement on the approval of S.414 (Bayh-Dole) by the U.S. Senate on a 91-4 vote, April 13, 1980, quoted in Association of University Technology Managers, *Recollections* p.16.

The Act was by no means the first statute intended to use higher education institutions to contribute to economic welfare. More than a century earlier, the Morrill Act of 1862 (7 U.S.C. Sec 301 et seq.) made it possible for the states to establish "land-grant institutions" emphasizing the teaching and advancement of agricultural science and the mechanical arts. The Morrill Act land grants laid the foundation for a national system of state colleges and universities. Such institutions not only opened the door to higher education to thousands of farmers and working people, but also stimulated interaction with agricultural producers and food and equipment manufacturers.

The Bayh-Dole Act was intended to minimize the likelihood that government-funded inventions would languish for lack of incentives or government capacity to license them to private firms that could develop them into products and services. It also aimed to establish a more uniform policy that would reduce the transaction costs to institutions, give them incentives to acquire and license rights, and limit the risks to firms of investing in and commercializing inventions developed with federal funds.[11]

In giving universities the right to retain title, the government imposed a number of balancing conditions and limitations that do not apply to patent holders more generally and that would shape implementation of this ownership scheme. First, the Act stipulated that universities give a preference in licensing to small businesses and firms (whether large or small) that develop and manufacture domestically. Second, the statute retained a royalty-free paid-up license for government use of inventions. Third, the Act allowed a research sponsoring agency to assert a Declaration of Exceptional Circumstances (DEC), precluding the grantee or contractor institution from taking title, and to cancel an institution's existing patent rights ("march-in") in one of four specified circumstances, the most important being the institution's or licensee's failure to develop and commercialize the invention.[12] Another provision required the university to share royalties with faculty inventors and devote the balance of any income to research and education. In short, through these conditions, Congress sought to protect important public interests rather than leave them entirely to the discretion of inventors or their institutions. The Act also obligated universities to establish policies requiring disclosure of inventions by faculty, initially to the institution and, within two months, to the federal agency sponsoring the research. Universities were granted periods within which to elect or waive title and to file a patent application. Apart from these conditions and procedural requirements, universities were given broad latitude in how to organize themselves to implement technology transfer.

The combined effects of Bayh-Dole—institutional responsibilities and incentives for patenting and licensing—may have led more universities to enter

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[11] D. Mowery and B. Sampat. 2001. University patents, patent policies, and patent policy debates: 1925-1980. *Industrial and Corporate Change* 10:781-814.

[12] A Declaration of Exceptional Circumstances (DEC) must be for compelling reasons consistent with provisions within the Bayh-Dole Act and made in writing before entering into a funding agreement with a university. The agency must file a DEC with the Department of Commerce. NIH has issued several DECs in the past decade.

into technology transfer activities than otherwise would have been the case, and even establish technology transfer offices, although the latter was a growing trend even prior to 1980.[13]

The Bayh-Dole Act applies only to the results of federally funded research, not research financed by state and local governments, philanthropic organizations, for-profit entities, or by institutions themselves. In 2007, approximately 62 percent of all R&D spending at universities and colleges came from the federal government—a substantial majority—but the remaining 38 percent of research funding constitutes a considerable amount of research not covered by the legislation.[14] Although higher education institutions are free to enter agreements conferring title to inventions to other partners and sometimes do so, in practice most universities try to follow a uniform policy of acquiring and exercising title irrespective of the source of research funding. This is, in part, because of the undesirability of hindering the management of IP resulting from research activities with multiple funding sources, but also because of other reasons, such as the requirements of tax-exempt facilities financing or as partial compensation for institutional under-recovery of true overhead costs on sponsored research.

At the time the Bayh-Dole legislation was debated and enacted, there was considerable controversy, but not on grounds that retention of title by the government more effectively promoted the commercialization of research results. The government's poor track record in this respect was apparent to all close observers. Nor was there a great deal of concern expressed about the effects of technology ownership on the culture of the university. Rather, some members of Congress and some critics outside government were philosophically opposed to the transfer of ownership of taxpayer-funded assets to non-government entities for exploitation and profit. They argued that this obliged taxpayers to pay twice—first for the research and again for the products developed from that research.[15] After passage of the Act, opposition on these grounds dissipated over time. In 1983, President Ronald Reagan issued a memorandum extending the Bayh-Dole policy to all government contractors.[16] Nearly 30 years later, that remains federal policy without significant modification or variation from one federal program or agency to another.

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[13] D.C. Mowery and B.N. Sampat. 2005. The Bayh-Dole Act of 1980 and university-industry technology transfer: A model for other OECD governments? *The Journal of Technology Transfer* 30(1):115-127.

[14] National Science Foundation, Division of Science Resources Statistics. 2008. *Academic Research and Development Expenditures: Fiscal Year 2007*. Detailed Statistical Tables NSF 09-303. Arlington, VA. Available at: http://www.nsf.gov/statistics/nsf09303/.

[15] A.J. Stevens. 2004. The enactment of Bayh-Dole. *The Journal of Technology Transfer* 29(1):93-99; H.G. Rickover. 1978. Government patent policy. *Journal of the Patent Office Society* 60(1):14-26.

[16] The memorandum did not change the policy in the Department of Energy and NASA, whose organizational statutes required government ownership of inventions developed by large for-profit contractors and grantees. There is a residual issue that occasionally arises but has not gained broad support—an argument that the government should be able to recoup some portion of university revenue from licensing or corporate profits from marketing a government-funded invention.

Since 1980, most of the questions concerning university ownership of patented technology arising from federally sponsored research have centered on the effectiveness of university policies and practices and whether the academic environment is experiencing deleterious effects attributable to commercially motivated or related secrecy; delays in publication of research results; changes in faculty hiring, promotion, and tenure criteria; and redirection of research efforts away from curiosity-driven topics toward applications with the prospect of financial returns.[17] In short, concerns center on whether aggressive pursuit of commercialization undermines the traditional mission of universities with respect to the pursuit and dissemination of fundamental knowledge.[18] These questions are examined further in Chapter 2.

MEASURING UNIVERSITY PATENTING AND LICENSING AND THEIR RESULTS

Coincidental with the growth and professionalization of technology transfer as a component of the administrative structure of academic research institutions has been growing focus on the formal aspects of IP-based technology transfer—that is, invention disclosures, patents, licenses, new enterprises spun out of university research, and revenues.[19] These outcomes are relatively easy to count, are reported annually by most institutions, and are taken by some as real or proxy measures of the effectiveness of Bayh-Dole policy and universities' contributions to the economy. These metrics show steady increases in patenting and licensing activity over time.

According to a series of annual surveys begun in Fiscal Year 1991 by the Association of University Technology Managers (AUTM),[20] among 109 U.S. non-profit institutions responding in both 1996 and 2004, inventions disclosed by faculty increased from an average of 66.9 per institution in 1996 to 115.4 in 2004 (a growth of 72.5 percent).[21] New patent applications filed increased from an average of 22.8 per institution in 1996 to an average of 73.4 per institution in 2004 (a growth of 222 percent per institution). In Fiscal Year 2007, 193

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17 J. Boyle. 2008. *The Public Domain: Enclosing the Commons of the Mind*. New Haven, CT: Yale University Press.

18 S. Krimsky. 2004. *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?*

Lanham, MD: Rowman & Littlefield Publishers, Inc.

19 Almost all studies focusing on the relationship between academic research and innovation are based on manufacturing sectors. For a rare study of the services industry, see the case study on the financial services industry in Chapter 6 of Report of the Panel on the Financial Services Industry. National Academy of Engineering. 2003. *The Impact of Academic Research on Industrial Performance*. Washington, D.C.: National Academies Press.

20 Trends from the AUTM survey data should be interpreted with caution. Participation in the AUTM survey varies year by year, and it is possible that non-participation in a particular year is not random (e.g., a university choosing not to respond to the survey in a year of weak licensing activity). The cross-sectional data reported for a particular year (e.g., 3,633 issued patents in Fiscal Year 2007) is more reliable.

21 AUTM U.S. Licensing Activity Survey, FY2007. R. Tieckelmann, R. Kordal, and D. Bostrom (eds.). Available at: http://www.autm.net/Content/NavigationMenu/Surveys/LicensingSurveysAUTM/FY2007LicensingActivitySurvey/AUTMUSLS07FINAL.pdf.

institutions reported receiving 19,827 disclosures, an increase of 953, or 3 percent per institution compared with the 18,874 disclosures received from 189 institutions in 2006 (see Figure 1).[22] In addition, respondents reported 3,633 issued patents. There has been a steady increase in the ratio of new patent filings to disclosures received—from 26 percent in 1991 to about 60 percent in 2007. However, there is uneven distribution in this activity, with most institutions filing fewer than 100 new applications in 2007, and averages can be misleading. There are vast differences among institutions, and the range of activity is quite broad, from 4 to 661 disclosures.

Overall licensing activity also has increased. In 2007, respondents to the AUTM survey reported executing 4,391 licenses, of which 1,805 were exclusive and 2,586 were nonexclusive. Respondents also reported 30,351 active licenses/options for Fiscal Year 2007, an increase from 27,322 active licenses/options reported by respondents for Fiscal Year 2005.

This activity is not evenly distributed across research fields and technologies. The AUTM survey ceased to collect field data years ago,[23] but work supported by this committee indicates a high concentration in the life sciences in general and health biotechnology in particular. The 2009 survey of technology transfer offices by Maryann Feldman, University of North Carolina School of Public Policy, and Janet Bercovitz, University of Illinois at Urbana-Champaign, found that the life sciences accounted for 52.5 percent of the licensing activity among respondent offices (66), followed by material science (11.9 percent), software (9.3 percent), electronics (7.5 percent), and chemicals (4.0 percent). Write-in categories of "engineering" and "other" accounted for 9.3 and 5.4 percent, respectively. Naturally, the distribution differed by institution, but six universities with medical schools and one institution without a medical school reported that the life sciences accounted for 100 percent of their licenses.[24]

In an ongoing study of all of the invention disclosures reported to technology transfer offices in the University of California system (12 universities and laboratories in all) during the five-year period July 1, 1992, to June 30, 1997, Brian Wright and colleagues found that the life sciences and medical and pharmaceutical categories accounted for nearly 75 percent of the invention disclosures with a field identification, followed by electronics, software, and communication (10 to 12 percent combined) and chemicals (3.5 percent). The same life science categories also dominated the licenses associated with the disclosures filed during that period.[25]

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[22] Twenty-five percent of the disclosures were in the therapeutics/medical devices industry.

[23] A question about field of technology was reinstituted in the 2007 AUTM survey but drew a poor response rate.

[24] M. Feldman and J. Bercovitz. 2010. *Organizational Structure as a Determinant of Academic Patent and Licensing Behavior: A Survey of American Research Universities.* Report to the National Academy of Sciences Committee on Management of University Intellectual Property: Lessons from a Generation of Experience, Research, and Dialogue, pp. 4-5. Available at: http://www.nationalacademies.org/STEP.

[25] B. Wright, K. Drivas, and Z. Lei. 2009. *A Preliminary View of UC Data on Disclosures, Licensing, and Patenting.* Available at: http://www.nationalacademies.org/STEP.

These distributions should not be surprising. In part they reflect the relevance of university research to industrial R&D. In part they reflect the relative importance of patent protection in different industries. The pharmaceutical industry, whose development costs are substantial and whose products are long-lived yet easily copied, has relatively few patents per product, and places a much higher premium on patents than do the semiconductor and electronic hardware industries, whose products have relatively short life cycles and typically incorporate many patented inventions.

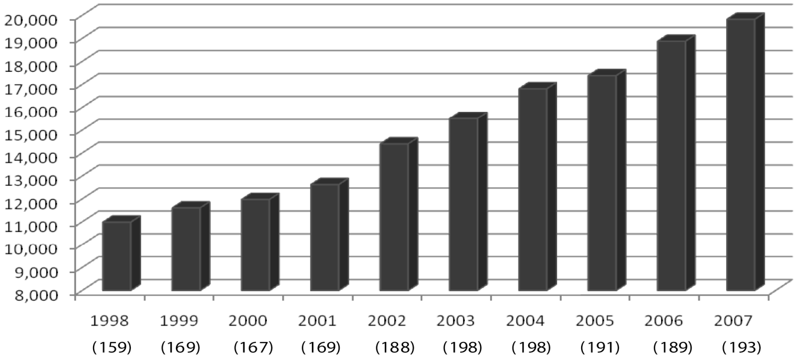

FIGURE 1 Number of disclosures reported as received in the year indicated by universities participating in the annual AUTM survey (number of respondents shown in parentheses). Source: AUTM U.S. Licensing Activity Survey: Fiscal Year 2007.

It is equally true that there is great variation in resources, effort, and outcomes across institutions. Fifty-nine respondents to the Feldman-Bercovitz survey provided annual technology transfer office expenditures for Fiscal Year 2007, ranging from $200,000 to $23 million (mean was $3 million, median $1.7 million). The number of technology transfer office employees ranged from 0 to 77 full-time equivalents (mean 6.4, median 4, 27 percent reported 2 employees or fewer); 2007 invention disclosures ranged from 4 to 1,411 (mean 130.5, median 83.5); patent applications ranged from 0 to 959 (mean 82); patent grants ranged from 0 to 331 (mean 26.3, median 18.5); licenses from zero to 231; and licensing income from $6,000 to $136 million.[26]

Licensing income can be impressive for some institutions, and this phenomenon has attracted attention and raised some controversy; some have expressed concern that the prospect of receiving income from licenses has shifted the emphasis of technology transfer activity away from careful consideration of broad dissemination and impacts on overall social welfare, an issue further explored in Chapter 2.

In Fiscal Year 2007, several universities generated significant licensing income.[27] According to the AUTM data, New York University (NYU) led the

[26] Feldman and Bercovitz, op. cit., pp. 7-8.

[27] Although such data are available on licensing, there are no comparable data on faculty income and how it is distributed.

university community with more than $794 million in revenues. However, the licensing income reported by NYU can be misleading. The reported NYU revenue, and similar very large revenue reports from universities in recent years, is almost wholly attributable to the sale of an entire royalty stream from one commercially successful drug, not a single year's annual royalties from a portfolio of inventions.[28] Most inventions that individually have yielded in excess of $1 million of income to universities are in the pharmaceutical area. In 2007, Northwestern University sold a portion of its worldwide royalty interest in Lyrica to Royalty Pharma. The arrangement provided Northwestern with an immediate payout of $700 million and the potential for more since it only sold a portion of its royalty interest.[29] The great majority of inventions generate modest revenues and many generate none; a handful of universities and a small fraction of all inventions are responsible for a large fraction of the revenues received. Trend data are also vulnerable to inconsistencies in survey participation. Some institutions have been reluctant to report single-year windfall events, and a few major research institutions do not participate in the AUTM survey at all.

Two decades of data collected from institutions by AUTM have shown that only 0.5 percent of license agreements generate more than $1 million in royalty income, suggesting that on average an institution would need at least 200 active license agreements to have one that generated more than $1 million. With about 10 licensing agreements concluded each year, an average academic institution could expect a return on that order once every 20 years.[30] In addition, it is worth noting that while only one out of every 200 license agreements is expected to generate more than $1 million in royalty income, all 200 license agreements involve associated staffing, operating, patenting, and licensing costs. To be complete, any discussion of the returns to universities from licensing would have to include the related costs of all agreements.

Further, the reported revenues must be considered in context, as some universities are high performers and others have received little if any licensing revenue. For example, in 2007, Stanford University ranked 10th among U.S. universities in licensing income, at $50 million from 986 active licenses. Stanford's research expenditures in 2007 were $700 million and its total budget for 2007-2008 was $3.8 billion, *excluding* the capital budget and the budget for hospital and clinical services. Thus, in 2007, licensing income was 1.3 percent of the budget. Similarly, MIT's licensing income was 2.8 percent of its budget and the University of Washington's licensing income was 2.3 percent of its budget.[31] The numbers are far more modest for a majority of institutions, many

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[28] It is unclear to the committee how the AUTM royalty income is reported, e.g., whether it includes the value of stock granted in exchange for a license and whether lump sum payments representing a future stream are distilled to account for payment only in the current year. Hence, data on royalty income should be interpreted with caution.

[29] Royalty monetization: High-profile deals generate excitement among TTOs *Technology Transfer Tactics*, November 2008, p. 2.

[30] R. Kordal and L.K. Guice. 2008. Assessing technology transfer performance. *Research Management Review* 16(1):45-56.

[31] Licensing revenues include the inventor's share (and the Bayh-Dole Act requires universities to share with the inventors a portion of licensing revenue), while research expenditures are borne by

of which are struggling to generate additional revenues through a variety of means. While the AUTM survey does not provide total university budgets, median and mean licensing income were equivalent to 0.9 and 4.1 percent, respectively, of research expenditures for reporting institutions. This reflects the skew of the distribution by a few high-income institutions (see Figure 2).

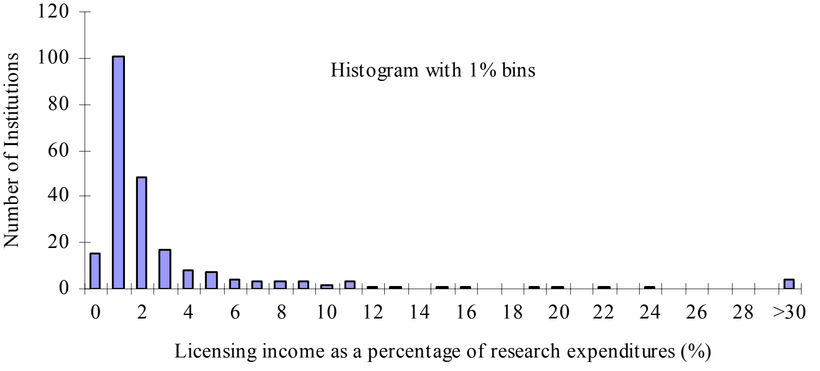

FIGURE 2 Histogram of licensing income as a percentage of university research expenditures, based on data from the AUTM U.S. Licensing Activity Survey: Fiscal Year 2007. While the mean value is 4.1 percent, the median is 0.9 percent. Three institutions were extreme outliers with values greater than 30 percent (65, 69, and 266 percent), illustrating the wide range of the data.

Moreover, most inventions—even those that have high social value when put into practice—do not generate significant licensing revenue. For example, in the past 40 years, Stanford's Office of Technology Licensing has received more than 8,000 invention disclosures. Half of these have resulted in patents, and one-half of those have been licensed. However, less than 1 percent of the Stanford disclosures have generated $1 million or more in cumulative royalties. Furthermore, many highly successful "Stanford startups" involved the participation of Stanford faculty, staff, and students, but not the licensing of any university intellectual property in order to launch the start-up. Examples include CISCO, Sun Microsystems, Rambus, Yahoo!, and VMWare.[32]

An analysis of the AUTM licensing activity surveys of 1995-2004 indicates that the annual income generated by licensing university inventions was 1.7 percent of total research expenditures in 1995 and 2.9 percent in 2004.[33] A 2006

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the universities. Hence, it is technically more accurate to compare net licensing revenues for the universities (after accounting for the share paid to inventors) to university research expenditures. However, data on net licensing revenues are not available.

[32] Information provided by Katherine Ku, Director, Office of Technology Licensing, Stanford University.

[33] P.M. Swamidass and V. Vulasa. 2009. Why University Inventions Rarely Produce Income? Bottlenecks in University Technology Transfer. *The Journal of Technology Transfer* 34(4):343-363.

analysis of academic licensing revenues from 1998 through 2002 found that net revenues were "on average, quite modest."[34]

Although licensing income is distributed in various ways (i.e., to the institution, department, center, laboratory, and individual), it does, in the aggregate, increase the pool of research funds available to the university, departments, and investigators. Some institutions or departments within institutions do have a meaningful fraction of their research supported by licensing income derived from patents,[35] but, within an institution, patenting and licensing activity may vary among departments. For example, Azoulay et al. reported that "patenting is concentrated among a relatively small number of departments and faculty members within medical schools. In particular, clinical faculty members were much less likely to be patent holders than their counterparts in basic science departments. In part, this difference reflects the fact that a substantial number of clinical faculty members are primarily engaged in clinical work."[36] Moreover, technology licensing income is highly skewed among institutions; a small number of technology transfer operations generate substantial net income, but for a very large number the costs incurred (e.g., salaries, legal fees) are a net drain on university resources.[37]

Although there are notable exceptions (e.g., discoveries instrumental to the development of new blockbuster drugs and royalty streams or other payments to universities), in the large scheme of things, licensing transactions have not been of high near-term economic value to either universities or businesses.[38] Surveys of university technology transfer offices suggest that, for the majority, the costs of patenting, licensing negotiations, and defense of IP exceed the revenues from licensing, buyouts, or legal settlements.[39] Moreover, one study has found that the returns to the institution from receiving equity in exchange for licensing IP are, on average, higher than those where the license provides only for cash royalties, although the data used in that study were largely from the 1990s, when the stock market and technology stocks in particular had positive performance.[40] Universities are likely to seek equity as they gain experience in licensing, but

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[34] H. Bulut and G. Moschini. 2006. U.S. Universities' Net Returns from Patenting and Licensing: A Quantile Regression Analysis. Center for Agricultural and Rural Development at Iowa State University Working Paper 06-WP 432. Available at: www.card.iastate.edu/publications/DBS/PDFFiles/06wp432.pdf.

[35] B.N. Sampat. 2006. Patenting and U.S. academic research in the 20th century: The world before and after Bayh–Dole. *Research Policy* 35(6):772-789.

[36] P. Azoulay, R. Michigan, and B.N. Sampat. 2007. The anatomy of medical school patenting. *New England Journal of Medicine* 15:357(20):2049-2056.

[37] J.G. Thursby and M.C. Thursby. 2007. University licensing. *Oxford Review of Economic Policy* 23(4):620-639.

[38] See, for example, *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected.* 2001. Available at: http://www.nih.gov/news/070101wyden.htm #execsum.

[39] Thursby and Thursby, op. cit.

[40] F.T. Rothermael, S.D. Agung, and L. Jiang. 2007. University entrepreneurship: A taxonomy of the literature. *Industrial and Corporate Change* 16:691-791.

the pattern reverses when an institution has executed a large number of licenses; in those cases, the frequency of licenses that involve taking equity declines.[41]

In the AUTM survey in 2007, 191 respondents reported the formation of 555 new start-up companies based on university technology. During the previous year 554 companies were formed by 183 reporting institutions. Some institutions have focused their technology transfer efforts more on incubating start-ups than on patenting and licensing. Licensing by universities to newly formed companies is a growing phenomenon, but one for which few data are available except for the number of companies started. Data are not collected by AUTM, or a similar group, on how arrangements with universities are structured, how long university involvement lasts, or how much money universities make from start-ups.

