IP

Intellectual Property

Policy Framework for Intellectual Property Derived from State-Funded Research:

Final Report to the California Legislature Governor of the State of California

January 2006

CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY
INTELLECTUAL PROPERTY STUDY GROUP

California Council on Science and Technology
Intellectual Property Study Group

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California Legislature
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Letter from CCST Leadership

Federal government support of basic scientific research and development (R&D) has been a longstanding cornerstone of American technological leadership. The rules that guide this support — what the government provides and what it expects in return — have been carefully hammered out by government with expert input from the public and private sectors. California now faces a similar set of issues. Like the federal government, it is involved in the creation of intellectual property (IP) through funding from a variety of departments and agencies. Of course, the same is true for other states; but California is in a league of its own as the nation's science and technology leader and home to an economy that dwarfs that of most countries, let alone other states. Although California does not sustain science mission agencies of the scope and scale of the National Institutes of Health or National Science Foundation, the IP its funding helps to generate has been sufficient to raise important questions about how to handle it. For over five years now, these questions have been surfacing in Sacramento, and the only answers so far have been the realization that the issues are complex and far-reaching.

This report is an effort to lay the groundwork for an informed discussion on building a comprehensive set of state policies governing the creation and administration of IP developed with state support. It lays out the essential parameters to consider, including ownership, the kinds of IP that need to be protected, and what's been tried elsewhere. There are many valuable lessons to be learned from the federal government and other organizations, and CCST has brought them together for policymakers to consider. We recognize that there are many related policy issues to consider, and many voices yet to be heard in what will hopefully be a thoughtful and constructive discussion. As its contribution to the discussion, CCST has drawn upon the expertise of its constituent institutions — top research universities, federally funded laboratories, and industry — to create a document that represents the consensus of the science and technology community on how federal policies and other models have shaped the environment for R&D, and what factors to consider in developing a set of policies for California.

The policy decisions the state ultimately makes will have potentially far-reaching consequences. California's vibrant culture of research and innovation is a tremendous asset, but it is an environment that must be carefully managed. There is a role for the state to play in overseeing IP, but in determining its role in managing IP, it must consider the full context of the environment in which research and development is carried out, including federal policies and the realities of the economics of science.

No state has ever taken this approach before to develop a comprehensive intellectual property policy framework. It is fitting that California is the first to have taken this step. It is our hope that the report will serve as a constructive resource for policymakers considering the future of IP policies in the state, and that as a result California can better support an environment to encourage exploration and innovation in years to come.

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Preface

California's high-tech economy is driven by the continual creation and development of innovative technologies. The output of those creative endeavors is called intellectual property, or IP, and the strategies used to protect and manage IP are critically important. The extent to which the development of new knowledge into new products is heavily influenced by the way that IP is handled at the federal and, to a lesser extent, state level. There is risk involved in translating creative ideas to marketable products, and barriers created by inefficient or conflicting policies can hinder the development and commercialization of new products and services. Time-tested models in the private sector and at the federal level show that these barriers can be reduced through efficiencies in time and money, leading to increased opportunities for research and development (R&D).

These models have not yet been applied systematically at the state level, however, and there is no comprehensive and coherent set of policies in place governing IP produced by state-generated works or state-funded works developed by third parties. A 2000 State Auditor's Report noted that California's approach to IP management is Balkanized and its policies are splintered among the various state agencies. The result is that each agency is free to negotiate its own contracts with the institutions that perform research and development with state funds, which includes universities and small and large businesses. Among the consequences of this splintered set of policies is a lack of consensus about IP data, incomplete understanding of the research enterprise and technology transfer, and few, if any, incentives to develop state-funded IP into marketable products.

The California Council on Science and Technology (CCST) was requested to conduct this study by Assembly Member Gene Mullin, who authored first Assembly Concurrent Resolution (ACR) 252 and later ACR 24. ACR 24 requested that the study group provide specific consideration to IP issues relevant to the recently established California Institute for Regenerative Medicine. The request was largely addressed in an interim report released in August 2005. In fulfillment of the expanded scope of ACR 24, some IP issues specific to CIRM are addressed in Appendix E.