Discussions about technology transfer have been skewed by the abundance of data regarding licensing and lack of reliable data about other forms of technology transfer. Despite the evidence that patenting and licensing are important modes of commercializing the results of academic scientific research,[42] there has been growing concern about relying solely on invention disclosures, patent applications, patents granted, and licenses as measures of the commercialization of university research, which "could lead to a systematic underestimation of commercialization and innovation emanating from university research."[43] Other modes of technology transfer are far less easily quantified, except in laborious studies such as that sponsored by the Kauffman Foundation of MIT alumni.[44] Moreover, some especially effective mechanisms of technology transfer—for example, the flow of students and trainees into industry and faculty consulting agreements—are not reported at all. Finally, the different mechanisms of technology transfer (publications, conferences/meetings, informal interactions, and consulting) tend to complement one another. Hence, if one means of technology transfer resulted in, for example, restrictions on publications or the public presentation of research results at meetings, the restrictions could adversely affect the transfer of results via the other relatively more important channels.[45]

Free exchange of information and presentation of knowledge through conferences and publications are critical to innovation; in particular cases, patenting and licensing can also play an important role. According to one study, faculty consulting, student recruitment, publications, and collaborative research

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[41] See M.J. Bray and J.N. Lee. 2000. University revenues from technology transfer: Licensing fees vs. equity positions. *Journal of Business Venturing* 15(5-6):385-392; M. Feldman, I. Feller, J. Bercovitz, and R. Burton. 2002. Equity and the technology transfer strategies of American research universities. *Management Science* 48(1):105-121.

[42] S. Shane. 2004. Encouraging university entrepreneurship? The effect of the Bayh-Dole Act on university patenting in the United States. *Journal of Business Venturing* 19(1):127-151.

[43] D.B. Audretsch, T. Aldridge, and A. Oettl. 2006. The Knowledge Filter and Economic Growth: The Role of Scientist Entrepreneurship. Prepared for the Ewing Marion Kauffman Foundation. March 29, 2006. p.7.

[44] E.B. Roberts and C.E. Eesley. 2009. Entrepreneurial Impact: The Role of MIT. Available at: http://entrepreneurship.mit.edu/sites/default/files/files/Entrepreneurial_Impact_The_Role_of_MIT.pdf.

[45] Cohen et al. 2002

rank higher than patenting and licensing activity as significant means of technology transfer from the perspective of MIT patent holders.[46] Despite faculty members generally being required to disclose to their institutions[47] inventions made using university resources—including grant funding—studies of technology transfer offices observe limited effectiveness in exploiting faculty inventions with commercial potential.[48] Reasons for this apparent ineffectiveness might include the fact that many inventions are very early stage, failure by faculty inventors or industry to perceive commercial potential, preference by inventors for results to remain open, faculty distaste for restrictions that might result from commercialization efforts (e.g., publication delays or failure to publish), lack of faculty interest in commercialization activity, or desire by faculty to pursue commercialization independent of the university. Another explanation is that the disclosed faculty inventions may not actually have much commercial potential.[49]

University efforts to commercialize patent-protected technology occur against a backdrop of an innovation system that more than ever involves collaboration among firms of all sizes as well as between industry and academia via various arrangements, many of them informal. A study of leading U.S. innovations over the past few decades found that the sources of these innovations have changed in two important ways.[50] First, large firms acting alone produce a smaller share of successful, award-winning innovations, while a much larger share comes from spin-offs from universities and federal laboratories. Second, the number of innovations arising from federally funded research has increased dramatically. The authors concluded that the U.S. innovation system has become much more collaborative and attribute this phenomenon to

- growing global competition, which is shrinking technology life cycles;
- the complexity of emerging technologies, which is beyond the internal R&D capabilities of even the largest firms;

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[46] Agrawal and Henderson, op. cit.

[47] As part of Bayh-Dole, universities require faculty to notify the university of inventions with potential commercial applications. This obligation was enforced by the courts in *Fenn v. Yale Univ., 2006 U.S. App LEXIS 12479,* where the U.S. Court of Appeals for the Second Circuit affirmed a district court order determining that Dr. John B. Fenn, a Nobel Laureate, had breached his contract with Yale University for failure to disclose in a timely manner.

[48] P.M. Swamidass and V. Vulasa. 2009. Why university inventions rarely produce income? Bottlenecks in university technology transfer. *The Journal of Technology Transfer* 34(4):343-363.

[49] J.G Thursby and M.C. Thursby. 2009. Chapter 6 Knowledge Creation and Diffusion of Public Science with Intellectual Property Rights, in Professor Hamid Beladi, Professor E. Kwan Choi (ed.) *Intellectual Property, Growth and Trade (Frontiers of Economics and Globalization, Volume 2),* Emerald Group Publishing Limited. p.199-232.

[50] F. Block and M.R. Keller. 2008. Where Do Innovations Come From? Transformations in the U.S. National Innovation System, 1970-2006. The Information Technology & Innovation Foundation. Available at: http://www.itif.org/files/Where_do_innovations_come_from.pdf. The study examined winners of the *R&D Magazine* "R&D 100" awards.

- the expansion of R&D capability in more industries, which is causing R&D investment to spread vertically in high-technology supply chains; and
- the priorities of other countries to improve their R&D capacity and competitiveness.

In addition, although the U.S. innovation system today is much more collaborative than it was several decades ago and the federal government is playing a much more supportive and important role in innovation, total industry spending is now twice that of the federal government.

Chapter 2 examines issues that have dominated discussion of the influence of IP-based university technology transfers on university research norms and quality since the current system of institutional ownership and centrally administered licensing became the norm. Chapter 3 briefly addresses university implementation of the Bayh-Dole Act and federal oversight. Chapter 4 presents the committee's findings and recommendations.

2

Influence of Technology Transfer on University Research Norms and Practices

INTRODUCTION

Two issues have dominated discussion of intellectual property (IP)-based university technology transfers since the current system was put in place at most universities. The first centers on whether efforts to commercialize technology have undermined traditional academic norms, and the second focuses on the effectiveness of universities in achieving the goals of the Bayh-Dole Act. This chapter addresses the first set of concerns, that is, whether the technology transfer system is having adverse effects on publicly funded science by inhibiting open communication of research results and sharing of research inputs and data, distorting research priorities, and detracting from faculty hiring and promotion based on scholarly excellence. Beyond concerns about the effect of commercial motives on the behavior of researchers and institutions, some observers have been apprehensive that patents on elements of research may block, limit, or delay follow-on investigation because of the difficulty and cost of securing rights to use those proprietary elements.

In addressing these hypotheses, the committee drew upon a variety of sources. The subject of university-owned IP has attracted a number of scholars in economics, sociology, and other disciplines who have produced a fairly extensive body of empirical research. Much of that research concerns the impact of IP on the university research enterprise.

The committee also probed the alleged adverse effects of promoting technology commercialization with presenters in pubic sessions, including the November 2008 workshop held in Washington. Further, the committee carefully considered the deliberations that led to the informal guidance issued in 2007 by members of the academic research community in response to concerns that overly aggressive proprietary behavior on the part of universities could be having adverse effects on the norms and missions of academic research (see Box 2A).

Box 2A
Nine Points to Consider in Licensing University Technology

1. Universities should reserve the right to practice licensed inventions and to allow other nonprofit and governmental organizations to do so.

2. Exclusive licenses should be structured in a manner that encourages technology development and use.

3. Strive to minimize the licensing of "future improvements."

4. Universities should anticipate and help to manage technology transfer-related conflicts of interest.

5. Ensure broad access to research tools.

6. Enforcement action should be carefully considered.

7. Be mindful of export regulations.

8. Be mindful of the implications of working with patent aggregators.

9. Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world.

Endorsing "consideration" of the Nine Points, AUTM urged its individual members to seek their institution's endorsement of the document by whatever internal decision-making processes are used. AUTM continues to seek endorsements of the document. As of January 2010, only 74 of AUTM's member institutions have signed on.

CONCERNS ABOUT UNINTENDED EFFECTS ON ACADEMIC NORMS

Regardless of whether the real contributions of patenting and licensing activity to commercialization of federally funded inventions can actually be isolated and measured, some observers have expressed concern about whether the drive to patent, license, and commercialize research discoveries is antithetical to the traditional norms and functions of the university, namely, to expose students to the latest advances in knowledge, to conduct systematic inquiries, and to widely communicate research findings.[51] Is it possible that the

[51] P. Dasgupta and P.A. David. 1994. Toward a new economics of science. *Research Policy* 23(5):487-521; see R.S. Eisenberg. 2003. Patent swords and shields. *Science* 299:1018-1019; D.

time and resources expended on, or potential conflicts of interest created by, seeking commercial applications divert faculty from their core mission of conducting curiosity-driven "fundamental" research? Does the potential of financial sponsorship and compensation influence research results or decisions about which results are made public and in what time frame? Does overemphasis on exclusive licensing result in higher costs or diminished access to products for consumers (a concern that is especially pertinent to the fields of drug development and clinical diagnostics) or to research materials for other academic scientists? Are institutions misusing or misinterpreting the Bayh-Dole Act in an attempt to increase revenues and protect their own investments in infrastructure and personnel?

Some critics have remarked on the privatization of the scientific commons associated with aggressive university commercialization efforts. These concerns center on whether the norm of open science that has traditionally dominated academic research would be threatened by restrictions on or delays of publication and limits on access to discoveries, data, instruments, tools, and other research inputs. Some assert "Bayh-Dole contributed to the creation of an 'anti-commons' by establishing incentives for universities to develop independent technology transfer programs and to manage IP in a highly individualized and even competitive framework."[52]

Researchers have tended to examine each of these propositions independently. A few have acknowledged that one of the difficulties is disentangling the effects of the acquisition and exercise of IP rights from other trends that may be influencing faculty and institutional behavior in the same direction—in particular, the intensification of reputational competition among research scientists. Cohen and Walsh have written, for example, that even before Bayh-Dole, "there was an earlier concern over the extent to which the drive for recognition among scientists and competition for priority and associated rewards also limited contributions to the scientific commons."[53] In their survey of biomedical researchers, they found that "excludability" can be a real concern with regards to materials, but patent protection per se is rarely used as a means of exclusion. Indeed, patenting requires disclosures, even if delayed.

Mowery, R.R. Nelson, B.N. Sampat, and A.A. Ziedonis. 2004. *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act*. Palo Alto, CA: Stanford University Press; R.R. Nelson. 2004. The market economy and the scientific commons. *Research Policy* 33:455-471; D. Bok. 2003. Universities in the Marketplace: The Commercialization of Higher Education. Princeton NJ: Princeton University Press; J. Washburn. 2005. University, Inc.: The Corporate Corruption of Higher Education. New York: Basic Books; E. Press and J. Washburn. 2000. The Kept University. *The Atlantic Monthly* 285(3):39-54.

[52] S. Boettiger and A.B. Bennett. 2006. Bayh-Dole: If we knew then what we know now. *Nature Biotechnology* 24(3):320-323.

[53] W.M. Cohen and J.P. Walsh. 2008. Real impediments to academic biomedical research. Innovation policy and the economy. *National Bureau of Economic Research* 8:1-30. P. 1.

CONCERNS ABOUT CONFLICTS OF INTEREST

Bayh-Dole's encouragement of university-industry partnerships and the significant increase in federal funding for academic research have left many concerned about the potential for conflicts of interest. Although the federal government has regulated financial conflicts of interest in federally sponsored research since 1995, reports in the press of high-profile incidents of researchers tied to corporate entities following improper procedures with human research subjects or reporting inaccurate results have caused major university groups to reevaluate academic conflict of interest policies and practices.[54] In addition, numerous journals have agreed to adopt a new standard conflict of interest disclosure form drafted by the International Committee of Medical Journal Editors that probes deeper into the financial and nonfinancial interests of published authors.[55] Furthermore, NIH has been amending its regulations on the "Responsibility of Applicants for Promoting Objectivity in Research." Noting that since the promulgation of regulations in 1995, biomedical and behavioral research and the resulting interactions among government, universities, and industry have become increasingly complex, the proposed amendments seek to "expand and add transparency to investigator disclosure of significant financial interests, [and] enhance regulatory compliance and effective institutional oversight and management of investigators' financial conflicts of interests."[56]

There is an inherent tension in the post Bayh-Dole environment, but by no means solely attributable to it, where universities are encouraged to efficiently transfer their knowledge to the private sector for the development of products that will benefit the public. Interactions between researchers and industry are critically important as the give and take of ideas and know-how creates a more fruitful and promising environment for translating the results of research into innovative products. Yet, this closeness also brings with it the risk that research, and the integrity of individual researchers and their institutions, may be compromised.

Conflicts of interest tend to arise under two broad categories: (1) those applicable to individual investigators who enter into agreements in which

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[54] See Association of American Universities (AAU). 2001. Report on Individual and Institutional Financial Conflict of Interest; Association of American Medical Colleges (AAMC). 2001. Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research. Available at: https://www.aamc.org/download/75302/data/firstreport.pdf; AAMC. 2002. Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research. Available at: https://www.aamc.org/download/75300/data/2002coireport.pdf; AAMC. 2008. Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research. Available at: https://www.aamc.org/download/157386/data/aamc-aau_coi_report.pdf; and IOM. 2009. Conflict of Interest in Medical Research, Education, and Practice. Washington, D.C.: National Academies Press.

[55] Some of the journals adopting the new disclosure form include *The Lancet*, *JAMA*, *New England Journal of Medicine*, and *The British Medical Journal*.

[56] "Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors: Proposed Rules," 75 Federal Register 98 (21 May 2010), pp.28697-28712.

financial considerations may compromise or give the appearance of compromising the researcher's judgment and (2) those applicable to institutions, when any of an institution's senior officials, trustees, or units has an external relationship or financial interest in a company that itself has a financial interest in an investigator's project.[57]

In most cases, there is a recognition and appreciation of the benefits that come from university-industry collaboration and a call for better management, disclosure, and transparency and, in some rare cases, the prohibition of activities that might undermine the integrity of an institution. The management of these relationships must be in line with the goals and values of the institution.

CONCERN ABOUT PUBLICATION DELAYS AND INCREASED SECRECY

A series of studies in the 1990s by Blumenthal and colleagues at Harvard Medical School called attention to an apparently rising incidence of delays in the publication of some biomedical research results.[58] The authors suggested that the delays were associated with commercial motives—to begin to capitalize on research discoveries or at least initiate the process of obtaining IP protection before disclosing the results to potential competitors. Likewise, an industry survey published in 2007 by Thursby and Thursby found that half of the firms sponsoring research at universities sought to include publication delay clauses in 90 percent of their contracts.[59] The average delay was four months, but some firms required as much as a year's delay.

In 2008, Huang and Murray examined 4,270 human gene patents and found that patent strategies in the area of human genetics resulted in modest but measurable decreases in the amount of public (published) genetic knowledge.[60] Limitations on publication of knowledge increased with broader patent scope, private-sector ownership, complexity of the patent landscape, and the gene's commercial potential.

In more recent years, concern about publication delays appears to have receded, in part because universities have standardized some of the terms under which they receive private research funding, accepting modest but not inordinate delays. The imperative for research scientists to publish their results serves as a strong counterweight to delays in publication; and certain features of the U.S. patent system—in particular, the ability to submit provisional (streamlined) patent applications to establish priority of invention in advance of

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[57] AAU, op. cit.

[58] D. Blumenthal, E.G. Campbell, M.S. Anderson, N. Causino, and K.S. Louis. 1997. Withholding of research results in academic life science: evidence from a national survey of faculty. *JAMA* 277:1224-1228; see also E.G. Campbell, B.R. Clarridge, M. Gokhale, et al. 2002. Data-withholding in academic genetics: Evidence from a national survey. *JAMA*. 287:473–481.

[59] J. Thursby and M. Thursby. 2007. University licensing. *Oxford Review of Economic Policy* 23(4):620-639.

[60] K.G. Huang and F.E. Murray. 2009. Does patent strategy shape the long-run supply of public knowledge? Evidence from human genetics. *Academy of Management Journal* 52(6): 1193-1221.

filing formal patent applications and to make inventions public within a year prior to filing a formal application without endangering patentability (known as the "grace period")—reduce the incentive to postpone disclosure.

However, these same features also contain potential pitfalls for universities. The lack of a one-year grace period in most other countries' patent systems virtually eliminates the benefit of the U.S. grace period for inventors whose discoveries will require patent protection abroad to fulfill their commercial potential.[61] Moreover, university technology transfer offices rely heavily on provisional applications for U.S. filings. In 2004, AUTM reported that 75 percent of the patent applications filed by universities and other nonprofit institutions were provisional applications,[62] but they accounted for only 30 percent of all patent applications received by the U.S. Patent and Trademark Office (USPTO) that year.[63] However, the protection provided by provisional applications can be illusory. Claims filed in regular non-provisional applications that rely on priority from provisional applications to overcome prior art can be rejected during prosecution or invalidated in later patent litigation if the provisional application is not drafted with sufficiently specific information to support those later claims.[64] Drafting a more detailed disclosure in a provisional application increases time and expense and may not be the norm for technology transfer offices with numerous early-stage invention disclosures and a limited prosecution budget.

Of course, there may be more subtle "secrecy" effects of the IP system and commercial motives, as is sometimes alleged. Some studies suggest that IP considerations have a far smaller effect on behavior than commercial motives more generally or scientific competition.[65] And such behavior could include withholding enabling information from published research papers or from students and even colleagues in routine communication. These effects, however, have not been studied systematically and would be exceedingly hard to investigate. No doubt they occur, but on what scale and with what motives is unknown. Again, peer reputational competition may induce such behavior as much as or more than IP considerations.

CONCERNS ABOUT DIVERSION AND DISTORTION OF RESEARCH EFFORT

Two hypotheses have been advanced to suggest that faculty involvement in patenting, technology transfer, and commercial exploitation of research results has adverse effects on academic research and teaching. The first is simply that

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[61] M.A. Bagley. 2006. Academic discourse and proprietary rights: Putting patents in their proper place. 47 B.C.L. REV. 217, 245.

[62] AUTM U.S. Licensing Activity Survey, FY2007 Survey Summary. op. cit.

[63] U.S. Patent and Trademark Office. 2004. Performance and Accountability Report for Fiscal Year 2004, at 116 tbl.1 (2004). Available at: http://www.uspto.gov/about/stratplan/ar/2004/2004annualreport.pdf.

[64] M. Bagley, op. cit. pp. 248-250.

[65] J. Walsh, W. Cohen, and C. Cho. 2007. Where excludability matters: Material versus intellectual property in academic biomedical research. *Research Policy* 36:1184-1203.

the former set of activities takes time and effort away from the latter activities. The second hypothesis is that preoccupation with commercial development shifts research effort away from fundamental, understanding-driven scientific inquiry toward work on applied research problems with practical applications. Some critics have charged that patenting and licensing activity has put "the profit motive directly into the heart of academic life," driving faculty away from traditional, socially more beneficial pursuits.[66]

Empirical research on this issue has measured the relationship of commercial activity to publication counts, citation counts as well as citation patterns, industry- and federally-sponsored research, and citation-based measures of the fraction of faculty research effort that can be classified as basic research. The majority of the studies have not found evidence of negative effects of commercially related faculty activity. There are several noteworthy results. First, only a minority of faculty are engaged in even the earliest stage of commercial activity, as indicated by disclosing inventions to their universities.[67] Second, several studies have found a strong *positive* relationship between various measures of research output and engagement in invention disclosure activity and patenting.[68] The only studies to find negative effects on faculty output suggest that this occurs for the few faculty members who repeatedly engage in commercial activity.[69]

In a theoretical study that examined the question of whether commercial activity diverts faculty from their traditional focus on basic research, Thursby, Thursby, and Gupta-Mukherjee[70] suggested a likely outcome is that faculty increase *both* basic and applied efforts, though the latter effort may increase relative to the former. These authors also provided empirical evidence in support of their theoretical model.[71]

In short, studies using different methodologies have not found an appreciable change in the orientation of research, even on the part of faculty

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[66] J. Washburn. 2008. *University Inc.: The Corporate Corruption of Higher Education*. New York: Basic Books.

[67] J. Thursby and M. Thursby. 2010. University licensing: Harnessing or tarnishing faculty research? *Innovation Policy and the Economy* 10(1):159-189.

[68] P. Azoulay, W. Ding, and T. Stuart. 2009. The impact of academic patenting on the rate, quality, and direction of (public) research output. *Journal of Industrial Economics* (57)4: 637-676; P. Azoulay, W. Ding, and T. Stuart. 2007. The determinants of faculty patenting behavior: Demographics or opportunities? *Journal of Economic Behavior & Organization* 63(4):599-623; Thursby and Thursby, 2009, op. cit.; J. Thursby and M. Thursby. 2010. Faculty participation in licensing: Implications for research. Res. Policy. doi:10.101b/;respol.2010.09.014; F. Murray. 2002. Innovation as overlapping scientific and technological trajectories: Exploring tissue engineering. *Research Policy* 31:1389-1403; K. Fabrizio and A. DiMinin. 2008. Commercializing the laboratory: The relationship between faculty patenting and the open science environment. *Research Policy* 37:914-931; P. Stephan, S. Gurmu, A. Sumell, and G. Black. 2007. Who's patenting in universities? *The Economics of Innovation and New Technology* 16:71-99; A. Agrawal and R. Henderson. 2002. Putting patents in context: Exploring knowledge transfer from MIT. *Management Science* 48(1):44-60.

[69] Thursby and Thursby, 2008, op.cit.; Fabrizio and DiMinin, op. cit.

[70] M. Thursby, J. Thursby, and S. Gupta-Mukherjee. 2007. Are there real effects of licensing on academic research? A life cycle view. *International Journal of Industrial Organization* 63(4):577-598.

[71] Thursby, Thursby, and Gupta-Mukherjee. 2008, op. cit.

members already active in commercialization efforts. But even if they had found such a change, a negative inference would presume that the preexisting balance between curiosity-driven research and research with potential commercial applications was optimal—an arguable premise.

CONCERNS ABOUT CHANGE IN FACULTY HIRING AND ADVANCEMENT CRITERIA

A third concern is that faculty involvement in commercial activity, including invention disclosures and patent filings, has crept into hiring, promotion, and tenure decisions. The evidence remains anecdotal, as no systematic surveys have been conducted. However, one group of researchers has searched the promotion and tenure guidelines of universities with highly ranked science and engineering departments for evidence of the role of patents and commercial activities in tenure and promotion decisions. They found approximately 15 institutions that include such criteria, albeit usually secondary to publications, and concluded it is likely that many other institutions also consider such activities on an informal basis.[72]

No doubt this has occurred in some fields and at some institutions, and has even been formalized in science and engineering departments at a few institutions; but nowhere has it been suggested that such considerations have supplanted rather than supplemented the long-standing criteria of the productivity and excellence of scholarly output. The empirical evidence cited earlier of a close association between research output and commercial involvement suggests that this would be an appropriate concern only if the traditional criteria for academic career advancement were being displaced.

CONCERNS ABOUT INTERFERENCE WITH FOLLOW-ON RESEARCH AND APPLICATIONS

The "anti-commons" hypothesis first articulated by Heller and Eisenberg[73] suggests that the proliferation of patents held by diverse stakeholders on upstream elements of biomedical research in particular could handicap or prevent follow-on research and applications because of the difficulty or cost of obtaining rights to use those patented inputs. On the one hand, academic researchers lack the experience and resources to conduct patent searches and negotiate licenses. On the other hand, previous studies have shown that most scientists do not check for IP when pursuing research leads, and they are not likely to be sued for infringement, although they may be warned to cease using

[72] H Sauermann, W Cohen, and P Stephan. February 2010. Complementing merton: The motives, incentives, and commercial activities of academic scientists and engineers. Unpublished Manuscript.

[73] M. Heller and R. Eisenberg. 1998. Can patents deter innovation? The anticommons in biomedical research. *Science* 280(5364):698-701.

unlicensed inventions.[74] Thus, the effects of the anti-commons might be somewhat attenuated in the university (i.e., more basic science) environment.[75]

Researchers have approached this topic using survey methods and bibliometric data. A 2004-2005 survey of approximately 2,000 randomly selected scientists in leading-edge biomedical research fields was conducted by Walsh, Cho, and Cohen and supported by funding from a previous National Research Council study committee. Their sample of investigators, analytical methods, and findings are reported in detail elsewhere,[76] and only the key points are summarized here.

Walsh and colleagues found a high level of commercial involvement on the part of biomedical researchers in their sample, a low level of awareness whether any of their research inputs were patented by others (and even less inclination to inquire), and thus an extremely low incidence of cases in which a lack of access to relevant technology protected by IP caused a line of research to be delayed significantly or redirected. No one reported an instance in which she or he had abandoned a line of work for that reason. Similar findings have been reported for biomedical scientists in Germany,[77] Australia,[78] and Japan.[79] The only evidence for a "modest" anti-commons effect, also in the biomedical research field, is in work by Murray and Stern,[80] who took a different research approach. They examined what happens to the citations to a scientific article before and after a patent issues on its subject matter and found that articles associated with patents are more highly cited than articles not associated with patents but that the citations are about 10 to 20 percent fewer than expected after the patent is awarded. This suggests that there may be some post-patent avoidance of certain

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[74] National Research Council. 2006. *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health.* Washington, D.C.: National Academies Press.

[75] R.S. Eisenberg. 2008. Noncompliance, nonenforcement, nonproblem? Rethinking the anticommons in biomedical research. *Houston Law Review* 45(4):1059-1099.

[76] J. Walsh, C. Cho, and W. Cohen. 2005. *Patents, Material Transfers, and Access to Research Inputs in Biomedical Research*. Available at http://www2.druid.dk/conferences/viewpaper.php?id=776&cf=8.

Also J. Walsh et al. 2005. View from the bench: Patents, research, and material transfers. *Science.* 309(5743) and J. Walsh et al. 2007. Where excludability matters: Material versus intellectual property in academic biomedical research. *Research Policy.* 36:1184-1203. The initial results are summarized in National Research Council. 2006. *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health.* Washington, D.C.: National Academies Press, pp. 100-132.

[77] J. Strauss. 2002. Genetic Inventions and Patents – A German Empirical Study. Presentation to the BMBF & OECD Workshop entitled "Genetic Inventions, Intellectual Property Rights and Licensing Practices." Berlin, January 24-25, 2002. Available at: http://www.oecd.org/dataoecd/36/22/1817995.pdf.

[78] D. Nicol and J. Nielsen. 2003. *Patents and medical biotechnology: An empirical analysis of issues facing the Australian industry.* Centre for Law and Genetics Occasional Paper No. 6.

[79] S. Nagaoka. 2006. *An empirical analysis of patenting and licensing practices of research tools from three perspectives.* Paper presented May 18, 2006 to the OECD Conference on Research Use of Patented Inventions, Madrid.

[80] F. Murray and S. Stern. 2007. Do formal intellectual property rights hinder the free flow of scientific knowledge? An empirical test of the anti-commons hypothesis. *Journal of Economic Behavior & Organization*

63(4):648-687.

research directions and possibly a small decline in "knowledge accumulation," although the authors refrain from drawing causal inferences. In any case, Murray and Stein conceded "though a key tenet of the anti-commons theory is that the effects are particularly salient for research tool patents, there is no evidence that the impact of patent grant is significant for theses types of inventions."[81]

There is, however, reason to be cautious in predicting the future. Not only is the patent landscape becoming more complex in many domains of research, but also the absence of evidence for a substantial patent thicket or a patent blocking problem is clearly linked to the general lack of awareness and concern among investigators about existing IP. That could change if patent holders, aware that universities are not shielded from liability by a research exception, take more active steps to assert their patents against them. More vigorous assertion of patents is not likely to result in more patent suits against universities—indeed, established companies may be reluctant to pursue litigation against research universities—but it could involve more demands by non-practicing patent holders for licensing fees, grant-back rights, and other terms burdensome to research. More assertions would, of course, prompt more defensive behavior on the part of institutions that are traditionally risk averse.

University efforts to raise researchers' awareness or even to try to regulate their behavior could be both burdensome on research and largely ineffective because of researchers' autonomy and their ignorance or at best uncertainty about what IP applies in what circumstances. It is much easier for corporations to exercise due diligence in the context of research that is centrally directed than it is for universities, where research is highly decentralized and decision making is fragmented.

CONCERNS ABOUT ACCESS TO AND SHARING OF RESEARCH INPUTS

In contrast to the lack of strong evidence that university management of IP rights interferes with academic research, the Walsh et al. survey did turn up evidence of a more immediate and potentially remediable burden on research, private as well as public. This burden stems from difficulties in accessing proprietary research materials, whether patented or unpatented, difficulties that seem likely to be related to scientific as well as commercial competition. Concern over the flow of research materials—which may be critical inputs for the success of a research project—is not new, nor has it gone unaddressed. The research tool guidelines developed and published by the National Institutes of Health (NIH)[82] address the process of materials exchanges, and NIH also has developed model Material Transfer Agreements (MTAs).[83]

[81] Ibid., p. 680.

[82] NIH. December 1999. *NIH Principles and Guidelines for Sharing of Biomedical Resources*—Final. Available at: http://www.ott.nih.gov/policy/rt_guide_final.html.

[83] See http://tto.ninds.nih.gov/Mta.asp

The Walsh et al. survey found that impediments to the exchange of biomedical research materials remain prevalent and may be increasing. For the period 1997-1999, Campbell and colleagues[84] reported on the basis of a previous survey that academic genomics researchers denied 10 percent of material transfer requests. In the Walsh et al. study, the comparable number for 2003-2004 was 18 percent. About half of academic respondents had had at least one request denied over a two-year period. Rates of refusal are higher for university-to-industry, industry-to-university, and industry-to-industry requests than for university-to-university requests. For academics, the most common reason given for denying or ignoring a request was simply the effort involved or the need to protect publications. For industry respondents the key reported reasons were the need to protect commercial value and the recipient's unwillingness to accept restrictive terms. Whatever the reluctant supplier's motive, the consequences of being denied a tangible research input can be more severe than the inability to license another's IP, since in the latter case work may proceed, albeit at some risk.

Walsh et al. found that fewer than one-half of material requests entailed an MTA between supplying and receiving institutions, and the process of negotiating an MTA did not often lead to a breakdown. However, MTAs often occasion delays, with 11 percent of the negotiated cases taking over one month to conclude. A more recent survey of agricultural biologists suggested that the problem is more severe in at least some subfields. According to Lei, Juneja, and Wright, their sample of agricultural scientists at four land-grant institutions "believe that institutionally mandated MTAs put sand in the wheels of a lively system of intra-disciplinary exchanges of research tools."[85] According to Feldman and Bercovitz, MTAs are no more popular with technology transfer personnel, who reported spending about 10 percent of their time negotiating them. "They are considered time consuming while offering little upside revenue potential."[86] Several leading research universities have recently made an effort to minimize the use of MTAs and, where deemed necessary, use only Simple Letter Agreements (SLAs).[87]

An area where patents seem to be having an inhibitory effect on research and related clinical practice involves gene-based diagnostic tests. The first concern is that a patent owner's refusal to make a patented gene available for licensing on reasonable terms will inhibit follow-on research on the incidence of mutations in the gene as well as limit patient access to testing at a reasonable cost and the possibility of obtaining a second opinion on the result. Exclusive licenses also limit the opportunity for the development of improvements in the test and verification of the result. An anti-commons effect can also be anticipated in the future as clinicians increasingly develop tests for multigenic traits. This set of issues is the focus of a March 2010 report by the Advisory

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[84] E.G. Campbell et al. 2002. Data withholding in academic genetics. *JAMA* 287(4):473-480.

[85] Z..Lei, R. Juneja, and B.D. Wright. 2009. Patents versus patenting: implications of intellectual property protection for biological research. *Nature Biotechnology* 17:(1)36-40.

[86] Feldman and Bercovitz, op. cit., p. 5.

[87] http://www.stanford.edu/group/ICO/researcher/documents/MTA9-18-09_000.pdf.

Committee to the Secretary of Health and Human Services on Genetics, Health, and Society.[88]

Mildred Cho and colleagues[89] conducted telephone surveys of U.S. clinical laboratory directors who were members of the Association for Molecular Pathology (corporate, university, private hospital, federal government, and other nonprofit laboratories). They analyzed the responses of 122 individuals, a large majority of whom had licenses to perform genetic tests for a wide variety of conditions, including hereditary breast and ovarian cancer (*BRCA1/2*), Canavan disease, hereditary hemochromatosis, and Fragile X syndrome, among others.

The results suggest that holders of gene-based diagnostic patents (many of them are companies) are active in asserting their IP rights. Sixty-five percent of respondents reported having been contacted by a patent or license holder regarding their potential infringement in performing a test. Twenty laboratories had received notification for one test, 51 had received notifications for up to three tests, and 26 for four or more tests. These enforcement efforts focused on 12 tests that, as a result, one or more laboratories had ceased to perform. In all, 30 laboratories responded that they had ceased administering at least one test. This number included almost all of the corporate laboratories and about one-quarter of university laboratories. Asked to evaluate their experience, respondents believed that patents had had a negative effect on all aspects of clinical testing and reported a decline in information sharing among laboratories. Inclination to undertake test development, too, was adversely affected, according to respondents. The viability of gene patents has been called into question as a result of a Federal District Court's decision in *Association for Molecular Pathology, et al., v. United States Patent and Trademark Office, et al.*, invalidating gene claims as outside the scope of patentable subject matter.[90] It is not known whether the decision will be upheld on appeal. In the meantime, the concerns described remain.

CONCLUSIONS

This chapter summarized a substantial body of research suggesting that the expansion of faculty entrepreneurial activity and institutional technology transfer activity at U.S. research universities has not seriously undermined the core missions of knowledge generation and dissemination. Despite repeated continuing expressions of concern, research has found little evidence that

[88] United States Dept. of Health and Human Services. Secretary's Advisory Committee on Genetics, Health, and Society. Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests. April 2010. Available at: http://oba.od.nih.gov/oba/SACGHS/SACGHS%20 Patents%20Report%20Approved%202-5-20010.pdf.

[89] M.K. Cho et al. 2003. Effects of patents and licenses on the provision of clinical genetic testing services. *Journal of Molecular Diagnostics* 5(1):3-8.

[90] *Association for Molecular Pathology, et al., v. United States Patent and Trademark Office, et al.* 1:09-cv-04515-RWS. United States District Court, Southern District of New York. March 29, 2010.

- commercially oriented faculty are less likely to publish in the open literature (on the contrary, they are more prolific producers of scientific articles);
- commercial motives have shifted effort away from fundamental research questions and toward more applied research questions;
- institutional or sponsor concerns to protect IP rights have resulted in more than modest delays in publication of research results; and
- commercial involvement and IP activity have replaced scholarly output and its quality as the principal criteria for academic employment and advancement.

Several studies address whether university IP has limited the incentive or ability of investigators to build on prior research because of delayed or denied access or excessive fees or coordination costs. A few studies found a statistically significant decline in citations to published knowledge after the grant of patents on that knowledge. But surveys of investigators have found the potential of an “anti-commons” effect to be mitigated by a variety of factors, primarily a lack of awareness of or concern about patents on inputs to academic research, but also other influences such as NIH guidance and occasional intervention to lower barriers to research tool access.[91] The sole documented exception where IP rights may have been problematic (i.e., gene-based diagnostic testing) is technology-specific. Moreover, because there are charges for diagnostic tests in most cases as well as research uses of such tests, this activity often lies on the border between research and commercial activity.

Other, subtler negative effects of faculty entrepreneurial activity and university patenting and licensing are difficult to investigate and quantify but may be occurring. If so, they should be considered along with other, positive effects associated with the activity. For example, participation in external networking and consulting—means of communicating the results of research—has probably increased along with formal technology transfer activity involving IP transactions. And although its distribution is highly skewed across institutions and research fields, income from IP-based transactions has increased the pool of research funds available to departments, research centers, and investigators.

Although these relationships bear close watching for changes, at this time the research evidence points to only one issue that needs to be addressed—the difficulty that researchers experience in accessing biological research materials, both patented and unpatented, may have increased over time. University-to-university requests are denied or ignored with some frequency, affecting whether the research can be undertaken at all or at least whether it can proceed expeditiously. When an exchange involves a formal agreement or an MTA, the process of negotiating an agreement frequently involves costs in terms of delays in proceeding with research, restricted freedom of action, and financial costs to institutions.

[91] Thursby and Thursby, 2008, op. cit.; Walsh et al. 2005 and 2007, op. cit.

3

Effectiveness and Accountability of University Technology Transfer Activities

INTRODUCTION

In addition to concerns about the effects of technology transfer practices on academic science and teaching, as discussed in Chapter 2, another major concern is whether the current technology transfer system is effective in achieving the Bayh-Dole objectives, which include

1. use of the patent system to promote the utilization of inventions arising from federally supported research or development;
2. encouraging maximum participation of small business firms in federally supported research and development efforts;
3. promoting collaboration between commercial concerns and nonprofit organizations, including universities;
4. ensuring that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery;
5. promoting the commercialization and public availability of inventions made in the United States by U.S. industry and labor;
6. ensuring that the government obtains sufficient rights in federally supported inventions to meet the needs of the government and protect the public against nonuse or unreasonable use of inventions; and
7. minimizing the costs of administering policies in this area.

Assuming that institutions have determined the appropriate measures for determining whether these purposes are being achieved, one must then ask whether there are characteristics of institutions' organization, objectives, staffing, and conduct of patenting and licensing that account for seemingly large differences in outcomes across universities. What organizational characteristics and practices are counterproductive? Alternatively, would a different system—for example, sponsor ownership and disposition of intellectual property (IP) or faculty inventor ownership and licensing—be more effective overall in achieving the goals of Bayh-Dole?

In the context of the university-ownership system, there are second-order issues that vary with the type of research sponsor. In the case of federally sponsored research, are universities accountable with respect to the objectives, conditions, and limitations stipulated in the Bayh-Dole Act? In the case of privately sponsored research, does the effort expended on negotiation of terms addressing the ownership or dissemination of IP that could result from the research to be sponsored represent a serious impediment to universities concluding sponsored research agreements with businesses or private foundations? If so, are these sponsors seeking relationships with non-U.S. institutions instead?

In addressing these questions, the committee drew upon a variety of sources. As discussed in Chapter 2, the subject of university-owned IP has attracted a number of scholars in economics, sociology, and other disciplines who have produced a body of empirical research. Much of that research concerns the impact of IP on the university research enterprise. There has been somewhat less systematic research on the relative effectiveness of different institutional practices and arrangements with private research sponsors and even less work comparing alternative systems of IP ownership and management. The committee's own inquiries, through testimony in public meetings and a two-day workshop held on November 20-21, 2008, provided additional, although limited, sources of evidence, as did the survey of technology transfer offices conducted by Feldman and Bercovitz,[92] for which this study provided partial support. Finally, the committee reviewed the recommendations of other groups, organizations, and individuals, ranging from guidance on licensing practices to calls for a new system of managing IP arising from academic research.

The federal government also plays a role in implementing Bayh-Dole in terms of oversight and monitoring. To address the issue of public accountability, the committee relied on reports of the U.S. Government Accountability Office (GAO; formerly, General Accounting Office), to which Congress assigned periodic investigative and reporting responsibility in the Bayh-Dole Act.

EFFECTIVENESS OF TECHNOLOGY TRANSFER IN COMMERCIALIZING UNIVERSITY RESEARCH RESULTS

Annually collected AUTM data dominate nearly all scholarly efforts to evaluate and compare institutions' performance in IP-based technology transfer. The principal metrics are number of invention disclosures received from faculty by the technology transfer office; the number of patents applied for and granted; the number of licenses executed; and the amount of revenue derived from licenses, investment liquidation, sales of IP rights, legal settlements, and related indicators. Several researchers have investigated the striking differences in

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[92] M. Feldman and J. Bercovitz, op. cit.

performance across institutions on these measures.[93] These scholars cite a number of contributing variables including the presence or absence of a medical school, the public or private status of the institution, the structure of incentives for faculty to participate in the system, and technology transfer personnel compensation (e.g., the presence or absence of incentive pay). But there is very little consistency in results across studies apart from the very strong correlations between various output measures and the scale of universities' research portfolios. For their sample of institutions, for example, Feldman and Bercovitz reported the following Pearson correlation coefficients between total research expenditures and invention disclosures (0.97), patent grants and applications (0.94), licenses (0.55), and start-ups (0.84), compared with office age, that is, experience (0.33 for invention disclosures) and the presence or absence of a medical or engineering school (not significant for any performance measure).

Kordal and Guice[94] argued persuasively that it is "inappropriate to compare institutions with widely varying sizes" of research portfolios and that "institutions should be compared to their peers." Grouping institutions in three categories—large, medium, and small—Kordal and Guice found just as large differences in revenue, invention disclosure and patenting rates, licensing, and start-up company activity within each of the three tiers as across them, suggesting that more fine-grain analysis could be revealing of ways to improve technology transfer performance based on the current set of metrics.

It would be most useful to know the extent to which such disparities among universities reflect differences in the organizational structure, staffing, and funding sources of technology transfer offices and their relations with research faculty, centers of entrepreneurial education, and other controllable variables as distinct from structural factors that are hard or impossible to change (e.g., scale and specialization of research portfolios, public versus private status, presence of certain academic units, historical reputations, mission or niche, and geographical proximity to potential investors and industrial partners). But this work for the most part remains to be done.

A more serious and challenging problem with the data regularly reported on university technology transfer activities is that they draw attention to the volume of technology transfer activity and away from its quality and efficiency (e.g., timeliness, extent of marketing outreach, character of relations with faculty

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[93] Inter alia, D.S. Siegel, M. Wright, and A. Lockett. 2007. The rise of entrepreneurial activity at universities: Organizational and societal implications. *Industrial and Corporate Change* 16(4):489-504; J.G. Thursby and S. Kemp. 2002. Growth and productive efficiency of university intellectual property licensing. *Research Policy* 31(1):109-124; R. Kordal and L. Guice. Op. cit.; D. Siegel, D. Waldman, J. Silberman, and A. Link. 1999. Assessing the Impact of Organizational Practices on the Performance of University Technology Transfer Offices: Quantitative and Qualitative Evidence. Paper presented to the NBER Conference on Organizational Change and Performance Improvement, Santa Rosa, CA; R. DeVol and A. Bedroussian. 2006. *Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization.* Santa Monica, CA: Milken Institute; S. Belenzon and M. Schneiderman. 2007. Harnessing Success: Determinants of University Technology Licensing Performance. Centre for Economic Performance Discussion Paper No. 779; and M. Feldman and J. Bercovitz, op. cit.

[94] Kordal and Guice, op. cit.

inventors) as well as its economic or social impact. The results that garner most of the attention—receipts from licenses, occasional infringement suit settlements, and sales of patents or rights to future revenue streams—may involve only one or two transactions. Yet the universities fortunate enough to score a big hit appear to be highly successful, while institutions unable to cover the cost of their technology transfer office operations, however active, are considered to be underperformers.

Furthermore, largely ignored in the literature and discussion are the principal avenues of transfer, that is, publication, networking, teaching, student placement, consulting, and collaboration. As a result, these avenues are not only undervalued but also underevaluated. We have no means of assessing changes, benchmarking institutions, or making international comparisons.

Scotland and by extension the United Kingdom have made the most concerted efforts to overcome these deficiencies. The Scottish Higher Education Funding Council (or Scottish Funding Council) pioneered this effort in 2000 for the simple reason that it set up a separate funding stream to support university technology transfer activities and needed an appropriate framework to evaluate those expenditures. The Scottish framework was further developed in a report by UNICO, the U.K. technology transfer association.[95] Addressing metrics for quality as well as quantity of technology transfer activity,[96] the report addressed all of the avenues of transfer and judged U.K. institutions on the whole to be well ahead of those in the United States, where "the key measure of success is the collection of revenues—an incomplete and poor measure of knowledge transfer performance." The report acknowledged, however, that one of the main reasons for U.K. progress was the government's introduction in 2001 of the Higher Education, Business and Community Interaction Survey covering a broad spectrum of university activities with both financial and other objectives, a survey whose only U.S. counterpart is the much narrower annual National Science Foundation (NSF) Survey of University and College Research Expenditures.[97] U.S. data collection efforts, both public (NSF, Office of Science and Technology Policy) and private (Association of University Technology Managers [AUTM] and the Association of Public and Land-grant Universities), are in flux, however, creating opportunities for improvements that are explored further in Chapter 4.

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[95] M.T. Holi and R. Wickramasinghe. Metrics for the Evaluation of Knowledge Transfer Activities at Universities. Available at: http://ec.europa.eu/invest-in-research/pdf/download_en/library_house_ 2008_unico.pdf.

[96] For example, suggested metrics for networking are the number of people met at events leading to other technology transfer activities (quantity) and the percentage of events leading to other technology transfer activities (quality); for consulting, the number of faculty contracts and length of their relationships with contractors (quantity) as well as the percentage of repeat business customers (quality); for teaching, the graduate rates of students and the rate at which employed in industry (quantity) as well as student and employer satisfaction after employment (quality).

[97] See http://www.nsf.gov/statistics/srvyrdexpenditures/.