In order to conduct this study, CCST convened two groups: a study group and a working group. The study group consists of a diverse collection of 17 leaders from California's science and technology (S&T) community representing a range of experience, expertise, and perspectives in research management, inventor to IP process, federal and state IP process and technology transfer, economics, and public policy. These groups were selected for their knowledge specific to IP policy. While each area of scientific research has its own concerns and issues for policymakers to consider, the analysis presented here is intended to help build a framework applicable across the board; we trust that further studies by experts in these respective fields will enable policymakers to refine policies relevant to individual concerns.

The study group is co-chaired by Alan Bennett, associate vice chancellor for research, University of California, Davis, and Stephen Rockwood, executive vice president, Science Applications International Corporation. Nine of the members are associated with CCST as board members, council members, or fellows. In addition, there are 11 members in the working group, which consists of subject matter experts familiar with IP issues and with the policy interface between the state government and the research community.

These groups represent a broad spectrum of IP-related expertise from many of California's leading institutions, both public and private. In addition, the report has benefited from the input of nearly 50 peer reviewers, both in and outside of CCST. Reviewers were drawn from private foundations, government agencies, academia, venture capital firms, state bond counsel, and high-tech industry, both biotechnology and other. The report has also benefited from the discussion that has ensued following the release of our interim report in August 2005, which has helped the study and working groups refine, clarify and expand key elements of this report in order to serve as a more useful resource to policymakers.

The following analysis and recommendations are intended as a resource for the state. It will hopefully serve as the starting point for a constructive discussion leading to an IP policy framework that will help ensure California maintains an environment conducive to innovation.

Executive Summary

Why does the state fund research?

The state government funds research to stimulate work on research questions that, when better understood or solved, may benefit the state. The benefits flow to the public and to the state in the form of new products, new jobs, increased economic activity, and potentially royalty revenues over a longer term. However, those benefits accrue only if the new knowledge is legally protected in ways that encourage and create incentives for additional investment from the private sector to develop and commercialize new products. Creating the climate for creative research and for investments by the private sector to commercialize new products is a critical issue. The policies for handling intellectual property, or IP, generated with state research funding is perhaps the best tool the state can use to maximize the movement of IP from the ideas to products, and ultimately benefiting the public. IP can be protected by copyrights, trademarks, trade secrets, and patents.

Creating the climate for creative research and for investments by the private sector to commercialize new products is a critical issue.

In order to proceed in developing an informed and effective IP policy framework for California, the Legislature passed ACR 252, which was chaptered in September 2004, requesting specifically that CCST:

"…create a special study group to develop recommendations to the Governor and the Legislature on how the state should treat intellectual property created under state contracts, grants, and agreements…"

This report responds primarily to that request and also to ACR 24, a resolution derived from ACR 252 that requests CCST to look at how IP derived from funding from the state's stem cell initiative could be handled. (Appendix F contains the full text of the two resolutions.) The purpose of this report is to discuss the likely benefits associated with IP created with California state funding, describe models for handling IP, and suggest a policy framework that might be beneficial to the public, the state and the environment for science and technology innovation.

The state clearly plays an important role in identifying what the research questions are in many sectors — in transportation, energy, education, biomedicine, the environment, etc. — and in providing appropriate incentives for the state's best researchers to work on finding answers to those questions. Given that the source of research funds is generally the state's general funds derived from tax revenues or from special fees collected for specific services, we have viewed the state's role as akin to the federal role in supporting research for the public benefit. Our analysis and subsequent conclusions and recommendations are consistent with that primary assumption.

Although state funding is important, clearly non-state funding drives the research conducted in the state's academic and nonprofit research institutions.