PERFORMANCE IN LAUNCHING NEW FIRMS

The attractions of using university-developed technologies to create entirely new enterprises rather than license to established firms have become widely recognized. Entrepreneurial faculty members often aspire to play leading roles in new ventures. The creation of jobs in new, generally local, firms is visible to communities and political leaders whose support of the university is important. Founding a company like Google or Yahoo! that becomes a global leader adds luster to the university and may hold the promise of significant financial benefits for individual and institutional stakeholders if the firm goes public. Such prospects account for the increasing emphasis in technology transfer practice on start-ups or spin-offs. According to the AUTM survey, the number of start-ups grew from 241 in 1994 to 555 in 2007, the most recent survey year.

The conditions for start-up success are much more stringent, however, than they are for licensing existing companies. Only a fraction of faculty invention disclosures lend themselves to the formation of a stand-alone company. The head of a major university business school-based innovation center estimated that a robust university research enterprise including a medical complex and a highly ranked engineering school generates no more than six viable stand-alone business prospects a year. Although 20 institutions exceeded that number of start-ups in 2006, according to the AUTM survey, the ratio of start-ups to licensing agreements with established firms ranged from 1:1.5 to 1:22 for those institutions.[98]

In addition to the challenge of selectivity, the university must anticipate the need for three other critical elements—a viable business plan, investment capital, and managerial talent other than the faculty inventor. The committee heard from university officials and venture capital investors representing a variety of views on how these requirements are best met. Some of the investors were of the view that the university could play no constructive role other than securing and licensing any underlying IP. University representatives, on the other hand, described strikingly different start-up programs as successful. One model, clearly suited to an environment with an active venture investment community, relies simply on technology transfer office networking—introducing ideas and faculty inventors to potential early-stage investors. At the opposite extreme, the institution may have an innovation center independent of the technology transfer office to help finance development of the technology to the point where it may attract investor interest, a graduate business school program where students develop business plans for faculty or student start-up concepts, a seed capital fund with alumni contributors, and an incubator or science park where fledging companies share low-cost space and services while struggling to take off. The latter model clearly encompasses activities extending

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[98] D. Bostrom and R. Tieckelmann. 2006. AUTM US Licensing Activity Survey: FY 2006. Deerfield, IL.

well beyond the competence and resources of the average technology transfer office, although technology-licensing personnel may provide coordination.

At present, few evidence-based generalizations can be drawn to guide technology transfer offices in the selection of candidates for spin-offs; decisions as to whether to source the requisite business plan, capital investment, and management from inside the institution or externally; and means of sustaining the firm until the later-stage equity investors exit by organizing an initial public offering or selling out to an established company. It might be that university equity participation in start-ups is superior to negotiating an ongoing stream of royalties as long as it is relative to passive experienced management, because holding equity is less of a drain on the firm's limited capital in a phase of growth without profits. On the other hand, the prospect that the university's initial equity share will be diluted in successive rounds of financing should dampen expectations of a large return on the investment.

Beyond such operational principles, authors of literature surveys agree that empirical research has yet to produce consistent findings. Di Greggorio and Shane wrote: "We find no effect of local venture capital activity and only limited support for an effect of the commercial orientation of university research on technology transfer office start-up rates. The two additional policy variables that we tested—the presence of a university-affiliated incubator and whether or not the university is permitted to actively make venture capital investments in licensees—do not appear to have an impact on start-up activity."[99]

RELATIONS WITH PRIVATE RESEARCH SPONSORS

Relations between universities and private research sponsors are not well studied or understood. There is certainly much anecdotal evidence, however, that relations could be better. In widely publicized congressional testimony in 2007, one prominent information technology executive complained that aggressive university patenting, overvaluing of intellectual assets, and hence unrealistic licensing terms impeded both product development and university-industry collaboration, encouraging companies to find other research partners, including offshore.[100] Similar complaints have been repeated periodically, with some firms admitting that they prefer foreign to domestic university partnerships because academic institutions abroad are less insistent upon IP ownership and agreements are more quickly negotiated.[101] A study by Thursby and Thursby of executives responsible for corporate R&D location decisions provided some

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[99] D. Di Gregario and S. Shane. 2003. Why do some universities generate more start-ups than the others? Research Policy 32(2):209-227.

[100] W. Johnson (Vice President, University Relations, Hewlett-Packard). 2007. Bayh-Dole–The next 25 years. Testimony before House Committee on Science & Technology, Subcommittee on Technology and Innovation, July 17.

[101] D. Kramer. 2008. Universities and industry find roadblocks to R&D partnering. *Physics Today* 61(5):20-22.

evidence of such attitudes, although research cost and quality considerations weighed more heavily in location decisions.[102]

When pressed, corporate representatives generally distinguish between U.S. universities with experienced, well-functioning technology transfer operations and institutions—generally less experienced—that place a premium on revenue generation.

Members of the academic research community have responded to industry complaints by claiming that some companies look to universities as "work for hire" organizations and that companies contribute equally to delays. While such exchanges often devolve into generalities, perhaps the best evidence that university-industry relationships involving IP are in need of improvement is that efforts to bridge the gap are ongoing (see Box 3A). They have been moderately productive, less at the level of general principles than at the level of facilitating negotiations over details of research collaborations.

Box 3A
University-Industry Dialogue

A 2006 joint project between the National Council of University Research Administrators and the Industrial Research Institute, facilitated by the Government-University-Industry Research Roundtable at NAS, resulted in *Guiding Principles for University-Industry Endeavors*. The authors recommended that universities avoid licensing future inventions, noting that licensing is often the most contentious part of negotiations. Because future inventions are often hypothetical (and sometimes do not arise at all), it is beneficial to both parties to defer the argument. Instead, the group recommended that universities establish a general framework for future IP, but not a specific agreement. A permanent institutional framework, the University-Industry Demonstration Project, was established to continue to address contentious issues in university-industry relations as they arise.

The project also is developing a software tool intended to streamline negotiations by suggesting agreement clauses based on the situation. Interview questions are used to define variables such as type and size of the university and company involved, the level of confidentiality needed, national security concerns, whether student thesis work may result, or even the amount of funding anticipated.

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[102] J. Thursby and M. Thursby. 2006. Where is the new science in corporate R&D? *Science* 314:1547-1548.

CONSIDERATION OF ALTERNATIVE MODELS OF TECHNOLOGY TRANSFER

A few scholars have taken issue with the prevailing model for managing faculty-produced IP irrespective of whether it is publicly or privately financed.[103] Leading criticisms of this system include the following:

- Inappropriate and contradictory incentives: University administrators have incentives to use technology transfer offices as generators of all-important unrestricted revenue rather than focusing on transferring technologies effectively.
- Information asymmetries: Technology transfer personnel have little knowledge of the invention and, generally speaking, inadequate knowledge of the marketplace for it, while the inventor understands the invention thoroughly and often foresees its potential applications. By controlling the inventor's ability to market her or his invention, the technology transfer office reduces incentives for faculty disclosure and unnecessarily constrains market opportunities. If the inventor aims to start a new company, his or her incentives are more closely aligned with the licensee, against the technology transfer office.

These observations led Kenney and Patton to conclude that technology transfer offices tend to become revenue maximizers, neglecting some inventions with little profit potential altogether and ignoring some commercialization avenues for the inventions they do care about. The proposed solution to this problem is faculty ownership of inventions and ability to patent and license as they see fit, engaging professional help within their own institution or elsewhere as the need arises. Litan, Mitchell, and Reedy suggested other mechanisms for diluting or breaking the institutional technology transfer office monopoly, in particular, regional consortia and Internet-based marketing.[104]

These critics of the status quo recognize and articulate an often overlooked truth—not everyone involved in the technology transfer process has the same goals or complementary knowledge and skills, making success difficult to achieve. But their arguments for the superiority of an inventor-driven system of technology transfer are largely conjectural. There is certainly anecdotal evidence of faculty dissatisfaction with the technology transfer office-dominated model as

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[103] M. Kenney and D. Patton. 2009. Reconsidering the Bayh-Dole Act and the current university invention ownership model. *Research Policy* 38(9):1407-1422.

[104] R.E. Litan, L. Mitchell, and E.J. Reedy. 2007. Commercializing University Innovations: Alternative Approaches. National Bureau of Economic Research Working Paper; also The University as Innovator: Bumps in the Road. *Issues in Science and Technology* 23(4):57-66. A recent version of the proposal suggests that faculty inventors could be given free reign to seek assistance in licensing their inventions while ownership is retained by the home university and any revenues are allocated in accord with the university's standing policy. See Memorandum from Robert Litan and Lesa Mitchell to Esther Lee, U.S. Department of Commerce. 2009. Accelerating the Commercialization of Government-Funded University-Based Research. This variation is discussed in Chapter 4.

well as evidence of faculty entrepreneurial success independent of such offices,[105] but there is no systematically collected evidence that inventors have knowledge and skills superior to those of technology transfer personnel and their service providers in the various components of IP acquisition, management, and licensing

International comparisons are a possible source of such evidence. Goldfarb and Henrekson[106] found the American system to be more effective than that of Sweden, which has a professor's privilege system, in promoting commercialization. They argued that this stems from greater competition within the U.S. system for resources and faculty as well as the incentives toward commercialization brought about by the Bayh-Dole Act. In 2001, Denmark passed its Law on University Patenting, which was inspired by the Bayh-Dole Act and which ended professor privilege. On the basis of an empirical analysis, Valentin and Jensen argued that this law had a largely negative effect in reducing collaborations between industry and with academic researchers.[107] They further noted that over the same period of time they did not observe the same pattern in Sweden, a similar country but one that did not change from a system of professor's privilege to one of university ownership. The fact is that there are many confounding variables in cross-national studies that undermine claims of superiority for one ownership model over another.

FEDERAL OVERSIGHT AND MONITORING

The Bayh-Dole legislation provides statutory provisions in the form of three government authorizations to promote "free competition and enterprise without unduly encumbering future research and discovery":

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[105] Field studies (A.N. Link, et al., op. cit.; and A.N. Link, D. Siegal, and D. Waldman. 2003. Assessing the impact of organizational practices on the productivity of university technology transfer offices: an exploratory study. *Research Policy* 32(1):27-48), survey work (J. Thursby, A. Fuller, and M. Thursby. 2009. U.S. faculty patenting: Inside and outside the university. *Research Policy* 38(1):14-25), case studies (J. Bercovitz and M. Feldman. 2006. Entrepreneurial universities and technology transfer: A conceptual framework for understanding knowledge-based economic development. *Journal of Technology Transfer* 31:175-188), and a recent study of leading National Cancer Institute scientists (T. Aldridge and D.B. Audretsch. 2010. Does policy influence the commercialization route? Evidence from National Institutes of Health funded scientists. *Research Policy* 39:583-588) point to the propensity of some scientists to work directly with firms in commercializing their research inventions, seemingly without engaging their technology transfer offices. Whether these are "backdoor" transactions in violation of employment agreements to assign title to their universities is not at all clear. Thursby et al. studied 5,800 patents with at least one university faculty inventor and found that about one-quarter of them were assigned to firms. But on the basis of interviews with inventors and university and industry licensing officials, they concluded that a majority of the firm assignments resulted from individual consulting arrangements and represented more incremental advances than inventions assigned to universities.

[106] B. Goldfarb and M. Henrekson. 2003. Bottom-up vs. top-down policies towards the commercialization of university intellectual property. *Research Policy* 32(4):639-658.

[107] F. Valentin and R.L. Jensen. 2007. Effects of academia-industry collaboration of extending university property rights. *Journal of Technology Transfer* 32(3):251-276.

1. *Government use rights*: The government retains a royalty-free license to use a patented invention for its own purposes.
2. *Determination of "exceptional circumstances"*: The government, following certain procedures, may decide in advance that it will retain the right to elect title to an invention because doing so will better serve one of the Act's seven objectives. This in effect means either seeking and retaining patent protection or permitting the invention to enter the public domain.
3. *Invoking "march in" post facto:* This can occur when the funding agency determines that the patent holder is neglecting to "work the patent" diligently, private patent rights conflict with other governmental policies, or "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."

Two conditions are required for these general welfare supporting provisions to have any practical meaning and the government's leverage to be used appropriately and sparingly. First, there must be consistent oversight and interpretation of the statute. Second, the government must have access to relevant information. Both conditions appear to have diminished over time.

The Bayh-Dole Act necessarily left most implementation and enforcement authority with the funding agencies awarding grants, entering contracts, and executing other funding arrangements to support research (e.g., see below on NIH policies). The Department of Commerce was charged with writing the regulatory framework for enforcing the Act, collecting and synthesizing reports from funding agencies, and chairing an interagency committee to help ensure consistent interpretation and action across the agencies.[108] Successive GAO reports have made clear that since the promulgation of implementing regulations (37 CFR 401.1-17) and the formation of the interagency committee, Commerce Department oversight has atrophied.[109] Responsibilities originally assigned to the Office of General Counsel were shifted to the Assistant Secretary for Technology Policy, and then with the elimination of that office in 2007 to the National Institute of Standards and Technology (NIST). Physically and bureaucratically, responsibility is now far removed from the Office of the Secretary of Commerce where it once resided.

NIH GUIDANCE REGARDING GOVERNMENT-SPONSORED RESEARCH RESULTS

Of the federal agencies covered by the Bayh-Dole legislation, NIH has issued the most guidance laying out its interpretation of its role as a research sponsor in promoting transfer of federally funded discoveries to applications.

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[108] U.S. General Accounting Office. 1999. Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision. GAO/RCED-99-242.

[109] U.S. General Accountability Office. 2009. Federal Research: Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions. GAO-09-742.

Since 1994, NIH has issued three sets of guidelines for grantees to ensure researchers' access to the results of previous work with regard to NIH-funded projects:

1. Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts (1994)
2. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources (1999), and
3. Best Practices for the Licensing of Genomic Inventions (2005).

In brief, the guidelines state that grantees should pursue a patent on research discoveries only if further development and investment are required to make them useful. The guidelines cite the Bayh-Dole objective of maximizing the use and wide availability of publicly supported inventions, especially research tools for which scientific research laboratories are the primary consumers. With regard to licensing terms, the guidelines support royalty-free nonexclusive licensing to all nonprofit research entities. "When transferring an NIH-funded research tool to a for-profit entity that intends to use the tool for its own internal purposes, Recipients are entitled to capture the value of their invention. Arrangements such as execution or annual fees are an appropriate way for Recipients to do so."[110]

To facilitate the unencumbered exchange of research materials, the guidelines urge use of a streamlined standard agreement, the Uniform Biological Material Transfer Agreement. NIH condones exclusive licenses when additional investment is required or when exclusivity will promote rather than restrict distribution—for example, when a company can quickly produce and distribute a key research tool at a reasonable price. When exclusive rights are granted, the guidelines urge licensors to limit field of use and duration and use benchmarks to ensure that the technology is being advanced and marketed effectively. In general, background rights for inventions developed with federal funds should be granted so that further research and development is not hindered. In addition, universities should not claim royalties or rights to "reach-through" inventions because doing so could retard or prevent research tool use.

In a 2006 report, *Reaping the Benefits of Genomic and Proteomic Research*, the National Research Council (NRC) broadly supported the NIH guidelines, recommending that NIH require grantees to adhere to its dissemination and licensing guidelines and urging other granting agencies to adopt and enforce similar guidelines. The NRC report noted that although guidelines are useful, they are limited to NIH grantees and NIH does not have regulatory or enforcement authority. The NRC committee also urged "Universities should adopt the emerging practice of retaining in their license agreements the authority to disseminate their research materials to other research institutions and to permit those institutions to use patented technology in their nonprofit activities."

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[110] http://ott.od.nih.gov/pdfs/64FR72090.pdf.

Similarly, a 2003 NAS report, *Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences*[111], recommended that inventions used to generate data for scientific publications should be made available to other laboratories for research purposes within 60 days of request. If the invention is patented, then a royalty-free, nonexclusive license should be granted. University administration should enforce this availability. Moreover, the report recommended that universities and faculty not claim exclusive rights to commercialize "reach-through" inventions. This claim would prevent the use and dissemination of research materials and scientific progress. A 2010 draft report by the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) also promotes nonexclusivity in licensing of diagnostic genetic/genomic technologies, in addition to a research exemption for the use of patent-protected genes.[112]

Through a provision of the Bayh-Dole Act, an agency can use a Determination of Exceptional Circumstances (DEC) to retain patent rights as a condition of funding when it will better promote the policy and objectives of the statute. This authority has been used by NIH only on rare occasions, such as the NIH Mammalian Gene Collection initiative and disease-specific knockout mice, due in part to the lengthy approval process within many agencies. In a few instances NIH has attempted informally to persuade university patent holders to change licensing practices or terms (e.g., with regard to the University of Wisconsin stem cell patents). The Bayh-Dole statute includes two other authorities that have been rarely exercised enabling the government to condition or even cancel patent rights in certain circumstances. The government retains rights to use inventions developed with federal funds for its purposes and to delegate that authority to "funding recipients to use the government's licenses for specific contracts, grant awards, or cooperative agreements meeting a federal government need." [113]This authority has rarely been invoked, but it has been suggested that it might be applicable when, for example, a diagnostic technique is being used in the context of a federally sponsored clinical drug trial.

The final authority is the right to "march in" and assert government title to an invention when one of four conditions is not satisfied by the patent holder. NIH has been petitioned to march in on three occasions, but in no case did it exercise the right.[114] Arno and Davis argued that NIH should assert march-in

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[111] National Academy of Sciences Board on Life Sciences. 2003. Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences. National Academies Press.

[112] SACGHS. Approved February 5, 2010. Revised Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests. Available at: http://oba.od.nih.gov/oba/SACGHS/SACGHS%20Patents%20Report%20Approved%202-5-20010.pdf.

[113] U.S. General Accounting Office. 2003. Technology Transfer: Agencies' Rights to Federally Sponsored Biomedical Inventions. GAO-03-536.

[114] U.S. Government Accountability Office. 2009. Federal Research: Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions. GAO-09-742.

rights if and when drug prices reduce patient access,[115] but Raubitschek and Latker, both of whom were involved in early implementation of the statute, reviewed the legislative history and strongly disagreed that price is an appropriate ground for march-in.[116] The three NIH cases took from 5 to 30 months of fact-finding.[117] If the agency does decide to march in, the patentholder has extensive recourse through appeals and further administrative action, imposing a further burden on the agency officials. McGarey and Levy noted the value of the authority as a threat but doubted the practical likelihood of march-in given the procedures stipulated by the implementing regulations crafted by the Department of Commerce.

INFORMATION ACCESS

The national system of innovation, in which universities and university technology transfer play an important part, is constantly changing. Systematic collection, analysis, and reporting of data on how the system is working are needed to enable improvements over time. This report draws on a body of scholarship and, in turn, data that are illuminating but incomplete. Curiously, existing data are almost entirely privately collected and reported. Data about what happens to the inventions arising out of federally funded research are far harder to find and interpret than are data about research grants and contracts and their results. Patents themselves are public, although not always readily identifiable by source, but the terms on which they are licensed and how they are exploited are not.

A 2003 GAO report summarized the most recent data at the time:

> Few of the biomedical products that federal agencies most commonly buy appear to incorporate federally funded inventions. In 2001 the government had licensing rights in only 6 brand name drugs associated with the top 100 pharmaceuticals that VA procured and in 4 brand name drugs associated with the top 100 pharmaceuticals that DOD dispensed. GAO was unable to determine the extent to which the government had rights to other types of biomedical products because there are no databases showing the underlying patents for most of these products and such products may incorporate numerous components that might not be covered by identifiable patents.”[118]

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[115] P. Arno and M. Davis. 2001. Why don't we enforce existing drug price controls? The unrecognized and unenforced reasonable pricing requirements imposed upon patents deriving in whole or in part from federally funded research. *Tulane Law Review* 75:631-693.

[116] J. Raubitschek and N. Latker. 2005. Reasonable pricing—a new twist for march-in rights under the Bayh-Doyle Act. *Santa Clara Computer and High Technology Law Journal* 22:149-167.

[117] B McGarey & A Levy. 1999. Patents, products, and public health: An analysis of the CellPro march-in petition. *Berkeley Technology Law Journal* 14:1095-1116.

[118] U.S. General Accounting Office. 2003. op. cit.

As noted above, regulatory provisions associated with Bayh-Dole stipulated the need for all grantees or contractors to report on the use of inventions resulting from federally funded research.[119] To facilitate compliance with this requirement, the Interagency Edison (iEdison) tracking system and database was designed, developed, and implemented by NIH in 1995. iEdison facilitates and enables grantee and contractor organizations to directly input invention data as one means of fulfilling the reporting requirement. Since 1997, iEdison participation has grown to more than 1,300 registered grantee or contractor organizations supported by any of more than 29 covered federal agency offices.[120] Use of iEdison, however, is voluntary for inventions and patents developed under federal funding agreements. Recognizing that the GAO investigations occurred some time ago, the committee was unable to find any current assessments or validation of the data provided to iEdison. Without a reasonably complete list of government-sponsored inventions, effective oversight is impossible.

Public accountability for disposition of the inventions arising from public funding depends not only on a reasonably complete inventory but also on an understanding of what is done with the IP. The information reported to iEdison and to agencies that do not use it is highly confidential. Section 205 of the Bayh-Dole Act, using language identical to the Freedom of Information Act's (FOIA's) exception for business proprietary information obtained by the government, mandates such confidentiality. The Bayh-Dole regulations even more strongly reinforce confidentiality, stating "the agency agrees it will not disclose such information to persons outside the government without permission of the contractor."[121]

Maintaining the anonymity of parties to perhaps even certain terms (e.g., royalty rates) of licensing agreements is appropriate and important, but that does not preclude analysis of the data and reporting of generalized findings without identifying either individual institutions or their business partners. The Technology Transfer Commercialization Act of 2000 attempted to address the lack of such analysis by requiring that agencies report to the Office of Management and Budget (OMB) the success of their technology transfer programs.[122] A congressionally mandated GAO report in 2002 found that in the first required reporting year, agencies were not fully compliant.[123] Agencies did not submit the reports in a timely manner, many were incomplete, contained information believed to be inconsistent or inaccurate, and varied in data elements used, even though the Department of Commerce had issued guidelines and a sample format for the agencies to use. GAO did not believe that the deficiencies in the reports were the result of adjustments to a brand new

[119] 37 CFR 401

[120] https://s-edison.info.nih.gov/iEdison/.

[121] 37 CFR 401.14(h)

[122] U.S. General Accounting Office. 2002. Intellectual Property: Federal Agency Efforts in Transferring and Reporting GAO-03-47.

[123] Ibid.

reporting requirement, observing that agencies already should have been tracking this information to comply with the Bayh-Dole Act.

Assessment of how the system is working should not depend wholly on agencies' compliance with congressional mandates. Many of the government's most sensitive and secure civilian data systems—for example, Census and even Internal Revenue Service records—are accessible by qualified independent researchers who agree not to disclose any identifying information. But that seems highly unlikely to occur if such access requires the consent of every data source.

CONCLUSIONS

Universities in the United States are very diverse in terms of size, research portfolio, and culture. Consequently, approaches to technology transfer must be framed squarely within the established mission of individual universities. The goal of technology transfer offices must be to advance the university's success in learning, discovery, and societal engagement and to facilitate the transfer of publicly funded innovations into benefits for society. In evaluating their individual technology transfer offices, universities must measure themselves against their own mission and yet recognize that they are part of a larger education and research enterprise.

4

Findings and Recommendations

THE PURPOSE AND CONTEXT OF IP-BASED TECHNOLOGY TRANSFER

Discovery, learning, and promotion of social well-being are mutually supportive core university missions. Transfer of new knowledge to those in society who can make use of it for the general good contributes to each of these missions. These transfers occur through publications, employment of graduates, conferences, consultations, and collaborations as well as by obtaining patents on inventions and discoveries that meet the U.S. Patent and Trademark Office's tests for patentability and licensing their use on terms negotiated with private enterprises. Often these mechanisms are complementary and operate in tandem. It is also important to recognize that none of these avenues is a one-way street. Science, technology, and business information flowing back from other sectors adds to the stock of academic knowledge and helps to inform faculty and students about opportunities to apply their research findings. This is especially true of mechanisms that enable or depend on repeated personal contact, as is often the case with licensing. Moreover, several of these mechanisms probably exceed licensing in economic and social impact. And the United States has a history of successful, mutually beneficial relations between public and private universities and the private sector long predating the prominence of intellectual property (IP) in those relationships.

It is nevertheless the case that only patenting and licensing by universities are regulated by national policy related to the dominant role of the federal government in funding academic research. Thirty years ago, after considerable debate, this policy underwent a major change with passage of the Bayh-Dole Act, accelerating this activity and bringing about greater uniformity in the way research agencies treat inventions arising from the work they sponsor. The change also led many universities for the first time to organize how they handle IP stemming from both publicly and privately sponsored research. Although the post-1980 system has remained stable, it has nevertheless generated a good deal of debate about whether it is as effective as it could be and more effective than alternatives, and whether it has produced unintended effects that are adverse to other modes of technology transfer and even to the norms of the research university community. It is for these reasons that this study focused on the university's management of IP but in the context of all of the strategies and mechanisms for transmitting knowledge and in recognition of their interactions and role in the core mission of the university.

Finding 1: The first goal of university technology transfer involving IP is the expeditious and wide dissemination of university-generated technology for the public good. The public good might include inputs into further research; new products and processes addressing societal needs; generation of employment opportunities for the production, distribution, and use of new products. Although the transfer methods will vary among institutions depending on the history, location, and composition of the institution's research portfolio, the goal of expeditious and wide dissemination of discoveries and inventions places IP-based technology transfer squarely within the research university's core missions of discovery, learning, and the promotion of social well-being.

Finding 2: The transition of knowledge into practice takes place through a variety of mechanisms, including but not limited to

1. movement of highly skilled students (with technical and business skills) from training to private and public employment;
2. publication of research results in the open academic literature that is read by scientists, engineers, and researchers in all sectors;
3. personal interaction between creators and users of new knowledge (e.g., through professional meetings, conferences, seminars, industrial liaison programs, and other venues);
4. firm-sponsored (contract) research projects involving firm-institution agreements;
5. multifirm arrangements such as university-industry cooperative research centers;
6. personal individual faculty and student consulting arrangements with individual private firms;
7. entrepreneurial activity of faculty and students occurring outside the university without involving university-owned intellectual property; and
8. licensing of IP to established firms or to new start-up companies.

All eight mechanisms, often operating in a complementary fashion, offer significant contributions to the economy. The licensing of IP, although not the most important of these mechanisms, is more often discussed, measured, quantified, and debated than all of the other mechanisms combined and is the subject of our remaining findings and recommendations.

THE BAYH-DOLE SYSTEM AND ALTERNATIVES

> **Finding 3:** The system put in place by the Bayh-Dole Act, that is, university ownership of inventions from publicly funded research and latitude in exercising associated IP rights subject to certain conditions and limitations, is unquestionably more effective than its predecessor system—government ownership subject to waiver in circumstances that varied from agency to agency—in making research advances available to the public.

This is a widely accepted judgment, but it is important to understand why this is the case. In the pre-1980 system of government ownership of inventions arising from federally funded research—whether in government laboratories, universities, or companies—the incentives to pursue further development and commercialization were severely attenuated and the capacity to do so severely limited. Government agencies, in particular, had no incentive and negligible capacity. And where research performers had the possibility of persuading federal agencies to transfer rights to them, the uncertainty of success and the complexities of obtaining waivers of government ownership under different agency rules were often high. Most institutions had no reason to hire specialized personnel and create administrative units to handle these matters. The Bayh-Dole Act substituted a system of university and small business ownership and removed the inconsistencies and uncertainties in agency policies with respect to performer rights, a considerable achievement. The change was followed by a surge not only in patenting and licensing activity but also in universities creating internal capacity to undertake this new level of activity. These developments since implementation of Bayh-Dole were no doubt encouraged by broad scientific advances, many of which were the result of significant increases in the NIH budget, a rise in activity in the fields of molecular biology and bioengineering, an overall increase in domestic outlays for biomedical research, and other policy changes that strengthened and extended IP rights generally and patent rights in particular.

> **Finding 4:** The Bayh-Dole legal framework and the practices of universities have not seriously undermined academic norms of uninhibited inquiry, open communication, or faculty advancement based on scholarly merit. There is little evidence that IP considerations interfere with other important avenues of transferring research results to development and commercial use.

The potential for adverse effects exists, but countervailing pressures have largely protected the norm of open scientific communication. The most obvious example is the resolution of the tension between the need for secrecy to protect proprietary advantage and the norm of timely disclosure of research results. The fact that academic reputation depends heavily on publication means that there is strong resistance to demands on the part of corporate research sponsors and commercial licensees for delays in research publication. As a general matter, universities have acceded to delays that are reasonably short.

Many of the concerns that have been expressed from time to time—about publication delays, shifts in research priorities, and especially about the potential of upstream patenting to interfere with the conduct of research—have been investigated, sometimes repeatedly, by empirical researchers. Where they have found changes in behavior, for example, in the sharing of unique research materials among researchers in the life sciences, these seem associated more with reputational competition and with prior commercial involvement that may or may not have involved formal IP rights. Of course, the deepening of commercial ties in some fields may have subtle adverse effects on communication of research results.

As some potential for unintended adverse effects on the academic research system remains, we do not suggest that these issues can be safely ignored in the future. Rather, the watchword in university management of IP should be "First, do no harm."

The question of the effectiveness of the current system of university ownership and management of most IP arising from research is difficult to address for at least 3 reasons

1. As always, the question "relative to what other system or systems?" needs to be answered.
2. Despite a uniform overarching policy, universities have wide latitude even in managing federally sponsored research, and there is great heterogeneity in universities' resources, capacities, and practices.
3. Empirical research on universities' patenting and licensing activity has relied almost entirely on what we consider to be a seriously deficient set of criteria represented by the metrics used in the annual survey of technology transfer offices by the Association of University Technology Managers (AUTM)—the number of patents relative to the number of invention disclosures or the amount of research funding, the number and charter of licensing agreements, and the amount of revenue collected by royalty-bearing licenses and related income sources (e.g., sales of IP, successful patent enforcement actions or settlements)—rather than any direct measure of public availability of the patented technology and benefit from it, economic, social, or otherwise. Studies have also paid little attention to different roles of patents in different fields of technology.

There is considerable anecdotal evidence of such benefits, for example, in AUTM's "Better World" compilation of cases, but there is no systematically collected evidence enabling reasonably firm conclusions about the sources of variation in institutions' performance on the important dimensions.

No one has seriously suggested returning to the pre-1980 regime. The only alternative to the status quo that has attracted support from some observers and academic scholars is one giving university faculty inventors much greater leeway and autonomy from university central authorities in managing their own inventions.

In many institutions, faculty are encouraged to explore possible applications of their technology; seek out and recruit potential investors and licensees; advise the negotiations; and participate actively in the ensuing enterprise, whether as a principal in a start-up company or as a consultant to an established firm that licenses her or his technology. This is commonplace and should be standard practice. Faculty initiative in seeking licensing opportunities is not the systemic change that critics of the status quo advocate. Nor does this refer to instances in which university officials evaluate an invention, decide for whatever reason not to pursue its commercialization, and allow a willing university inventor to retain rights. That, too, is accepted practice consistent with the Bayh-Dole Act, 35 USC 202(d), subject to the funding agency's approval.

The proposed changes are more far-reaching, either to permit inventors routinely to assume ownership and pursue commercial opportunities on whatever terms they wish or to create a hybrid system in which faculty are to pursue licensing or business creation opportunities through entities outside their institutions, either other university technology transfer offices or private service providers. In the latter but not the former version, the home institution would retain ownership and the right to receive any revenue from a resulting agreement.

Faculty ownership has been the traditional practice in a number of countries abroad, where it is commonly known as "professor's privilege," and in the past in a few institutions in the United States. It is fair to say that it has progressively given way to university IP ownership and management in both U.S. and non-U.S. settings. That by itself is not evidence that faculty ownership is inferior, as local conditions may account for the change in some cases. Unfortunately there has been little comparative research on changes over time or differences across countries, but one Swedish-U.S. comparative study suggests that faculty ownership and exercise of IP is not more effective in commercializing academic research results.[124]

The relevant question that we considered is whether claims that faculty ownership is superior to the status quo are at this point sufficiently persuasive to consider changing the current system, a step perhaps requiring changes to the Bayh-Dole Act and certainly to its implementing regulations. Those arguments revolve around the alleged superior faculty knowledge of critical elements of the technology transfer process and stronger faculty incentives relative to those of technology transfer personnel. It is also argued that these personnel are strongly motivated to raise revenue for their institutions and thus focus their efforts on the few inventions with very large royalty potential. Finally, there is also a scale argument—that significantly more technology will be commercialized through the efforts of thousands of entrepreneurial faculty than by the fewer number of staff employed by university technology transfer offices.

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[124] B. Goldfarb and M. Henrekson. 2003. Bottom-up vs. top-down policies towards the commercialization of university intellectual property. *Research Policy* 32(4):639-658.

Finding 5: A persuasive case has not been made for converting to an inventor ownership or "free agency" system in which inventors are able to dispose their inventions without university administration approval. If evidence is developed suggesting that either would be more effective than the current system, other significant practical consequences and policy issues would have to be considered, such as the potential for conflicts of interest and adverse effects on public accountability.

Finding 6: Nevertheless, proposals to empower faculty and other university-based inventors by giving them ownership or rights to market their inventions independent of university oversight reflect a feeling in some quarters that in the current system of university management, inventor initiative is not sufficiently valued and encouraged. In fact, successful commercialization often depends upon active inventor engagement and, in some cases, the inventor playing a lead role.

Previous research together with research supported by this committee strongly suggests that expertise and experience in the multiple diverse sets of expertise involved in formal technology transfer transactions vary greatly across university technology transfer offices. One can presume that the same is true of faculty inventors, although they have been less studied. In general, faculty are neither trained nor expected to be knowledgeable about the complex array of economic and legal issues and technical matters that are involved in determining how an invention can best be licensed. In principle, the expertise of faculty and that of technology transfer personnel are somewhat complementary, with, for example, inventors usually having a better grasp of their technology and its potential applications, and technology transfer personnel usually having a better grounding in the process of obtaining patent protection and negotiating licensing terms. That distribution of expertise is probably the norm, but no doubt it varies from case to case. It should lead to cooperation, but it can also lead to misunderstandings and conflict.

What is crucially missing from arguments for changing the current system, however, is any evidence of the degree to which faculty inventors would be motivated to commercialize their inventions if their institutions did not provide internal support in the form of hiring professional personnel and paying or securing payment of the costs of patenting and negotiating licenses. In the absence of such evidence, it is reasonable to presume that the incentive structure of the academic system, with its emphasis on building a scholarly reputation, weighs heavily on most research faculty as do the opportunity costs of time spent in other, often unfamiliar pursuits. Evidence for the assertion that an inventor ownership system would generate much more commercialization activity than the current system is lacking.

In the event that evidence is developed strongly supporting inventor ownership or disposition of IP rights derived from sponsored research, then other possible effects of changing the current system should be examined. Most university inventions are the products of research collaborations, and resulting patents list co-inventors. Disagreements between faculty members or between faculty members and students about how to commercialize a joint invention could hobble their efforts. By the same token, commercial value is often associated with combinations of technology from different inventors. Single inventors, even more than single universities, could be handicapped in assembling related IP for licensing because they would ordinarily not have rights in the related IP.

Aside from these practical considerations, the committee has strong public policy reservations about any proposal to assign IP to inventors:

- Compliance with the Bayh-Dole Act's limitations and conditions on publicly funded inventions, including the requirement that a share of any resulting revenue be directed back into support of research, may be harder to monitor and achieve from individual inventors than from research institutions accustomed to ensuring compliance with the variety of federal requirements associated with research funding.
- Similarly, with inventor ownership it could become much more difficult to encourage observance of the good licensing practices evolved by members of the university community and supported by AUTM and by this committee.
- The exercise of IP rights has the potential to create either institutional or individual faculty conflicts of interest and commitment; the institution needs to be able to anticipate these circumstances and resolve cases uniformly.

As noted above, some critics of the current system have proposed a hybrid model combining home university ownership with inventor "free agency" or autonomy to seek assistance outside the university in patenting and licensing their technology or creating a new firm to commercialize it. The inventor's options could include his or her "home" technology transfer office, the technology transfer of another institution, or a private service provider. Clearly, such a change would require some thought about the payment systems that would incentivize competition among the potential "agents" for the technology. In addition to stimulating more commercialization activity, the intended benefit of this arrangement is to create competition among technology transfer offices for faculty clients and thus give offices an incentive to improve their performance. Although preserving some of the current system's accountability, this compromise raises several practical questions in addition to the payout arrangement. Should the university restrict the set of potential agents and, if so, on what grounds would they be selected? To the extent that there are concerns about undue focus on revenue generation by technology transfer offices, is there any reason to expect that faculty inventors and their external agents would be less preoccupied with that objective? Why would any external agent or prospective licensee pursue an agreement if the owner of the technology could, in the end, veto its terms? It may be possible to address these questions satisfactorily. The point here is simply that that has yet to be done.

IMPROVING THE SYSTEM OF UNIVERSITY IP MANAGEMENT

The system of IP management that has evolved in nearly all U.S. research universities is certainly not immutable and in many ways could be improved. The committee's findings point in particular to the need for greater

- clarity and balance in what goals are to be served and how performance is judged;
- flexibility in how technology transfer offices are organized and conduct their business;
- observance of community-generated "good practice" guidelines, such as the Nine Points to Consider in Licensing University Technology;
- flexibility in the terms of research sponsorship, licensing agreements, and exchanges of research tools and materials;
- recognition of the limited role of university-owned IP in transferring technology to established firms;
- development and use of broader measures of performance and new modes of evaluation of technology transfer; and
- transparency and accountability to the public.

The remainder of this chapter recommends approaches to achieving these needs.

INSTITUTIONAL TECHNOLOGY TRANSFER MISSION AND PRINCIPLES

Few universities give a clear policy mandate to their technology transfer offices and personnel, or they give equal emphasis to multiple objectives.[125] The four mandates most commonly articulated are (1) knowledge dissemination, (2) regional economic development, (3) service to faculty, and (4) generation of revenue for the institution. More recently, a fifth goal has been advanced by some groups: addressing humanitarian needs, especially food and health needs in developing countries but also therapies for diseases affecting small populations underserved by commercial markets. These goals are often in tension with one another, making patenting and licensing decisions difficult, performance hard to evaluate, and possibly distorting effort.

Recommendation 1: The leadership of each institution—president, provost, and board of trustees—should articulate a clear mission for the unit responsible for IP management, convey the mission to internal and external

[125] M. Sharer and T.L. Faley. 2008. The strategic management of the technology transfer function – aligning goals with strategies, objectives, and tactics. *Lew Nouvelles* 43(3)170-179.

stakeholders, and evaluate effort accordingly. The mission statement should embrace and articulate the university's foundational responsibility to support smooth and efficient processes to encourage the widest dissemination of university-generated technology for the public good. Whether the primary emphasis is on global, national, regional, or local benefits is likely to depend significantly on the nature of the IP and vary with the type of institution (public or private), its history, research intensity, primary sources of financial support, and educational characteristics. This places IP-based technology transfer squarely within the university's core mission to advance discovery and learning and to contribute to the well-being of society while recognizing institutional differences. Also, industry research sponsors should explicitly allow requests by other academic scientists for materials developed in the course of studies they have sponsored at a university.

The licensing of technology to the private sector can yield financial returns to the university and faculty in many forms, including opportunities for faculty involvement in further development of the technology; follow-on corporate-sponsored research agreements with the institution; donations to the institution from successful entrepreneurs; and direct revenues from licenses, infringement litigation, and sale of IP rights. Although it is reasonable to seek to defray the cost of technology transfer operations, patenting and licensing policies and practices should not be predicated on the goal of directly raising substantial, positive net revenue for the institution. Not only is the likelihood of very significant payoff from IP-based transactions slim and disappointed expectations high, but also that misplaced priority may divert universities from their mission to advance social welfare. More specifically, it unduly risks narrowing the focus and elevating the effort to commercialize those few inventions that appear to offer the greatest prospect of financial return to the neglect of others that may yield equal or greater social benefits. As with research itself, it is exceedingly difficult in technology transfer to predict with confidence what the successes will be. This does not mean that institutions, especially ones with substantial biomedical research portfolios, should be unprepared in the event that an opportunity for substantial revenues arises. This should involve consideration of what distribution of revenue (among the investors, the originating laboratory or department, and the institution) is appropriate in such circumstances.

INVOLVEMENT OF STAKEHOLDERS

In addition to university administration support and guidance, a successful technology transfer program depends on consultation with and involvement of three stakeholder communities: investors, business, and faculty.

Faculty generally knows the characteristics of their inventions and possible applications better than university administrative personnel and may well be more familiar with potentially interested investors and business partners. Where this is the case it is appropriate for faculty to assume a lead role in identification of and discussions with prospective licensees or with prospective investors in a new start-up enterprise, subject to university approval of formal agreements. It is also appropriate for faculty inventors to have the option of taking title if the university decides not to pursue transfer of an invention. Finally, anticipating that disputes will arise between inventors and their institutions' administrations over patenting and licensing matters, the university should establish a fair and transparent process for appealing technology transfer office decisions,[126] as well as consulting with the funding agency that has residual rights before the inventor.

> **Recommendation 2:** Universities with sizable research portfolios should consider creating a standing advisory committee composed of members of the faculty and administration; representatives of other business development units in or affiliated with the institution such as business incubators, research parks, proof-of-concept centers, and entrepreneurial education programs; members of the relevant business and investment communities; and, if appropriate, local economic development officials. The committee should meet regularly to help the technology licensing unit elaborate practices consistent with the institution's goals and policies, consider how best to exploit inventions where the path to wide availability and broad public benefit is not clear, and identify new opportunities.
>
> A separate committee of faculty, employee, and administration representatives (who may or may not also serve on the advisory committee) should be charged with advising on university policy regarding technology transfer and hearing and helping to resolve disputes between inventors and the technology transfer office with respect to the protection and commercialization of inventions. Both the full advisory committee and the internal committee should make recommendations to the provost or other executives of the university.

Rules of confidentially would apply to particular cases. Generally speaking, this is not to suggest that the advisory committee consider individually how to handle particular invention disclosures, a process that could occasion counterproductive delays. But there may be exceptional cases that are

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[126] Because these disputes will involve employees of the institution and thus personnel matters, the most appropriate composition of the internal panel is one composed of university personnel.

precedent-setting or pose particularly difficult issues in design of a development strategy and these cases may benefit from a broader perspective than that of the technology transfer office personnel. The internal committee should not be charged with investigating disputes over inventorship, which is a legal matter.

ORGANIZATIONAL GUIDELINES AND USE OF EXTERNAL RESOURCES

The principle of university management of IP does not necessarily dictate one mode of organization or locus of the function. These can vary with the characteristics and needs of institutions and the mandate given to the technology transfer office. Each university should determine, however, who the responsible party would be (e.g., the technology transfer office, the office of sponsored research, or university general counsel) for submitting any of the required reporting under Bayh-Dole with respect to disclosure of new inventions, decision on whether to retain title to the invention, and information regarding the utilization of the invention.

> **Recommendation 3:** There is a strong theoretical case and some empirical evidence that the technology licensing unit is more effective when exposed to broader issues in the financing and conduct of research. That objective is best served by locating the technology transfer office in proximity and making it accountable to the university's research management, for example, reporting to the provost or vice provost for research and allied or integrated with the office of sponsored research.

Whether technology transfer and research administration functions are formally combined is less important than whether technology transfer personnel carry out the fundamental purpose of maximizing transfer for productive use for societal benefit and understand that their responsibility is first and foremost to serve the institution's core missions, perceive the institution's stake in productive long-term relationships with private and public research sponsors, and cultivate fair and open relationships with faculty and staff who generate the inventions being managed.

The principle of university ownership does not mean that the responsible unit must perform internally all of the functions typically associated with current technology transfer offices.[127] Indeed, some of these must be conducted cooperatively within the institution—with faculty, other administrative offices, and academic units–and may be more effective if shared with or outsourced to entities outside the institution, for example, contract consultants, local economic development agencies, and even other universities or groupings of institutions.

Despite the scarcity of research findings on the comparative effectiveness of technology transfer activities across institutions, one set of differences is strikingly obvious: Institutions vary greatly in size, composition, and resources;

[127] See below for our preliminary effort to distinguish technology transfer office functions appropriate for outsourcing from those that may not be appropriate to delegate.

in the scope and diversity of their research portfolios; and in their proximity to entrepreneurial investment and business environments oriented toward high technology. Thus, both the volume of potentially commercially viable research results and the "demand" for them vary greatly from one institution to another. Because of the wide variability in size, scope, and mission of institutions, there cannot be a single template for technology transfer that all institutions should attempt to model.

It makes little sense for small institutions with narrow research portfolios to try to imitate the characteristics and practices of major research universities with large and diverse portfolios and technology transfer operations. Nevertheless, this has been the pattern, perhaps strongly motivated by the uniform set of organizational and performance characteristics collected and publicized by the annual AUTM survey. This is not optimal, and for some institutions it means relatively large wasted expenditures and low reputational rankings.

> **Recommendation 4:** Smaller institutions and those with less experience should consider the following options for technology transfer policies and practices: (1) permitting greater outreach by faculty and others who have the experience and inclination to pursue entrepreneurial development of their ideas; (2) inter-institutional agreements—collaborating with larger institutions in the same region or in fields with complementary research strengths or engaged in research collaborations; or (3) outsourcing certain functions to private entities with appropriate skills and contacts, perhaps focused on particular technology fields or markets. The latter practices may also be appropriate for larger institutions with IP portfolios in fields such as information technology, where aggregations of patents are often necessary to achieve value.