Although state funding is important, clearly non-state funding drives the research conducted in the state's academic and nonprofit research institutions. Consequently, the IP policies and procedures that are well-established in these research institutions are in keeping with federal regulations.

Intellectual Property

Intellectual property is the intangible output of creative human endeavors, including research. It can take many forms, such as articles, books, inventions, art forms, algorithms, software, and research tools and is legally protected through a variety of mechanisms, including patents, trademarks, copyrights and trade secrets.

The success of the state's investment in research will depend greatly upon researchers' ability to access data and information, often for multiple purposes.

Of particular importance to research is the treatment and dissemination of research tools and databases. The success of the state's investment in research will depend greatly upon researchers' ability to access data and information, often for multiple purposes. This kind of access is consistent with federal guidelines, particularly those of the National Institutes of Health (NIH). The National Academy of Sciences recently reaffirmed the importance of this kind of access to research.

Objectives for State IP Policies

Through its support of research, the state's mission is to make grants with an ultimate goal of enabling researchers to discover and develop new knowledge that will ultimately be commercialized into new products that benefit the public. The primary objectives of the state's IP policies, therefore, should be to maximize its effectiveness in supporting this mission.

Examples of such objectives might be:

- *Support the open dissemination of research results and transfer of knowledge, where appropriate.*
- *Ensure that discoveries and research tools that are useful for further research are made broadly available to the research community.*
- *To the extent possible, preserve the ability for grantees to leverage non-state funds in their related research.*
- *Encourage practical application of state-funded research results for the broad public benefit.*
- *Accelerate the transition of discoveries from research to commercially available products, preventive measures, diagnostics, and treatments.*
- *To the extent possible, balance existing investments with state investments such that each receives appropriate return.*
- *Promote collaboration between commercial entities and nonprofit research institutions.*
- *Encourage private investors to invest in further research and development of new technologies resulting from state-funded research.*
- *Minimize policy administration costs.*
- *Be mindful of the time delay and private investment needed before significant benefits accrue to the state.*

Ownership of IP Derived from State Funding

Ownership of intellectual property resulting from sponsored research is a central issue in establishing an intellectual property policy. From this primary characteristic many other

policy considerations follow. Long-standing federal policy allows grantee ownership of the outputs of research (e.g., research articles, patentable inventions, databases, research tools, computer programs), which can be protected in a number of ways (copyright, patent, trade secret) depending on the intended or potential use of the IP. In particular, since 1980, the Bayh-Dole Act has permitted universities and other nonprofit recipients of federal funding as well as technology based small businesses to own patents arising out of federally sponsored research.

The state also is a stakeholder in the intellectual property generated by its funding of public universities and other research institutions. Clearly, consistency with federal statutes and policy suggests that ownership of IP resulting from state-sponsored research also should reside with the grantee.

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In considering who is best able to manage IP resulting from state-funded research, strong arguments have been made that IP management should occur at a level that is as close as possible to the research itself — and perhaps more importantly — as close to the researchers as possible. This was the conclusion of the California Technology, Trade and Commerce Agency report of 2003, which recommended that the University of California (UC) — the recipient of the most research funding from the state — decentralize its technology transfer programs to the local campus level. UC has been decentralizing technology transfer for several years and the process is to be completed by July 2007.

If the state or state agency that is the source of funding were to manage IP resulting from its sponsorship, an allocation of additional funds would be required to invest in patent filings as the research results emerge from the laboratory. The source of funding and professional staff required to provide that technical function at the state level is unknown. Research universities and not-for-profit research institutions, which have addressed this issue over the last 20 years, have either established fund sources to support patent filings or utilize the royalty stream resulting from past inventions to support the costs of new patent filings.

Strategies for IP Management

The Federal Bayh-Dole Model

Up through the 1970s, agreements on ownership of inventions derived from federally funded research were negotiated individually with each government agency. This yielded inconsistencies and high transaction costs that too often contributed to ineffective transfer of university IP to private firms for commercialization. Moreover, many promising federally funded research discoveries were not put into widespread use because IP rights were not being licensed for further development. Without strong IP protection, clarity of ownership and the ability to obtain exclusive licenses, companies had little incentive to invest in transforming research discoveries into marketable products that would benefit the public.

The Bayh-Dole Patent Act of 1980 led to the development of consistent invention policies for federally funded research conducted at universities and in small businesses.

The Bayh-Dole Patent and Trademark Amendments Act of 1980 (Bayh-Dole) led to the development of consistent invention policies for federally funded research conducted at universities and in small businesses. It permitted grantees to patent inventions resulting from

federally funded research, which they could then license to other entities, including to private firms willing to invest in commercialization.

Bayh-Dole is quite simple in concept and in practice. It allows universities and other research institutions to claim ownership of inventions developed through federal funding. It also creates a number of requirements for entities that elect to own those inventions.

Under Bayh-Dole, those institutions:

- Must file patents on inventions for which they decide to claim ownership.
- Must have written agreements with faculty and staff requiring disclosure and assignment of inventions.
- Must share a portion of the revenues with inventors.
- Must use any excess revenue to support research and education.

In turn, the Government funding agency:

- Retains non-exclusive rights to the invention for its own uses.
- Retains march-in rights. This permits the government to step in and work to achieve the practical application of the invention if the patent holder or licensee has not done so expeditiously.
- Requires that any manufacturing that results from inventions made with federal funding occur substantially in the United States.

Additional Models for Managing IP: Experiments in Licensing Agreements

In addition to the Bayh-Dole Act, some private groups have invested in exploring other models, with a particular focus on experimenting with licensing agreements. Two privately funded programs are the International AIDS Vaccine Initiative (IAVI) and the Grand Challenges in Global Health Initiative. Both have initiated new strategies for IP that "commit funding recipients and entities seeking to commercialize research to ensure that resulting therapies and products are accessible and affordable to designated low-income populations."

A significant commonality between these private initiatives and federal policies is that the grantee owns all IP generated with funding from these sources.

A significant commonality between these private initiatives and federal policies is that the grantee owns all IP generated with funding from these sources. The experimentation begins with the licensing strategies used to move new knowledge to products that benefit the public.

Return on Investment

Return on the government's investment in research was debated extensively at the federal level prior to and following the passage of the Bayh-Dole Act in 1980, and continues to be a subject of discussion today. These discussions may prove to be of value to the state as it considers how to maximize the state's return on investment, both directly and indirectly.

Who captures the benefits from R&D?

Those who invest in R&D can expect that a substantial fraction of the social return to their investment will not accrue personally to them. There are substantial spillovers between scientific research and innovation, as well as substantial time lags. The principal benefits of R&D have long been understood to be long-term and to manifest in a variety of ways, few of which benefit financially the originator(s) of the research directly.

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In considering a set of state IP policies, it is important to understand that the reward system that motivates researchers depends in large part upon their ability to share some or all of their research, in order to obtain recognition.

Defining "return on investment"

In the near term, economic benefits will most likely accrue to the state from its investment in research through retention and recruitment of high-quality research personnel and enhanced business activity in support of research institutions and programs. In some cases, state funding can be used to leverage additional research funding from federal and private sources. Both of these benefits align with the intent of ACR 252 to encourage participation of small businesses and promote collaboration between commercial concerns and nonprofit organizations, including universities.

Royalty revenues and revenue sharing

We do not recommend that the state focus on royalty revenues as a significant financial return, because history shows that this expectation will not be met and the cost of administration will likely exceed the returns. In any scenario other than the extremely rare "blockbuster" invention, and regardless of the state's IP policies, state-funded innovations and the revenues generated from them cannot realistically be expected to have any significant direct effect on the state's revenues for the immediate future.

However, in those exceptional cases where the licensing royalties are large (for example, with net revenues to the licensor greater than $500K), we recommend the state policy include a revenue sharing agreement between the institution owning the IP and the state agency, with an agreed fraction of the returns going to the agency to support further research within their charter.