Larger institutions should consider agreements with other institutions for work sharing, especially in areas where investigators of both institutions are research collaborators. Typical technology transfer office functions that may be amenable to sharing or outsourcing to specialized contractors are the following

- invention disclosure evaluation and market assessment;
- patent filing strategy, application preparation, and prosecution;
- licensing versus start-up selection;
- licensing strategy and negotiation;
- marketing and business plan development;
- ongoing management of contracts and licenses; and
- database and financial management.

Functions that may be inappropriate or less amenable (in whole or in part) to outsource are

- contract and license review and approval;

- Bayh-Dole compliance;
- advising university leadership about institutional policies; and
- decisions regarding intellectual property enforcement.

There are technological fields in which technology transfer outsourcing or IP aggregation across fields may be particularly appropriate for small and large institutions alike. In information technology applications, for example, individual or small numbers of patents tend to be much less useful than in life science. Bringing related informational technology patents together for licensing could occur either directly through a technology transfer office's coordination of its holdings and strategies or through specialized third parties, subject to the caveat listed in the next section that universities should be cautious about using third-party aggregators that seek solely to enforce their patents against producers and service providers.

PATENTING, LICENSING, AND ENFORCEMENT PRACTICES

> **Recommendation 5:** Universities should pursue patenting and licensing practices that, to the greatest extent practicable, maximize the further development, use, and beneficial social impact of their technologies.

Exclusive licenses generally should be reserved for technologies that require significant follow-on investment to achieve commercialization, or where exclusivity is needed to confer a competitive advantage (so-called rival-in-use technologies). For technologies that are not rival-in-use or require little or no follow-on investment, nonexclusive licenses are generally warranted. Many or most research tools, for example, should be managed in a fashion that is consistent with the broadest possible use and access, for example, by royalty-free licenses or royalties limited to recouping university direct expenses in acquiring patents and managing the licensing process. There may be several reasons for patenting a technology that is made available without a fee or only a modest fee, including an important one being "defensive," that is, to preclude patenting by another party that would restrict the availability of the technology. Nevertheless, such inventions are also candidates for deposit into the public domain, and the decision whether to patent or not patent should be carefully considered.

Beyond these general propositions, licensing approaches can vary considerably, even for comparable technologies, depending on circumstances peculiar to the invention, business opportunity, licensee, and institution. Moreover, the distinction between exclusive and nonexclusive licenses need not be as sharp as often suggested, since exclusive licenses can be limited in time, field of application, and geography, and nonexclusive licenses can be limited to a few licensees using the technology for different purposes. Nevertheless, there are other values shared across institutions and articulated in public policy that university licensing should reflect. Recognizing the desire to encourage universities to continue to have their licensing policies reflect shared core values, the Dean of Research at Stanford University convened a small meeting in 2006 of research officers, licensing directors, and a representative from the Association of American Medical Colleges to discuss university technology transfer in the broader context of public policy. After much discussion over the course of the following year, in March 2007, representatives of the 12 participating organizations drafted a set of points for consideration by universities when making decisions regarding technology licensing. These "Nine Points" have since been endorsed by AUTM and over 70 other research organizations, including a number of non-U.S. universities.

Recommendation 6: This committee reviewed the "Nine Points to Consider in Licensing University Technology" and endorses the guidelines most closely related to its charge[128]

- Universities should reserve the right to practice licensed inventions and to allow other nonprofit and governmental organizations to do so. In most cases this should not require a negotiated licensing agreement, although notice of intent to use the invention and awareness of any terms and limitations on use may be required through use of an online click-through license or other simple mechanism.
- Universities should also endeavor to structure licenses, especially exclusive licenses, in ways that promote investment, diligent development, and use, with milestone criteria to back up such requirements.
- Universities should strive to minimize the licensing of "future improvements."[129]
- Universities should try to ensure broad access to research tools.
- Universities should anticipate and do their best to manage or eliminate technology transfer–related conflicts of interest.
- In cases where there is a market for the sale of unlicensed patents, universities should try to ensure that purchasers operate under a business model that allows for commercialization rather than a model based on threats of patent infringement litigation to generate revenue.
- Universities should be careful to avoid working with private patent aggregators whose business model is limited to asserting patents against established firms rather than seeking to promote further development and commercial application of the technology.
- Universities should try to anticipate which technologies may have applications that address important unmet social needs unlikely to be

[128] Unlike the drafters of the "Nine Points," this committee did not consider the relationship between licensing patents and compliance with national security export controls.

[129] The "Nine Points" document points out that licensees often seek guaranteed access to future improvements on licensed inventions and that such access may effectively entangle a faculty member's research program to the company. As such, the "Nine Points" discourage giving exclusive licensees rights to "improvement" or "follow-on" inventions and instead state that licensed rights should be limited to existing patent applications and patents and only to those claims in any continuing patent applications that are (1) fully supported by information in an identified, existing patent application or patent and (2) entitled to the priority date of that application or patent.

served by terms appropriate for commercial markets and to structure agreements to allow for these applications. The principal examples are technologies suited to meeting the agricultural, medical, and food needs of developing countries.

In considering enforcement of their IP, universities should be mindful that their primary mission is to use patents to promote technology development for the benefit of society and that involvement in legal disputes with outside entities can reflect poorly on an institution. Some observers have encouraged universities to see "gold in them thar patents" by enforcing patent rights through litigation and pointing to some lucrative outcomes.[130] Others have cautioned that litigation is a two-edged sword, and universities can find themselves on the losing side.[131]

Caution seems particularly appropriate in enforcement of patents on far upstream basic research discoveries. In March 2010, the Court of Appeals for the Federal Circuit reaffirmed a three-judge panel decision in *Ariad v. Lilly,* invalidating patents of Harvard, MIT, and the Whitehead Institute for Biomedical Research on the cell signaling pathway NF-kappa-B for lack of sufficient written description. In a concurring opinion, Judge Pauline Newman wrote, "the subject matter is indeed basic research, which was taken to the patent system before its practical application was demonstrated." In addition, prosecution of a patent infringement suit is usually exceedingly expensive and in most cases a drain on university resources with very substantial opportunity costs. Accordingly, enforcement through litigation is rarely the preferred option to resolve a dispute, although it is an option important for universities to retain.

Recommendation 7: A university's decision to initiate legal action against an infringer should reflect its reasons for obtaining and licensing patents in the first instance. Examples include

- contractual or ethical obligations to protect the rights of existing licensees to enjoy the benefits conferred by the licenses;
- disregard by infringer of scientific or professional norms and standards, such as use of medical technologies outside standards of care or professional guidelines; and
- disregard by an infringer of the institution's legitimate rights, for example, as evidenced by a refusal to negotiate a license on reasonable terms.

FACILITATING MATERIAL TRANSFERS

Although only partially related to protecting IP interests, evidence suggests a growing reluctance on the part of research scientists to share biological

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[130] A. Poltorak. 2009. Thar's Gold in Them Thar Patents. *University Business*. Available at: http://www.universitybusiness.com/viewarticle.aspx?articleid=1408.

[131] J Sarnoff and C Holman. 2008. Recent developments affecting the enforcement, procurement, and licensing of research tool patents. Unpublished Manuscript.

research materials. Moreover, in a significant number of cases, institutions require the use of Material Transfer Agreements (MTAs) to handle requests for such exchanges. MTAs are intended to protect the institution's ownership interest in the research material and impose conditions on distribution and use. In the committee's judgment, the use and complexity of these agreements and the time consumed in negotiating them have become overly burdensome.

Recommendation 8: To facilitate the exchange of scientific materials among investigators, especially those engaged in nonprofit sector research, research sponsors should explicitly encourage and monitor compliance with requests for materials. Moreover, technology transfer offices should in the future either

- cease requiring use of Material Transfer Agreements when their investigators and colleagues at other nonprofit research institutions are exchanging non-hazardous or non-human biological material for in vitro research or
- use only the Uniform Biological Material Transfer Agreement or the Simple Letter Agreement recommended by the National Institutes of Health (NIH).

NIH should reiterate its support of these options; monitor the actions of grantees and contractors with regard to material sharing; and, if necessary, require their compliance with this policy. Industry sponsors should follow similar practices, encouraging material exchanges and refraining from demanding overly restrictive conditions. University technology transfer and sponsored research offices should discourage investigators from entering into sponsored research agreements where the terms governing material exchanges between nonprofit institutions deviate from this policy.[132]

LAUNCHING START-UP ENTERPRISES

Launching a stand-alone new firm may be the best or only option for commercializing a new technology, particularly when its use would displace existing methods and disrupt established business models. Institutions that are inclined or encouraged to engage in launching new firms as a major part of their technology transfer mission need to recognize a number of conditions for success that universities traditionally have not provided and that licensing to established firms does not demand.

[132] This recommendation is similar to a recommendation of the National Academies' Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation. NRC, 2006. This formulation was endorsed May 7, 2009, by 11 leading U.S. research universities including the California Institute of Technology, Columbia, Harvard, Johns Hopkins, MIT, Princeton, Stanford, University of Chicago, University of Pennsylvania, Washington University, and Yale.

First, a technology or idea generated in the course of research, although at an early stage of development making it unattractive to established firms, nevertheless must have the potential to meet a market need that may not have been conceived. Formal protection of the idea or technology through patenting may or may not be critical to commercializing it; in any case, it is only the first step. Second, the need must better lend itself to exploitation by a new, small firm, than by an existing enterprise. Third, there must be a plan to develop the business, which may change radically as the enterprise develops but nevertheless focus attention on the pathway to commercialization. Fourth, the business needs investment capital. Finally, the enterprise requires skillful management to grow and provide returns to the investors. However important it is for the faculty inventor to provide ongoing technical advice to the new enterprise, rarely is she or he suited to the role of senior manager.

Notwithstanding these conditions encountered in launching start-ups, in recent years a number of institutions have successfully launched start-ups based on their faculties' technologies. The generally large institutions that have successfully spun off a number of companies have created a culture that recognizes and rewards entrepreneurial activity. Some are fortunate to be located in highly entrepreneurial business environments where angel and venture investors are seeking out new opportunities. In these localities, the institution can assist in connecting the researcher and her or his idea to a community of strategists, inventors, and managers. In other cases, universities have created assets that previously did not exist in the university or the community and that provide a supportive infrastructure for new business development and growth. The capabilities vary from institution to institution but include

- on-campus and off-campus incubators and science and technology parks that enable start-ups to access expertise and share facilities and services;
- entrepreneurial centers that train students and advise faculty on business plan development;
- centers that provide funds for follow-on pre-commercial technology development; and
- early-stage investment funds drawing from endowments, alumni, or other university-affiliated sources.

When launching a start-up enterprise, the technology transfer office, which is able to acquire IP protection but usually not equipped to develop a business plan or marshal capital and managerial talent, tends to play a subordinate role in the process and sometimes is seen as a regulatory obstacle focused on licensing terms that may or may not reflect the risks and uncertainties entailed in taking an entirely new enterprise from formation to commercial success. Rarely embedded in the infrastructure created to support entrepreneurship, the technology transfer office may view the other elements as competitive, when there is a premium on effective collaboration if spin-offs are to succeed.

Two caveats require consideration: first, the development of an entrepreneurial culture in an institution and establishment of a suite of university services to support entrepreneurial ventures can be a lengthy and expensive process.[133] Second, the return to the institution is rarely the payoff from an equity investment in a Google or a Yahoo! that has a successful initial public offering. Initial public offerings became increasingly rare following the dot-com crash of 2001[134], and the university's initial ownership stake is likely to be diluted in successive rounds of private financing before going public. Rather, the rewards can be the availability of a new technology, university association with the creation of new jobs, and the goodwill of successful entrepreneurs. Thus, the committee believes that best practices for the development of an entrepreneurial culture require the following

Recommendation 9: Universities engaged in licensing technologies to a new enterprise should ensure that a process is in place not only for securing IP protection but also for evaluating whether the technology is more appropriate for development and commercialization by a start-up rather than an established firm and for determining that the requisite assets for the start-up's viability are in place or in process. These assets generally include a clear conception of market need, a vetted business plan, investment capital, and management with appropriate skills. In some universities, diverse units might contribute to creating some of these assets. In other cases, they are largely handled externally. Regardless of the extent of the university's involvement, the technology transfer office can increase the odds of a university spin-out company's success by helping to ensure that such assets are available from internal or external providers. To the extent possible the university administration should try to ensure that the key inputs are available and coordinated.

The technology transfer office can enhance the cooperation of faculty, staff, and student researchers and contribute to entrepreneurial success by streamlining the licensing of new ventures.

Recommendation 10: Universities seeking to encourage entrepreneurship should consider instituting an expedited procedure and more standardized terms for licensing university-generated technology to start-up enterprises formed by faculty, staff, or students of the institution. The decision to extend such a license should depend on the existence of a vetted business plan, absence of conflicts of interest, and evidence that the principals, per Recommendation 9, have sought out competent managerial

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[133] See Jon Fjeld: The Challenges of Creating New Ventures to Commercialize University Technologies, presentation to the Committee on the Management of University Intellectual Property, The National Academies, August 28, 2008.

[134] National Research Council. (2009) *Investor Exits, Innovation, and Entrepreneurial Firm Growth: Questions for Research. Summary of a Workshop.* Washington, D.C.: National Academies Press.

and other expertise to enhance the enterprise's commercial viability. There may be circumstances justifying the university's departure from the standardized, expedited procedure for specific inventions or inventors. However, both the conditions and the grounds for discrimination should be articulated *ex ante* to avoid arbitrariness in the process, align expectations, and make the process as efficient as possible. With respect to the university's equity stake and/or royalty rates, these terms are likely to vary from institution to institution and from one technology field to another, but they should reflect sensitivity to the exigencies facing start-up enterprises in their earliest phases, and they should provide for predictability and simplicity with a view toward reducing transaction costs that may be especially burdensome for prospective entrepreneurs with limited time and resources.

This recommendation is intended to support venture creation as a vehicle for technology transfer for social good and, to this end, is also intended to encourage staff cooperation with the technology transfer office, facilitate cooperation among elements of the support structure for entrepreneurship, and result in more accurate reporting of entrepreneurial activity.

RELATIONS WITH PRIVATE RESEARCH SPONSORS

Although privately sponsored research is largely unregulated, most universities have claimed ownership of the inventions derived from it and disclosed by faculty and staff. This is because it is in the financial interest to do so and because it makes for greater administrative simplicity, especially when a research area or research team has a mix of public and private support. For some public institutions, the practice may be dictated by state law. Licensing terms in the case of federally sponsored research are minimally constrained by the Bayh-Dole Act (e.g., small business preference, domestic exploitation preference) and to some limited extent by agency sponsor (e.g., NIH guidance on exclusivity versus nonexclusivity). In the case of privately sponsored research, licensing terms are set case by case by individual agreements. Accordingly, there is much greater heterogeneity.

Negotiating the terms of IP arrangements with private sponsors often has been perceived by observers to be accompanied by friction and delays. These have not been systematically documented, but they have been the subject of ongoing discussion in various university-industry forums. Collective efforts to reduce the friction and delays perceived to be associated with many negotiations over the terms of research sponsorship agreements (e.g., discussions by the Government-University-Industry Research Roundtable at The National Academies, and the University-Industry Demonstration Partnership's "turbo negotiator" software for streamlining IP negotiations) have focused on improving understanding and acceptance of the objectives and constraints on both sides of a relationship rather than on changing its terms. These efforts have had partial success, but complaints about the intransigence or ignorance of one side or the other remain common. Systematic data on time to agreement and issues arising in negotiations have not been collected, although there is some survey evidence to suggest that the greater ease of negotiating IP terms with some non-U.S. institutions is a factor (cost is another) in U.S. multinational companies' decisions to locate R&D activities offshore[135]. Less attention has been paid to the emergence of non-traditional types of agreements in part, perhaps, because neither the university nor the firm is eager to advertise its willingness to negotiate such terms.

Universities generally insist on acquiring title to inventions resulting from foundation- and corporate-sponsored research for several reasons. Where publicly and privately sponsored research activities are so commingled that the source of funding for a particular invention cannot be identified, it may not be possible to hand title to the sponsors. Further, foundations and corporate sponsors often decline to pay anything near the university's full research overhead costs or even the federal rate, thus imposing a financial burden on the institution. Nevertheless, there may be circumstances where exceptions are justified to promote commercialization.

There are now several examples of arrangements that depart from the norm of university ownership and licensing for a fee.[136] Although they have not been evaluated in operation, some of these appear to offer promise of reducing friction and delay in the negotiation of sponsorship agreements with private partners. Examples brought to the committee's attention include the following:

- Corporations offer and universities accept a percentage premium on research contracts in lieu of negotiating future royalty terms.
- For work that does not represent leading-edge, knowledge-enhancing research, some universities give corporate sponsors title to results.
- Universities grant corporate sponsors royalty-free nonexclusive licenses to research results where the company pays the full costs of the research in question.

Recommendation 11: University technology licensing and sponsored research offices should explore arrangements with private research sponsors that promise to obviate the often protracted process of negotiating licensing terms, the principal source of friction and delay in reaching agreement.

ENSURING EVALUATION AND ACCOUNTABILITY

INSTITUTIONAL LEVEL

Recommendation 12: Universities should periodically review the operations of their technology transfer offices in a manner similar to the

[135] Thursby and Thursby, 2006, op. cit.

[136] Some IP property arrangements with for-profit entities may call into question the eligibility for tax-exempt bond financing of facilities in which the research work is performed.

evaluation of academic and administrative units. This could involve the formation of a visiting committee with members drawn from other institutions' technology transfer offices generally recognized as high performing; members of the relevant business and investment communities; and representatives of research sponsors, faculty, and economic development organizations.

The reviewers' evaluation should focus on the broader technology transfer environment of the university and the roles of various stakeholders in it. Care needs to be taken to ensure that outside evaluators understand the scope of the technology transfer unit's responsibilities, the reasons for its location in the institution's administration, and its relationships with other entities involved in the process.

If possible, the process should entail efforts to ascertain the views of faculty members, research sponsors, and those responsible for related activities within the institution. Careful thought must be given to what performance measures should be posed to these constituents. Such measures should extend well beyond number of patents applied for and issued, number of formal licensing agreements, and revenue received. Appropriate process metrics include how long agreements take to negotiate, satisfaction with service among faculty and licensees, how many technologies are being promoted at any time, how well technology transfer personnel qualifications are suited to this diversity, how many contacts are made in the course of marketing the technologies, and whether the technology transfer office is imposing out-of-pocket costs on the institution that are unjustified or unsustainable. In addition, an effort should be made to develop outcome measures appropriate to the university's mission, such as the number of people benefited or the extent of reduction in mortality and morbidity. Financial self-sufficiency should not be the pivotal criterion if the university sees as its mission ensuring that its research has the broadest utility and impact.

NATIONAL LEVEL

Because of the measures used, data regularly reported on university technology transfer activities can provide only a narrow window on the totality of knowledge transfer and exchange activities that are occurring in a university at any time. These data suffer from two major deficiencies. First, they largely ignore the principal avenues of transfer—publication, networking, teaching, student placement, consulting, conferences, public meetings, and collaboration—which are largely outside the remit of technology transfer offices. For these avenues, at least in the United States, there are no simple statistics for assessing changes, benchmarking institutions, or making international comparisons. The second deficiency is that the data used draw disproportionate attention to the volume of transactions—number of invention disclosures filed, patents issued, licenses concluded, spin-offs created—and the resulting revenue totals. Institutions fortunate to receive windfall income from one or two inventions appear to be highly successful; institutions unable to cover their technology transfer operational expenses are likely to be considered underperformers.

AUTM's annual survey, although it provides much useful information, fails to put IP-based transactions in the context of knowledge dissemination broadly, ignores vast differences in capacity—not merely performance—among institutions, and distorts incentives especially for the least well-endowed and experienced institutions. AUTM has formed a committee to design a more comprehensive survey of university technology transfer. The Association of Public and Land-grant Universities is developing a similar template for individual public institutions to use in self-assessment. Both rely to a large extent on the U.K. measurement efforts described above as a model.

Moreover, the National Science Foundation is considering adding a technology transfer module to its annual survey of university and college R&D expenditures. NSF has asked the university community to identify new measures that contribute to understanding of the role of universities in economic growth; lend themselves to statistically meaningful national characterizations; and can be collected by academic institutions. In responding to NSF's request, over the past year considerable attention has been paid to identifying metrics other than traditional ones (such as patents, licensing, and revenues) that capture three broad areas of university activity: (1) development of human capital and the movement of knowledge; (2) entrepreneurial endeavors; and (3) partnerships and other means of faculty, staff, and student interactions. It is critical that the data collected are based on comparable measures across all institutions reporting so as to allow for effective analysis and evaluation.

> **Recommendation 13:** Principal university and professional organizations and federal science agencies should coordinate efforts to develop a more balanced set of measures of total university knowledge exchange with the private sector to improve understanding of the process and its performance. This should result in a manageable set of questions incorporated in National Science Foundation's annual survey of higher education institutions' expenditures on research and development and in other private surveys. To the extent possible, the responses should be capable of being linked to other data sets on research outputs, new business creation, and industrial performance.

This effort will of necessity take into account the relative strengths of different survey instruments, mandatory data reporting requirements discussed below, the capacity of respondents within a single institution and across institutions to provide reliable comparable responses, and the costs of increasing reporting requirements.

The Bayh-Dole Act is a sound and flexible framework for promoting the commercialization of university-developed inventions resulting from federally sponsored research. The committee has no reason to believe that either governmental retention of title or routine retention of title by individual inventors would yield more commercial applications or achieve a better balance of the public's stakes. Although the Act is effective in its primary purpose, successive administrations have not maintained an effective framework for government oversight, failing to assign oversight responsibility clearly; describe its components; and to establish a comprehensive, accessible data collection system to support it.

As discussed in Chapter 2, the Bayh-Dole Act, at 35 USC Sec. 206, authorized the Department of Commerce to develop and, if need be, revise regulations to implement sections 202-204, and report annually to Congress on federal technology transfer activities. In addition, Department of Commerce representatives have served on an interagency working group on technology transfer and, on occasion, have reviewed agency Determinations of Exceptional Circumstances (DECs) with a view to encouraging consistency. The General Accounting Office (GAO) described this as a "coordinating" role.[137] Within the Department of Commerce, these functions have been reassigned several times, ending up in 2007 delegated to the National Institute of Standards and Technology (NIST). The President's Council of Advisers on Science and Technology has twice recommended that this function be upgraded and expanded.