The desire for substantial return on investment, in particular by means of high royalty rates on early stage research products, should be balanced with the need to create incentives for the much greater commercial investment that is necessary to develop useful products. Ideally, the state should focus on providing incentives for commercial investment and development of new technologies within the state of California. That strategy will potentially contribute the largest economic impacts in the near term through job creation.

Ideally, the state should focus on providing incentives for commercial investment and development of new technologies within the state of California.

It should also be noted that at the federal level, after considerable debate on the topic of the return on investment to the government, the NIH decided that

the single most important goal for biomedical research was the rapid development and commercialization of products, and that direct financial considerations should be secondary. The same goal can be accomplished at the state level for state-funded research, as it is the most practical benefit to the public.

The State's Handling of IP Generated with State Funding

If the state chooses to play an oversight role, we propose a mechanism that both preserves the state's rights, and minimizes the costs of doing so. We recommend the establishment of an office within a single agency that would serve four functions: track IP generated by state employees; track IP that emerges through state funding of research; monitor the licensing and use of IP; and collect any revenues that the state may receive.

The alternative is to enter into a contract with a private firm to provide those services to the state, in much the same way as the state hires other kinds of expertise. A third alternative is to contract with the University of California to perform this function, as it already manages several state research programs, and has well-established IP management capabilities.

Recommendations

As the state develops its IP policies, consideration should be given to the likely and fairly frequent circumstance where state funds for research would be leveraged with federal funds. At a minimum, the state should recognize that existing institutional policies are driven by Bayh-Dole. Consistency between federal and state policies would avoid conflicts in determining ownership and royalties from cumulative research results involving related projects, possibly supported by a variety of funding sources. To minimize confusion and maximize the return on grant funds, the state's policies should be consistent with, although not necessarily identical to, Bayh-Dole.

We recommend four general principles for the state's IP policy:

- The policy is consistent with the federal Bayh-Dole Act.
- The policy creates incentives for commerce in California from state-funded research to the greatest extent possible.
- The policy encourages timely publication of results to diffuse knowledge widely, and provides guidance on the kinds of data that are desired to be placed in the public domain or available under open source, Creative Commons, or other broad-use licenses, including software and special databases.
- Requires diligent commercialization of IP-protected technology into products that benefit the public.

With these principles in mind, we recommend that the state develop IP policies that accomplish the following:

1. ***Permit grantees to own IP rights from state-funded research.***
2. ***Where appropriate, require that grantees (institutions, individuals, or both) provide a plan describing how IP will be managed for the advancement of science and benefit to California.***
3. ***Grant basic research funds without requiring that grantees commit to providing a revenue stream to the state. If, however, a revenue stream develops over time, require that revenues be reinvested in research and education.***

4. ***Generally, make state-developed research tools widely available to other researchers.***
5. ***Require diligent efforts to develop state-funded IP into applications and products that benefit the public.***
6. ***Retain within the state Bayh-Dole-like "march-in" rights if the owner of IP is not undertaking appropriate steps to transfer or use the technology to benefit the public.***
7. ***Leave license particulars to the owner who is in the best position to judge how best to ensure that discoveries are made widely available through commercialization or otherwise.***
8. ***Reserve the right to use IP by or on behalf of the state for research or non-commercial purposes.***
9. ***Establish and maintain state-administered functions to track all IP generated through state funding.***

Conclusion

State government plays two important roles in funding science and technology research that will encourage the movement of new knowledge into the marketplace and therefore benefit Californians. Its first role is to identify and prioritize the research questions in those areas for which it provides funds, and the second role is to foster the discovery of answers to these questions by providing effective incentives to the state's research community.

California remains a place where high-quality research, entrepreneurship and innovation occur on a large scale. Careful attention to how state policies for IP can create incentives for both researchers and commercial partners will help California continue to be the leader in the nation's research and economic life.

1. Introduction

Key Points:

- **Intellectual property (IP) takes many forms, such as articles, books, inventions, art forms, algorithms, software and research tools. It is protected through a variety of mechanisms, including patents, trademarks, copyrights and trade secrets.**
- **The key role of state funding of research is to encourage researchers to work on questions that, when better understood or solved, will benefit the state.**
- **Although state funding for research is substantial, it is dwarfed by federal and industry funding. IP policies and procedures that are in keeping with federal regulations are well established in universities and other research institutions.**

Intellectual property, or IP, is the intangible output of creative human endeavors. It can take many forms, such as articles, books, inventions, art forms, algorithms, software, and research tools and is legally protected through a variety of mechanisms, including patents, trademarks, copyrights and trade secrets.

Since 1980, the Bayh-Dole Act has permitted universities and other nonprofit recipients of federal funding as well as technology based small businesses to own patents arising out of federally sponsored research. The Bayh-Dole Act applies only to IP generated with federal funding in universities and businesses.

The state is also a stakeholder in the intellectual property generated by state funding of public universities and other research institutions. An attempt was made in 1999-2000 to extend the benefits of technology licensing to the state. Lt. Governor Cruz Bustamante proposed legislation (SB 875) that would have created an office in the Technology, Trade and Commerce Agency to oversee the exploitation and protection of state-owned IP. It was determined, however, that this legislation was premature because the state did not know the extent of its IP and had no mechanism for assessing it. Consequently, SB 875 was converted into a bill that would have authorized the identification and cataloguing of the state's IP, as a preliminary step to establishing technology licensing rights. Ultimately, the bill did not pass for budgetary reasons.

At the same time, in 2000, the California Bureau of State Audits performed an inventory study of California's IP.[1] In this study, the state auditor concluded that the state did not know what IP was in its portfolio, and recommended that the Legislature clarify state IP law and designate a single agency as the lead for developing state IP policy. Since that time, there has been discussion of a "California Bayh-Dole Act" which has identified the existing inconsistencies among state agencies and the potential economic benefits that such an act could bring to the state.

In February 2003, the California Intellectual Property Rights Act (AB 1616) was introduced, which would have represented a reaction against the premise of Bayh-Dole by dedicating all

[1] http://www.bsa.ca.gov/pdfs/reports/2000-110.pdf

state-owned IP to the public domain. The state's public and private universities and research institutions expressed concern, on the grounds that the bill would have significant unforeseen repercussions for state-funded research and would impact the research universities, in spite of amendments added to the bill intended to protect the University of California, California State University, and Community College systems.

At this point, the issues raised by the state auditor remain unsolved: the state still does not know exactly what IP it has and the process for IP policy management remains fragmented.

In order to proceed in developing an informed and effective IP policy framework for California, the Legislature passed ACR 252, which was chaptered in September 2004, requesting specifically that CCST:

> "…create a special study group to develop recommendations to the Governor and the Legislature on how the state should treat intellectual property created under state contracts, grants, and agreements…"

This report responds primarily to that request and also to ACR 24, a resolution derived from ACR 252 that requests CCST to look at how IP derived from funding from the state's stem cell initiative could be handled. (See Appendix F for the full text of the two resolutions.) The purpose of this report is to discuss the likely benefits associated with IP created with California state funding, describe models for handling IP, and suggest approaches to a policy framework that might be beneficial to the state and to the environment for science and technology innovation.

In the sections that follow, we will describe how and why the policies for managing IP can provide an important incentive for researchers. From a policy perspective, we lay out some key objectives the state ought to consider when setting IP policies. We describe the importance of ownership of IP, which drives the entire process. We also offer several examples of strategies for the management of IP, including the Bayh-Dole model, public domain, and patent pooling. We also describe a couple of emerging strategies for IP licensing that are being explored by private foundations. The report then examines the economics of science funding, and the pros and cons of requiring a return of royalty revenues back to the state. Finally, we suggest a mechanism for the state to handle and track IP developed with state funds, and offer recommendations for the state's IP policies. In addition, Appendix E, a supplement to our interim report released in August, provides additional analysis related to IP derived from stem cell research in response to ACR 24.