Recommendation 14: There should be a clear assignment of federal government oversight responsibilities, perhaps by Executive Order, including

- ensuring consistent implementation of federal technology transfer laws by all agencies;
- reviewing agency diligence and actions with respect to DECs, government use rights, and exercise of march-in rights;
- revisiting the Department of Commerce regulations implementing several provisions of the Bayh-Dole Act, including the conditions for access to and use of data gathered about inventions;
- heading an interagency committee on technology transfer that would, for example, evaluate and develop a government-wide position on proposed changes to the Act or system; and
- reviewing with other agencies and with representatives of research universities and relevant professional groups the data that should be collected from universities.

To play an effective role, the oversight unit needs to extend its outreach not only to other federal research agencies but also to the university research community.

Effective oversight also depends on the availability of relevant data, and here there is an even more glaring deficiency. The Bayh-Dole Act requires institutions to provide data on actions with respect to federally funded

[137] United States General Accounting Office. 1998. Resources, Community, and Economic Development Division, Technology Transfer: Administration of the Bayh-Dole Act by Research Universities. Washington, DC. RCED-98-126.

inventions to research-sponsoring agencies. In a progressive step, the data depository developed by NIH, iEdison, was made available to other agencies as a central depository for such data. However, GAO has found that institutional reporting is often incomplete and inaccurate, although the most recent review of the database occurred in 2003. Moreover, federal officials, who by regulation are the only parties allowed access to the data, are restricted to data or research supported by their agencies. These circumstances mean that even once there is a functioning oversight entity, it would be seriously handicapped in carrying out its charge.

Recommendation 15: Federal research agencies should reinvigorate the requirement that institutions reliably and consistently provide data to iEdison on the utilization of federally funded inventions, including licensing agreements and efforts to obtain such utilization. Such data should be available for analysis by qualified researchers who agree not to disclose the parties to or terms of particular agreements.

As a practical matter, government officials will have limited capacity to analyze the data required to be submitted; consequently, institutions' incentive to make sure that the data are complete is attenuated. Access should therefore not be limited to the Commerce Secretary's agents or other federal agency officials alone. To advance general understanding and public accountability of the university technology transfer system, qualified researchers should be allowed access to the data for analysis provided that the data are not publicly identified by institution, investigator, licensee, or other affected individual or entity. It does not appear that such access is barred by the Bayh-Dole Act,[138] but will likely require a change in the Commerce Department-issued regulation restricting access to the data to anyone other than a government employee without the permission of the grantee or contracting institution. This limitation, instituted to prevent disclosure of proprietary information, overshot its mark, hampering use and interpretation of the data to improve the system's functioning, including our own review. Approved researchers have for decades had access to equally sensitive government-held data—for example, personal and business proprietary information contained in Census records—without a serious breach of the non-disclosure conditions.

[138] The Bayh-Dole Act in 35 U.S.C. Sec. 202(C)(5)(2009) protecting from disclosure information from grantees and contractors tracks closely the language of the Freedom of Information Act (FOIA), 5 U.S.C. (b)(3) and (4), which the Supreme Court has ruled did not remove an agency's discretion to disclose information especially in de-identified form. *Chrysler v. Brown,* 441 U.S. 281 (1979). Further, case law suggest that information that is exempted from disclosure under FOIA exemption 4 and that therefore is governed by the Trade Secrets Act can be disclosed if release would not (1) damage the competitive position of the entity from which the information was obtained or (2) impair the agency's ability to collect the information in the future. Access to iEdison data by qualified researchers agreeing not to release information identifying a university, firm, or individual is not likely to have either of these effects.

Appendix A

From Concept to Application: Managing the Transfer of Academic Research Results

November 20-21, 2008

The National Academy of Sciences Lecture Room
2101 Constitution Avenue, NW
Washington, D.C.

AGENDA

Thursday, November 20, 2008

8:00 AM to 8:15 AM
Welcome
Mark Wrighton, Chancellor, Washington University in St. Louis, and Chair, Committee on Management of University Intellectual Property
Mark Fishman, President, Novartis Institutes for BioMedical Research, and Vice Chair, Committee on Management of University Intellectual Property

8:15 AM to 9:45 AM
Session 1: ***Organization and evaluation of the technology transfer function within institutions***
Moderated by **Wesley Cohen**, Professor of Economics and Management, Duke University

Panelists:

1. **Martin Kenney,** Professor of Human and Community Development, University of California at Davis
2. **Richard Helfrich,** Partner, Alameda Advisors, Inc.
3. **Dana Bostrom,** Director of Innovation & Industry Alliances, Portland State University
4. **Kristina Johnson,** Provost and Senior Vice President for Academic Affairs, The Johns Hopkins University
5. **Tony Hey,** Corporate Vice President, Microsoft Research

Discussion Questions:

— How well is the university system set up to deal (1) with technology commercialization and licensing in general; (2) across different technologies, for example, software versus biotech; (3) with different firms, large corporations versus start-ups? What differences do you see in approaches undertaken by state and private universities?

- What are the incentives for administrations, faculty, firms, and technology transfer (TT) officers to participate in the TT process? Is the current IP administrative structure on most campuses aligned with these incentives? Are these incentives serving the public interest, assuming that interest to be reflected in effective generation and diffusion of welfare-enhancing innovation?
- Do internal lines of reporting (e.g., via chief research/academic officer vs. via chief business/financial officer vs. via chief legal officer) affect the conduct of technology transfer office (TTO) functions?
- What is the optimal professional skill set of the TTO (e.g., legal, business development, technical specialization, etc.)? To what extent does the real world mix of skills in most TTOs differ from the optimal?
- To what extent do you think a principal TTO mission is and should be the earning of revenue for the institution? Have pressures to earn revenue intensified or been moderated in recent years? How can TTOs resist or reduce such pressure if that should be the case?
- How does AUTM survey reporting affect expectations about TTO performance, especially with respect to revenue raising? What changes could or should be made to support diffusion of welfare-enhancing innovation?
- It is well known that the cost of technology transfer administration on most campuses exceeds the revenue the institution earns through licensing royalties, equity, or lawsuit settlements. In these circumstances should every institution that conducts some research have a TTO?
- Some studies suggest that faculty evasion of the technology transfer office is significant and growing. If you agree, to what do you attribute this? Is it problematic?
- What are the pros and cons of alternative arrangements:
    - Professor's privilege?
    - Outsourcing?
    - Regional (or another basis) coalition of institutions?
- What is the nature of interest, across different nations, in alternative models for tech transfer, commercialization, and licensing?
- How well is the monitoring of the TTOs set up over time?

9:45 AM to 10:15 AM
Session 1 Open Discussion

10:30 AM to 12:00 PM
*Session 2: **Effects of technology transfer and intellectual property management on the norms of the university***
Moderated by **Margo Bagley,** Professor of Law, University of Virginia

Panelists:

1. **Jerome Kassirer,** Distinguished Professor of Medicine, Tufts University School of Medicine
2. **John Walsh,** Professor of Public Policy, Georgia Institute of Technology
3. **Melvin Bernstein,** Vice President for Research, University of Maryland
4. **Rochelle Dreyfuss,** Pauline Newman Professor of Law, New York University
5. **Sheldon Krimsky,** Professor of Urban and Environmental Policy & Planning, Tufts University

Discussion Questions:

— Is there more than anecdotal evidence that the prospect of patenting and commercializing research discoveries has
  - o Changed behavior regarding the disclosure of findings, presentation of papers, or informal conversation around research?
  - o Changed the kinds of research projects undertaken (e.g., more applied, less basic)?
  - o Led faculty to devote less time to teaching and research?
  - o Changed the criteria for faculty promotion and tenure decisions?

— To the extent such changes have occurred, has the quality of research suffered or benefited? Has there been a more rapid or frequent application of research results in the marketplace?

— Has university patenting in particular fields, e.g., biomedical research, inhibited access to foundational discoveries or research tools and thus caused investigators to abandon certain lines of research?

— How does the share of royalty revenue accruing to faculty inventors (vs. research labs, departments, general funds) affect university norms? Would reducing the share help reverse norm deterioration? What unintended effects might it have?

— To the extent that norms of sharing results, data, materials, etc., have deteriorated, is that a function of commercial motives or a function of other pressures, such as greater academic competition, not necessarily associated with formal intellectual property (not only patents but also copyright and trade secrecy)?

— Are national policies needed beyond the current ones (e.g., the informal NIH guidelines on data sharing, research tools, patenting and licensing of genomic conventions, etc.)? Should other federal research agencies adopt the NIH approach?

— With further evidence that IP protection of knowledge that is typically part of public domain ("Anticommons") can strain knowledge flow in academia, effectively taxing progress, are TTOs rethinking their IP strategy?

12:00 PM to 12:30 PM
Session 2: Open Discussion

1:30 PM to 3:00 PM
Session 3: ***Relationships with private research sponsors and best licensing practices***
Moderated by **Craig Alexander,** Vice President and General Counsel, Howard Hughes Medical Institute

Panelists:
1. **Diana Wetmore,** Vice President of Alliance Management, Cystic Fibrosis Foundation Therapeutics, Inc.
2. **Arvids Ziedonis,** Assistant Professor of Corporate Strategy, University of Michigan
3. **Allen Poirson,** Director of Scientific Programs and Licensing, Glaucoma Research Foundation
4. **Louise Perkins,** Chief Scientific Officer, Multiple Myeloma Research Foundation

Discussion Questions:
— Could the process of negotiating research sponsorship or patent licenses be made simpler and more transparent by standard terms, subject to "blockbuster insurance" ensuring appropriate payments to the university and inventor(s) in the event of a highly successful commercial product?
— Many sources have expressed a preference for nonexclusive licensing of patented university inventions on the assumption that access is less restricted. But aren't exclusive licenses frequently limited (by field of use, geography, development requirements, term limits, conditions for nonprofit research use, etc.)? And doesn't the availability of nonexclusive licenses depend on the price—possibly excluding would-be users?
— One company reported on the basis of more than 100 sponsored research agreements with universities that the incidence of commercializable results is very low compared to other benefits to corporate sponsors. One possible inference is that the transaction costs (actual costs, delays, etc.) frequently associated with negotiating special terms, including for IP, are not justified. Is this experience generalizable? Across different fields?
— US-based firms have increasingly concluded sponsored research agreements with researchers at foreign higher education institutions. How much of this is attributable to delays and difficulties in concluding agreements with domestic institutions vs. other factors (e.g., research capability, cost, etc.)?
— The university needs to preserve its ability to publish, teach, and otherwise disseminate the results of research conducted on campus. But aren't there standard terms that protect these values?
— Have not-for-profit foundation sponsors of research encountered resistance from universities to means of assuring all investigators access to research results, data, and materials? If so, does the resistance appear to come chiefly from investigators or university administrations?

— What types of agreements for handling IP have been put in place by foundations and corporations to reduce transaction costs, delays in coming to terms, and barriers to sharing research results and to accelerate application and commercialization?

3:00 PM to 3:30 PM
Session 3: Open Discussion

Friday, November 21, 2008

8:00 AM to 8:15 AM
Opening Remarks

8:15 AM to 9:45 AM
*Session 4: **Spawning new companies out of university research: Start-ups and spin-offs***
Moderated by **Darius Sankey,** Managing Director, Zone Ventures

Panelists:
1. **Thomas Fogarty,** Founder and Chairman of Fogarty Engineering and Institute for Innovation
2. **Donald Siegel,** Dean of the School of Business, State University of New York at Albany
3. **Case Grogan,** Licensing Associate, California Institute of Technology
4. **Steven Lazarus,** Managing Director Emeritus, ARCH Venture Partners
5. **Krisztina Holly,** Vice Provost for Innovation, University of Southern California

Discussion Questions:
— One source familiar with the research portfolio of a major university (with large engineering and medical faculties) estimated that it generates at most six inventions a year that can be the basis of new enterprises. Is that a reasonable estimate of the rate at which such ideas emerge?
— Under what circumstances is the creation of a start-up or spin-off likely to be the most appropriate way of exploiting a university invention vs. licensing an established firm? Are there any criteria for making this determination? Under what circumstances would a spin-off or start-up *not* be appropriate? Does field of technology (information technology vs. life sciences) make a start-up or spin-off more or less appropriate? Is there any rigorous analysis or rule of thumb that other things being equal that promoting spin-offs and start-ups has a higher return on investment of effort than other means of commercializing university technology? Who does or should decide?

- Beyond commercially promising technology, successful technology-based start-ups require at a minimum a sound business plan, management skill, and finance. How and from what sources are these acquired by university spin-offs? To what extent can these be supplied within the university community? From outside? What assets does the university require other than a functioning TT operation? What parts of the university can or must contribute? Is there a threshold university capacity to engage in start-up development? Can institutions with modest resources be successful?
- How important are the following:
  - Technology management/commercialization/entrepreneurship education at the institution?
  - Business school involvement?
  - Incubation on or near campus?
  - University equity participation in lieu of licensing royalties?
  - University-generated seed capital (e.g., through alumni)?
- What should be the terms of university equity participation, extent of management involvement, disposition of equity shares?
- Is there any agreement on how issues of individual and institutional conflict of interest should be handled?
- Are there local business conditions that strongly influence success?
- What counts as success? What is the rate of success? What is the attrition rate of university-based start-ups over 5 to 10 years? Does it differ from start-ups generally? How long does it take for university start-ups to establish themselves?
- Have recent court decisions (e.g., *Medimmune v. Genentech, eBay v. Merck Exchange*) had any impact on licensing terms for university-generated patents?

9:45 AM to 10:15 AM
Session 4: Open Discussion

10:30 AM to 12:00 PM
Session 5: ***Alternatives to intellectual property-based, revenue-generating licenses in promoting technology transfer***
Moderated by **Edward Lazowska,** Bill and Melinda Gates Chair in Computer Science and Engineering, University of Washington

Panelists:
1. **Arti Rai,** Elvin R. Latty Professor of Law, Duke University School of Law
2. **John Maraganore,** Chief Executive Officer, Alnylam Pharmaceuticals–***via conference call***
3. **Steven Lazarus,** Managing Director Emeritus, ARCH Venture Partners
4. **Dana Bostrom,** Director of Innovation & Industry Alliances, Portland State University

Discussion Questions:

— This panel explores the fact that while revenue-generating licenses receive a great deal of attention, they are, in fact, only one of a great number of ways to advance the public good through the transfer of university innovations into practice. We seek here to place revenue-generating licenses in their proper perspective.
— Looking back over the past 20 years, what would you suggest are the most important metrics for assessing the impact of university technology transfer, in rank order?
— How would you compare your rank-ordering to your perception of the motives and goals of the various "actors" in the process: university administrators, university technology transfer officers, faculty inventors, student inventors, regional economic development officials, established companies, venture investors, etc.?
— Again looking back over the past 20 years, how would you rank the effectiveness of various means of university technology transfer: revenue-generating licenses, publication in the open literature, mobility of students and faculty, consulting, industry-sponsored research, industrial affiliate programs, consortia through which participants receive access to technology via NERFs, open-source software, etc.?
— Assess the compatibility of each of these means with the traditional learning, discovery, and engagement missions of research-intensive universities.
— How much university spin-off and start-up activity is independent of formally licensed technology?
— What are the patterns of university faculty and TTO practice with respect to computer software?
— Recently there have been notable examples of contributions of research results to the public domain, such as Science Commons. In what circumstances are these appropriate and effective substitutes for technology transfer based upon revenue-generating licenses?

12:00 PM to 12:30 PM
Session 5: Open Discussion

1:30 PM to 3:00 PM
*Session 6: **Using research results to advance the greater social good***
Moderated by **Alan Bennett,** Executive Director, Public Intellectual Property Resource for Agriculture, Davis, California

Panelists:

1. **Bhaven Sampat,** Assistant Professor of Health Policy and Management, Columbia University
2. **Maria Freire,** President, The Albert and Mary Lasker Foundation

3. **Ashley Stevens,** Director of the Office of Technology Transfer, Boston University
4. **Labeeb Abboud,** Senior Vice President and General Counsel, International AIDS Vaccine Initiative

Discussion Questions:

— What do we know about the adoption of policies within universities to specifically address humanitarian applications of university research results? Does the data indicate that universities could be doing more?

— What is/should be the process within institutions to assess the potential humanitarian application of research results/invention disclosures? Who is involved? Is there an established process or is it case by case? Does it tend to be instigated by investigators or from outside the institution-student groups? Non-governmental organizations? Research sponsors?

— Are there different licensing terms for discoveries with potential to relieve poverty, hunger, disease, and environmental degradation in poor countries? How do licensing terms differ for discoveries with first world applications that do not promise to become commercial markets (e.g., orphan disease treatments)? From discoveries with applications that promise significant commercial markets?

— In what circumstances have pools of IP owned by universities overcome barriers to humanitarian applications of research advances?

— Has the experience been successful? What would you do differently or advise other institutions to do differently?

— There seems to have been progress in addressing the IP needs for certain areas of health and agricultural development. Are there emerging technology sectors needed for global development that represent the next big challenges? How can universities position themselves now to address emerging challenges?

— Our discussion has largely focused on patented technologies. What about access to information and materials? To what extent should universities focus their attention in these areas and with what relative priority?

3:00 PM to 3:30 PM
Session 6: Open Discussion

Appendix B

List of Presenters by Meeting[1]

First Meeting of the Committee
June 30-July 1, 2008
National Academy of Sciences Headquarters
2100 C Street, NW, Washington, D.C.

John Raubitschek, US Department of Commerce (Ret.)
Bob Hardy, Council on Government Relations
Richard J. Johnson, Covington and Burling, LLP
William Zerhouni, Covington and Burling, LLP
John Vaughn, Association of American Universities
Louis Masi, IBM
Erik Iverson, Bill and Melinda Gates Foundation
E. Jonathan Soderstrom, Yale University on behalf of Association of University Technology Managers
Wendy Streitz, University of California System on behalf of Council on Government Relations

Second Meeting of the Committee
August 28-29, 2008
The Keck Center
500 Fifth Street, NW, Washington, D.C.

Susan Butts, The Dow Chemical Company
Mark Allen, Georgia Institute of Technology
Marvin Parnes, University of Michigan
John B. Parks, University of South Carolina
Mark Rohrbaugh, National Institutes of Health
Ann Hammersla, National Institutes of Health
William Rees, Department of Defense
Paul Gottlieb, Department of Energy
Amy Northcutt, National Science Foundation
Linda Katehi, University of Illinois at Urbana-Champaign
Greg Simon, *FasterCures*
Stephen Dahms, Alfred E. Mann Foundation
Robert Lodder, University of Kentucky

[1] Affiliations are at the time of the meeting.

Management of University Intellectual Property Conference
November 21-22, 2008
Third Meeting of the Committee
National Academy of Sciences Headquarters
2100 C Street, NW, Washington, D.C.

Labeeb Abboud, International AIDS Vaccine Initiative
Forest Baskett, New Enterprise Associates
Melvin Bernstein, University of Maryland
Dana Bostrom, Portland State University
Rochelle Dreyfuss, New York University
Thomas Fogarty, Fogarty Engineering
Maria Friere, Global Alliance for TB Drug Development
Case Grogan, California Institute of Technology
Richard Heilfrich, Alameda Capital
Tony Hey, Microsoft Research
Krisztina Holly, University of Southern California
Kristina Johnson, The Johns Hopkins University
Jerome Kassirer, Tufts University
Martin Kenney, University of California at Davis
Sheldon Krimsky, Tufts University
Steven Lazarus, ARCH Venture Partners
John Maraganore, Alnylam Pharmaceuticals
Louise Perkins, Multiple Myeloma Research Foundation
Allen Poirson, Glaucoma Research Foundation
Arti Rai, Duke University School of Law
Bhaven Sampat, Columbia University
Donald Siegel, State University of New York at Albany
Ashley Stevens, Boston University
John Walsh, Georgia Institute of Technology
Diana Wetmore, Cystic Fibrosis Foundation
Arvids Ziedonis, University of Michigan

Fourth Meeting of the Committee
February 17-18, 2009
The Keck Center
500 Fifth Street, NW, Washington, D.C.

Ed Roberts, Massachusetts Institute of Technology
Lesa Mitchell, Ewing Marion Kauffman Foundation

Appendix C

Biographical Information of Committee and Staff

Mark S. Wrighton, Chair, is chancellor and professor of chemistry at Washington University in St. Louis. Prior to moving to Washington University in 1995, he was a member of the faculty at the Massachusetts Institute of Technology (MIT) beginning in 1972. He was head of the Department of Chemistry at MIT from 1987 until 1990 when he was appointed provost. Dr. Wrighton was elected a fellow of the American Academy of Arts and Sciences in 1988 and of the American Association for the Advancement of Science in 1986. In 2001, he was elected to membership in the American Philosophical Society. Dr. Wrighton was a presidential appointee to the National Science Board (NSB) from 2000 to 2006, which serves as science policy advisor to the president and congress and is the primary advisory board to the National Science Foundation. While on the NSB, he chaired the Audit and Oversight Committee. He is co-author of the book entitled Organometallic Photochemistry and served as editor for the Physical Electrochemistry Division for the Journal of the Electro Chemical Society for three years. He served on the editorial advisory boards of Inorganic Chemistry, Chemical and Engineering News, Journal of Molecular Electronics, Chemtronics, Chemistry Materials, Inorganica Chimica Acta, and the Journal of Physical Chemistry and he was consulting editor for the textbook General Chemistry (1st, 2nd, 3rd, and 4th editions). Dr. Wrighton holds a Ph.D. degree in chemistry from the California Institute of Technology.

Mark C. Fishman (IOM), Vice-Chair, is President of the Novartis Institute for BioMedical Research (NIBR), and a member of the Executive Committee of Novartis, AG. From the NIBR headquarters in Cambridge, Massachusetts, he leads worldwide drug discovery research activities in Europe, the US, and China. Prior to joining Novartis, Dr. Fishman was Professor of Medicine at Harvard Medical School, Chief of Cardiology at the Massachusetts General Hospital (MGH), and founding Director of the Cardiovascular Research Center of the MGH where Dr. Fishman's group discovered many of the genes that guide early embryonic organ development, by performing one of the first genetic screens in the model organism, the zebrafish. At Novartis, he has had the opportunity to introduce novel approaches to drug discovery, especially based in principles of developmental biology and translational medicine, and seen these mature into a rich pipeline of new medicines, some already registered for cancer, immunology, and neurology. Dr. Fishman is a Fellow of the American Academy of Arts and Sciences and a member of the Institute of Medicine of the National Academies, US. A graduate of Yale College and Harvard Medical School, he completed his Internal Medicine residency, Chief Residency, and Cardiology training at the MGH.