State-generated and State-funded Research

The state's consideration of IP extends to two broad categories: state-generated and state-funded IP. We define state-generated IP as the IP created by employees of state agencies in the performance of their duties. The state auditor's 2000 survey of state-generated IP found 1,822 registered copyrights and trademarks, and only 15 patents. The ownership of such works would reside with the state.[2] This report does not address in detail the ownership or management of this state-generated IP, as the issues are straightforward, non-controversial.

State-funded IP is defined as IP generated through research — the creation of new knowledge that can be protected by copyright, patent, physical property right or trade secret — through

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[2] California State Auditor, State-Owned Intellectual Property: Opportunities Exist for the State to Improve Administration of Its Copyrights, Trademarks, Patents, and Trade Secrets (2000-110: November 2000) p. 51.

grants and agreements issued by state agencies, primarily to universities and nonprofit research institutions. This report focuses, in particular, on the IP produced within the science and engineering communities with funding from the state. The most common expected outputs of state-funded research are patentable inventions, research tools, computer programs, databases and research articles. Across the nation and internationally, ownership of this IP generally resides with the grantee.

Why does the state fund research?

We begin by stating our assumptions about the role of state agencies in funding research. Given that the source of funds is generally the state's general funds derived from tax revenues or a special fund financed by fees collected by the state from specific individuals for specific services (e.g., the Genetic Disease Testing Fund),[3] we have viewed the state's role as akin to the federal role in supporting research for the public benefit. At the federal level, that funding flows to research institutions from the so-called science-mission agencies, primarily the National Institutes of Health, National Science Foundation, Department of Energy, the National Aeronautics and Space Administration (NASA), and a variety of research offices within the Department of Interior, Department of Commerce, and the Department of Defense. At the state level, research funding comes from agencies such as the Department of Health and Human Services and the California Energy Commission, and our analysis, conclusions, and recommendations reflect our primary assumption that the state's goals should mirror the federal government's goals in funding research.

Our assumption about the state's role is based on

- Knowledge and experience with the flow of research funding from the federal level to research institutions,
- Acknowledgement of the scale and critical role of federal funding for science and technology research in universities and nonprofit institutions, and
- The size of California's investments in research, and the potential for leveraging those funds with federal funds, and vice versa.

Some in the state, however, have asserted that the state's role in funding is more equivalent to that played by venture capitalists.[4] We disagree for the following reasons.

First, there is substantial uncertainty as to whether or not the state can use state funds as venture capital, in the strict sense. By definition, venture capital is money made available for investment in innovative enterprises or research, in which both the risk of loss and potential for profit may be considerable. Venture capital is money that is placed at high risk — with the potential of high return, or no return at all. If the source of funds is general funds, the state must be cautious about putting that money at risk in the same way as done by venture capitalists.

Moreover, venture capital generally comes into play after the basic research has been performed and new knowledge is created and brought into the public domain through some type of IP protection. It is not used to support basic research. The additional investment capital from the venture capital community becomes critical to move IP through the next stages of research and development to commercialize products. In many areas, the state plays the catalytic role of

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[3] The state's new stem-cell initiative, funded by bonds, is a special case; the tax-related issues and the range of options for the use of bonds will need to be evaluated by the U.S. Internal Revenue Service.

[4] CA Senator Deborah Ortiz, Press Release, August 23, 2005.

supporting the initial basic research, and not the riskier role of product development, which has traditionally been in the realm of the commercial sector.