Craig A. Alexander is vice president and general counsel of the Howard Hughes Medical Institute. As Head of HHMI's legal office, he oversees a staff of attorneys who attend to all of the Institute's legal affairs, including matters directly related to HHMI's scientific endeavors, intellectual property, the transfer of scientific materials, and scientific collaborations. Promoted to his current position in January 2006, Mr. Alexander had served as HHMI's deputy general counsel since 1994. Mr. Alexander joined HHMI as an associate general counsel in 1992 from the Indianapolis law firm of Sommer & Barnard, P.C. Before that, he handled many matters involving HHMI while an associate in the Washington, D.C. office of Paul, Weiss, Rifkind, Wharton & Garrison. A *magna cum laude* graduate of the Georgetown University Law Center, where he was an editor of the law journal, Mr. Alexander received a bachelor's degree in accounting from Butler University in Indianapolis. He is also a certified public accountant. A member of the tax, science, and technology sections of the American Bar Association, Mr. Alexander is also a member of the National Association of College and University Attorneys.

Margo Bagley is a Professor of Law at The University of Virginia School of Law, where she teaches a variety of intellectual property courses including patent law and international patent law and policy. Her scholarship has focused on a number of aspects of patent law, including university-industry technology commercialization issues, the role of morality in biotech patenting, access to essential medicines, and business method patents. Professor Bagley also has taught international patent law and policy in Germany, China and in Singapore. Professor Bagley is a registered patent attorney and practiced law with Smith, Gambrell & Russell, LLP and Finnegan, Henderson, Farabow, Garrett & Dunner, LLP before becoming a law professor at Emory University in 1999. At Emory, she helped develop and implement the TI:GER (Technological Innovation: Generating Economic Results) multidisciplinary collaborative program for teaching technology commercialization in conjunction with faculty at the Georgia Institute of Technology; she joined the University of Virginia faculty in 2006. Prior to pursuing a career in law, Professor Bagley worked in products research and development at the Procter & Gamble Company and as a senior research analyst for the Coca-Cola Company. Professor Bagley holds a B.S. in Chemical Engineering from the University of Wisconsin and a J.D. from Emory University.

Wendy H. Baldwin is Vice President and director of the program on Poverty, Gender, and Youth at the Population Council. Dr. Baldwin works with the Council's regional directors and professional staff on program development, identifying policies and programs to improve the future of young people. She also represents the Council to governments, donor agencies, and population and development organizations. Dr. Baldwin joined the National Institutes of Health (NIH) in 1973, where she served as chief of the Demographic and Behavioral Sciences branch at the National Institute of Child Health and Human Development, and eventually as the deputy director. She ended her NIH tenure in 2003 as deputy director for extramural research for the NIH, directing the office responsible for extramural policies and procedures including Edison, the invention reporting system. She spent four years as the executive vice president for research at the University of Kentucky where she was responsible for the economic development and technology transfer activities. She has testified many times before Congress on topics from stem cells to adolescent pregnancy and has served on committees of the National Academy of Sciences, the American Association for the Advancement of Science, and the Department of Health and Human Services. For the past 20 years she has done work with the World Health Organization in different capacities.

Alan Bennett is professor of Plant Sciences at UC Davis where he has been an active researcher, educator, policy advisor and technology transfer advocate. He has published over 150 scientific research papers in the area of plant molecular biology and is recognized as an “ISI Most Cited Author”. His research has focused on mechanisms of plant cell wall assembly and disassembly which has applications in diverse areas ranging from fruit development to optimization of biofuel feedstocks. Bennett is a Fellow of the American Association for the Advancement of Science (AAAS) and a Senior Fellow of the California Council for Science and Technology (CCST), a science policy advisory council for the State of California. He is also a Senior Advisor to Mars, Inc. and has extensive experience advising and crafting the research agenda of large multinational businesses as well as startup biotechnology companies. Bennett has also been a leader in establishing international research partnerships, particularly in Latin America. He was a primary proponent of a partnership between California and Chilean Universities for research and educational exchanges where he worked closely with the US Ambassador to Chile as well as the Chilean Minister of Foreign Affairs. He currently maintains an office in Chile under the auspices of the Fundacion Para la Innovacion Agraria to support university research and technology commercialization partnerships. Bennett has provided leadership in developing both State and National intellectual property policies. In 2007, he co-chaired a California task force to recommend a technology transfer policy for the California Institute of Regenerative Medicine (stem cell research) and he recently served on the National Academy of Sciences Committee on the “Management of University Intellectual Property”. Bennett is currently working with the US Patent and Trademark Office to provide educational programs throughout the world to “foster innovation and competitiveness by delivering IP information and education in countries with immature IP protection systems”. Bennett co-founded and serves as Chairman of a private non-profit foundation (PIPRA Foundation) whose mission is to accelerate the deployment of technologies for improving the lives of the poor in developing countries. PIPRA Foundation now has support from the Bill and Melinda Gates’ Foundation and is a partner with the World Economic Forum (WEF) and the World Intellectual Property Organization (WIPO) to establish the Global Responsibility Innovation Alliance (http://www.grialliance.org/). Bennett served for over 18 years in a range of

University of California leadership positions, including Department Chair, Divisional Associate Dean in the College of Agricultural & Environmental Sciences, University of California Systemwide Executive Director of Research Administration and Technology Transfer and Associate Vice Chancellor for Research at UC Davis. In these capacities, he has been responsible for research and teaching budgets, for establishing and overseeing research policy and for the management of a portfolio of over 5000 patented inventions, 700 active licenses and revenue in excess of $350MM. He earned B.S. and Ph.D. degrees in Plant Biology at UC Davis and Cornell University.

Wesley Marc Cohen is professor of economics and management at Duke University. After a year as Research Fellow in Industrial Organization at the Harvard Business School and twenty years teaching in Carnegie Mellon University's Department of Social and Decision Sciences, Wesley Cohen (Ph.D., Economics, Yale University, 1981) joined the faculty of the Fuqua School of Business, Duke University, as Professor of Economics and Management in September 2002 and was named the Frederick C. Joerg Distinguished Professor of Business Administration in April, 2004. He also holds secondary appointments in Duke's Department of Economics and School of Law, and is a Research Associate of the National Bureau of Economic Research. Professor Cohen also serves as the Faculty Director of the Fuqua School's Center for Entrepreneurship and Innovation. With a research focus on the economics of technological change and R&D, Professor Cohen has examined the determinants of innovative activity and performance both within and across industries, considering the roles of firm size, market structure, firm learning, knowledge flows, university research and the means that firms use to protect their intellectual property. In recent years, much of his work has focused on the economics and management of intellectual property. He has published in numerous scholarly journals, including the *American Economic Review*, the *Economic Journal, Science*, the *Review of Economics and Statistics*, the *Journal of Industrial Economics*, the *Administrative Science Quarterly, Management Science, Research Policy* and the *Strategic Management Journa*l. He also co-edited the volume, *Patents in the Knowledge-Based Economy*. He served for five years as a Main Editor for Research Policy and served on the National Academies' Committee on Intellectual Property Rights in the Knowledge-Based Economy, and on the National Academies' Panel on Research and Development Statistics at the National Science Foundation. He has taught courses on the economics of technological change, industrial organization economics, policy analysis, organizational behavior, corporate strategy, entrepreneurship and the management of intellectual capital.

Robert Cook-Deegan has been the Director of Duke University's Center for Genome Ethics, Law & Policy in the Institute for Genome Sciences and Policy since July, 2002. Prior to coming to Duke, he was director of the Robert Wood Johnson Foundation Health Policy Fellowship program at the Institute of Medicine (IOM). He worked at the National Academies in various capacities for eleven years. He is the author *of The Gene Wars: Science, Politics, and the Human Genome.* Dr. Cook-Deegan was a congressional science fellow 1982-83, and spent six years at the congressional Office of Technology Assessment. He received his bachelor's degree in chemistry, magna cum laude, in 1975 from Harvard College, and his MD degree from the University of Colorado in 1979.

Mark S. Kamlet is provost and professor of economics and public policy at Carnegie Mellon University. Dr. Kamlet joined Carnegie Mellon's central administrative team after eight-year tenure as dean of the H. John Heinz III School of Public Policy and Management. Dr. Kamlet became a member of the faculty in 1976 and was named a professor in 1989 with a joint appointment in the Heinz School and the College of Humanities and Social Sciences (H&SS). Before becoming dean of the Heinz School in 1993, Dr. Kamlet was associate dean of H&SS and head of its Department of Social and Decision Sciences. Dr. Kamlet served on a U.S. Public Health Service panel to produce national guidelines on applying cost-effectiveness analysis in health care and on three National Institute of Health (NIH) consensus panels to make recommendations on national policies relating to prenatal genetic testing, neonatal screening, and end of life care. He serves on the Institute of Medicine's Health Promotion and Disease Prevention Board, and the Institute's Committee on Poison Prevention and Control. He was recently appointed by the director of NIH to be a member of the Public Access Working Group, which will monitor the impact of open access to results of NIH-funded research. He also has served as chairman of the board of Carnegie Learning and iCarnegie. Dr. Kamlet was instrumental in drafting rules and procedures for the Allegheny County Executive and County Council, and led the county's transition team in the area of information technology. He received his bachelor's degree in mathematics from Stanford University in 1974. Kamlet earned master's degrees in economics (1976) and statistics (1977) and a Ph.D. in economics (1980) from the University of California at Berkeley.

Greg Kisor is vice president and portfolio architect at Intellectual Ventures where he focuses on a variety of projects relating to intellectual property and invention. Prior to joining Intellectual Ventures, Mr. Kisor spent 10 years at Intel Corporation where he held numerous jobs including Principal Engineer & Chief Patent Technologist. As Chief Patent Technologist he was responsible for IP strategy, portfolio developments and license negotiations. Prior to his role as Patent Technologist at Intel Mr. Kisor was the Lead architect for many of Intel's products, including Video & Data Conferencing, Java Implementations, and Digital Video Strategy. Mr. Kisor was Chairman of the United States JPEG Committee and has held many high positions in International Standards, including Head of delegation to ISO/IEC JTC1 SC29 Image Compression Standards. Mr. Kisor also has held engineering and lead architect positions at National Semiconductor and IBM. Mr. Kisor currently holds 15 patents with many more pending and received his B.S.E.E. from the Brigham Young University in 1988.

David Korn (IOM) became Vice-Provost for Research of Harvard University in November 2008, where he is also Professor of Pathology at Harvard Medical School. Prior to that, he was senior vice president for biomedical and health sciences research at the Association of American Medical Colleges in Washington, D.C., a position he assumed on September 1, 1997. Dr. Korn served as Carl and Elizabeth Naumann Professor and Dean of the Stanford University School of Medicine from October 1984 to April 1995, and as Vice President of Stanford University from January 1986 to April 1995. Before that he had served as Professor and Chairman of the Department of Pathology at Stanford, and Chief of the Pathology Service at the Stanford University Hospital, since June 1968. Dr. Korn has been Chairman of the Stanford University Committee on Research; President of the American Association of Pathologists (now the American Society for Investigative Pathology), from which he received the Gold-Headed Cane award for lifetime achievement in 2006. Dr. Korn was a founder and Chairman of the Board of Directors of the California Transplant Donor Network, one of the nation's largest Organ Procurement Organizations, and a founder of the Association for the Accreditation of Human Research Protection Programs. He is a member of the Institute of Medicine of the National Academy of Sciences, and a founder of the Clinical Research Roundtable. Dr. Korn served on the Boards of Directors of the Stanford University Hospital from October 1982 to April 1995, the Children's Hospital at Stanford from October 1984 to its closure, and the Lucile Salter Packard Children's Hospital at Stanford from October 1984 to April 1995. He was a member of the Board of Directors of the California Society of Pathologists from 1983-86. He is co-chairman of the National Academies' Committee on Science, Technology, and Law, on which he has been a member since its inception.

Katharine Ku is Director of the Office of Technology Licensing (OTL) at Stanford University. OTL is responsible for the licensing of various state-of-the-art university technologies and industry sponsored research agreements, material transfer agreements and collaborations. In 2010, Stanford received $65.05 M in gross royalty revenue from 517 technologies, with royalties ranging from $3.00 to $37.95 M. Thirty-nine of the 517 inventions generated $100,000 or more in royalties. Three inventions generated $1M or more. OTL will likely evaluate more than 400 new invention disclosures in 2010. OTL spent $6.3M in legal expenses and concluded 77 new licenses. Of the new licenses, 31 were nonexclusive, 31 were exclusive and 15 were option agreements. OTL received equity from 9 licensees. From 1994-98, in addition to her OTL responsibilities, Ku was responsible for Stanford's pre-award Sponsored Projects Office. Ku was Vice President, Business Development at Protein Design Labs, Inc. in Mountain View, California from 1990-1991. Prior to PDL, Ku spent 12 years at Stanford in various positions, worked at Monsanto and Sigma Chemical as a research scientist, administered a dialysis clinical trial at University of California, and taught chemistry and basic engineering courses. Ku has been active in the

Licensing Executive Society (LES), serving as Vice President, Western Region and Trustee of LES and various committee chairs. She also has served as President of the Association of University Technology Managers (AUTM) from 1988-90. She received the AUTM 2001 Bayh-Dole Award for her efforts in university licensing. In 1999, Stanford OTL received the Licensing Executives Society Achievement Award for licensing, the Society's most prestigious award. Ku was a member of the National Academy of Sciences committee which recently issued a report entitled Management of University Intellectual Property: Lessons from a Generation of Experience, Research, and Dialogue. She is the Secretary of the Certified Licensing Professional (CLP) Board of Governors. Ku has a B.S. Chemical Engineering (Cornell University), an M.S. in Chemical Engineering (Washington University in St. Louis) and is a registered patent agent.

Edward D. Lazowska holds the Bill & Melinda Gates Chair in Computer Science & Engineering at the University of Washington. Dr. Lazowska received his A.B. from Brown University in 1972 and his Ph.D. from the University of Toronto in 1977, when he joined the University of Washington faculty. Dr. Lazowska's research and teaching concern the design, implementation, and analysis of high-performance computing and communication systems, and, more recently, data-intensive science. Dr. Lazowska has chaired the NSF CISE Advisory Committee, the DARPA Information Science and Technology Study Group, and the President's Information Technology Advisory Committee. He is a member of the Microsoft Research Technical Advisory Board, and serves as a board member or technical advisor to a number of high-tech companies and venture firms. He is a Member of the National Academy of Engineering and a Fellow of the American Academy of Arts & Sciences. Twenty Ph.D. students and 23 M.S. students have completed degrees working with him.

Marshall Phelps, Jr. recently retired as Microsoft Corporation's corporate vice president, IP Policy and Strategy. He was responsible for setting the global Intellectual Property Strategies and Policies for Microsoft Corporation. In addition, Phelps interfaces with governments, other companies in the technology industry and outside institutions to broaden awareness of intellectual property issues.

Before transitioning to vice president in 2006, Phelps served as the deputy general counsel for intellectual property in Microsoft's Legal & Corporate Affairs group, where he supervised Microsoft's intellectual property groups, including those responsible for trademarks, trade secrets, patents, licensing, standards and copyrights. He oversaw the company's management of its intellectual property portfolio, which comprises some 13,000 patents issued and more than 12,000 trademark registrations worldwide. Phelps joined Microsoft in June 2003 after a 28-year career at IBM Corp., where he served as vice president for intellectual property and licensing. Phelps was instrumental in IBM's standards, telecommunications policy, industry relations, patent licensing program and intellectual property portfolio development. Also, Phelps helped establish IBM's Asia Pacific headquarters in Tokyo and served as the company's director of government relations in Washington, D.C.

Upon retiring from IBM in 2000, he spent two years as chairman and chief executive officer of Spencer Trask Intellectual Capital Company LLC, which specialized in spinoffs from major corporations such as Motorola Inc., Lockheed Martin Corp. and IBM.

Phelps holds a Bachelor of Arts degree from Muskingum College, a Master of Science degree from Stanford Graduate School of Business and a doctorate from Cornell Law School. He is an Executive-in-Residence at the Fuqua School of Business at Duke University, and also serves on the Board of Visitors. He has also recently been asked to advise Japan’s Ministry of Economy, Trade and Industry on IP matters. And he was elected to the initial class of the Intellectual Property Hall of Fame, in 2006.

Dorothy K. Robinson is vice president and general counsel at Yale University where she has served as Yale's general counsel since 1986 and as an officer of the University for almost as long. In addition to serving as Yale’s chief legal counsel, she also has general oversight of university federal relations. Ms. Robinson is a graduate of Swarthmore College and earned her law degree at the University of California’s School of Law (Boalt Hall). She is a member of the bar of Connecticut, New York, and California, as well as various federal courts. Before coming to Yale in 1978, Ms. Robinson practiced law with the firm of Hughes Hubbard and Reed in New York City. She served as Associate General Counsel at Yale until being named Deputy General Counsel in 1984 and Director of Federal Relations the following year. Ms. Robinson has served on the boards of various national higher-education-related organizations and on committees and task forces of those organizations.

N. Darius Sankey is a currently a Portfolio Director for Central Portfolio Management at Intellectual Ventures. During the course of writing this report, Dr. Sankey served as Managing Director at Zone Ventures, an affiliate venture capital fund of Draper Fisher Jurvetson based in Los Angeles. Dr. Sankey led the Zone Ventures technology assessment efforts and overseen its portfolio investments for over eight years, serving as a board member for several companies including Siimpel Corporation, Lumexis, Inc. and Microfabrica and Neven Vision (acquired by Google). He has led several transactions in the micro electronics, wireless telecommunications, media & entertainment, and business & consumer software sectors. Dr. Sankey has a strong interest in strategizing market applications for basic science research on the university level. This interest has also led him to a position as a visiting professor at the Rady School of Business at the University of California, at San Diego (UCSD). Before his tenure at Zone Ventures, Dr. Sankey worked as a management consultant at McKinsey & Company, Inc. and held strategic planning, consulting, and R&D positions at RAND and AT&T Bell Laboratories. Dr. Sankey holds a B.S. in Physics and Electrical Engineering from MIT and a Ph.D. in Optical Engineering from the Institute of Optics, University of Rochester.

Jerry G. Thursby (Ph.D., Economics, University of North Carolina, 1975) is a member of the strategic management faculty of Georgia Institute of Technology and holds the Ernest Scheller, Jr. Chair in Innovation, Entrepreneurship, and Commercialization. Prior to joining Georgia Tech in 2007, Professor Thursby was the Goodrich C. White Professor of Economics and Chair, Department of Economics, at Emory University. He has also held faculty appointments with Syracuse University, Ohio State University, and Purdue University. Dr. Thursby has published extensively in the areas of econometrics, international trade, and the commercialization of early stage technologies with a particular interest in the role of university science in national innovation systems. His work has appeared in such outlets as *American Economic Review, Journal of the American Statistical Association, Review of Economics and Statistics, Quarterly Journal of Economics, Research Policy, Management Science* and *Science.* Dr. Thursby currently serves on the editorial board of *The Journal of Technology Transfer* and is an associate editor of *The Journal of Productivity Analysis*.

Jennifer L. West is the Chair and Isabel C. Cameron Professor of Bioengineering at Rice University. Professor West's research focuses on the development of novel biofunctional materials. Part of her program has developed nanoparticle-based approaches to biophotonics therapeutics and diagnostics. An example of this work is the application of near-infrared absorbing nanoparticles for photothermal tumor ablation. In animal studies, this therapeutic strategy has demonstrated very high efficacy with minimal side effects or damage to surrounding normal tissues. Professor West founded Nanospectra Biosciences, Inc. to commercialize the nanoparticle-assisted photothermal ablation technology, now called AuroLase and in Phase I clinical trials. Professor West has received numerous accolades for her work. In 2008, The Academy of Medicine, Engineering and Science of Texas honored her with the O'Donnell Prize in Engineering as the top engineer in the state. In 2006, she was named one of 20 Howard Hughes Medical Institute Professors, recognizing integration of world class research and teaching. She has been listed by MIT Technology Review as one of the 100 most innovative young scientists and engineers world wide. Other recognitions include the Christopher Columbus Foundation Frank Annunzio Award for scientific innovation, Nanotechnology Now's Best Discovery of 2003, Small Times Magazine's Researchers of the Year in 2004, and the Society for Biomaterials Outstanding Young Investigator Award. Professor West has authored more than 95 research articles. She also holds 14 patents that have been licensed to seven different companies. West received a B.S. in chemical engineering from Massachusetts Institute of Technology, and M.S. and Ph.D. degrees in biomedical engineering at the University of Texas at Austin.

Anne-Marie Mazza is the Director of the Committee on Science, Technology, and Law. Dr. Mazza joined the National Academies in 1995. She has served as Senior Program Officer with both the Committee on Science, Engineering and Public Policy and the Government-University-Industry Research Roundtable. In 1999 she was named the first director of the Committee on Science, Technology, and Law, a newly created activity designed to foster communication and analysis among scientists, engineers, and members of the legal community. Dr. Mazza has been the study director on numerous Academy reports including, *Managing University Intellectual Property in the Public Interest, 2010; Strengthening Forensic Science in the United States: A Path Forward, 2009; Science and Security in A Post 9/11 World: A Report Based on Regional Discussions Between the Science and Security Communities, 2007; Daubert Standards: Summary of Meetings, 2006; Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health, 2005; Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues, 2004; Ensuring the Quality of Data Disseminated by the Federal Government, 2003; The Age of Expert Testimony: Science in the Courtroom, 2002; Issues for Science and Engineering Researchers in the Digital Age, 2001;* and *Observations on the President's Fiscal Year 2000 Federal Science and Technology Budget, 1999.* Between October 1999 and October 2000, Dr. Mazza divided her time between The National Academies and the White House Office of Science and Technology Policy (OSTP), where she served as a Senior Policy Analyst responsible for issues associated with a Presidential Review Directive on the government-university research partnership. Before joining the Academy, Dr. Mazza was a Senior Consultant with Resource Planning Corporation. Dr. Mazza was awarded a B.A., M.A., and Ph.D., from The George Washington University.

Stephen Merrill has been Executive Director of the National Academies' Board on Science, Technology, and Economic Policy (STEP) since its formation in 1991. With the sponsorship of numerous federal government agencies, foundations, multinational corporations, and international institutions, the STEP program has become an important discussion forum and authoritative voice on innovation, competitiveness, intellectual property, human resources, statistical, and research and development policies. At the same time Dr. Merrill has directed many STEP projects and publications, including *A Patent System for the 21st Century* (2004), *Innovation Inducement Prizes* (2007), and *Innovation in Global Industries* (2008). For his work on patent reform he was named one of the 50 most influential people worldwide in the intellectual property field by *Managing Intellectual Property* magazine and earned the Academies' 2005 Distinguished Service Award. He is a member of the World Economic Forum Global Council on the Intellectual Property System. Dr. Merrill holds degrees in political science from Columbia (B.A.), Oxford (M. Phil.), and Yale (M.A. and Ph.D.) Universities. He attended the Kennedy School of Government's Senior Executives Program and was an adjunct professor of international affairs at Georgetown University from 1989 to 1996.