At the federal level, the closest analogs to investments in innovation are the SBIR (Small Business Innovation Research) and STTR (Small Business Technology Transfer) programs in many federal agencies.[5] The SBIR program is limited to small for-profit businesses; nonprofit institutions are not eligible to apply. SBIR is a highly competitive program that encourages a small business to explore its technological potential and provides the incentive to profit from its commercialization. It does not fund basic research; rather it provides incentives to move research to application. By including qualified small businesses in the nation's R&D arena, high-tech innovation is stimulated and the United States gains entrepreneurial spirit as it meets its specific research and development needs. In 2004, California companies received a total of 1328 SBIR awards (Phase 1 and Phase 2), for a total of almost $416 million, or 21% of the national total.[6] The STTR program is also highly competitive and requires cooperative R&D between small businesses and research institutions with the goal of commercialization. In 2004, California companies received 135 STTR awards (Phase 1 and Phase 2), for a total of over $37 million, or 18% of the national total.[7]

Between 1994 and 2003, California's Department of Technology, Trade and Commerce ran a state version of the SBIR known as the California Technology Investment Program (CalTIP). The state did not retain any intellectual property rights, as it was more focused on spurring innovation and moving new products to market.

Third, if the state's goal is a large payoff from its investment in research, that goal is in conflict with any related research funding from the federal government. The prevailing IP policy for research, the federal Bayh-Dole Act (see Appendix B) allows grant recipients to exploit the intellectual property they create. If the rules for state and federal funding are fundamentally inconsistent, the best researchers may well choose to propose research projects to whichever one provides the most incentives, and is most consistent with existing institutional policies.

Fourth, the financial return for venture capital investors is realized by taking equity ownership in the companies in which they invest. It is not clear that the state could be an equity owner of a product company without creating potential conflicts of interest for future procurements where bidders may include companies in which the state has a financial stake and others where it does not. We know of no other state model for funding that views itself in this way. We cannot recommend responsibly that California play the role of venture capitalist for research (in contrast to innovation) without fully exploring the legal, financial and public policy implications, which are beyond the expertise of this study group. Instead, we urge the state to continue its traditional role as funder of research for the public benefit.

Finally, we are uncomfortable with encouraging the state to act as a "venture capitalist." The key role of state funding for research, as we see it, is to generate knowledge by stimulating researchers to work on research questions that, when better understood or solved, may benefit the state. The state can play an important role in identifying what those questions are in many sectors — in transportation, energy, education, biomedicine, the environment, etc. — and in providing appropriate incentives for the state's best researchers to work on finding answers to

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[5] http://www.sba.gov/sbir/.

[6] http://www.sba.gov/sbir/indexsbir-sttr.html#sbirawards.

[7] Ibid.

those questions. The state is not, however, equipped to evaluate the research opportunity for commercial gain and royalty stream.

State's Current Investment in Research

The state's current research portfolio includes (but is not limited to) funding in the following science and technology areas: energy, HIV-AIDS, breast cancer, tobacco-related disease, sustainable agriculture, health and human services, children and families, transportation, energy research, and geothermal resources development. It also includes funding for the California Institutes for Science and Innovation administered by the University of California.

In the past, CCST has systematically researched and documented the R&D activity supported by the state of California. For fiscal years 1995, 1996 and 1997, data were collected that showed R&D activity to be $302.8 million, $313.4 million, and $316.0 million, respectively.

In 2005, an effort was made to collect this information with the preliminary finding being that the number remains relatively static at approximately $300 per year. Even factoring in the extra $300 million a year allocated for the California Institute for Regenerative Medicine – bringing the total to approximately $600 million — California's expenditures on state funded research are dwarfed by the over $15 billion spent for R&D in California each year by the federal government (twenty five times the state total).

The largest single research program is the Public Interest Energy Research (PIER) program. Managed by the California Energy Commission, the PIER program is funded by a collection of surcharges on retail electricity sales. Beginning in 1996, funds have been collected annually to ensure a continuation of public interest research, development and demonstration projects.[8] In 2004, the PIER research partners included universities (14%), small and large businesses (30%), utilities (21%), nonprofit organizations (29%), national labs (12%) and the state (4%). Since its inception through 2003, 33 products have been placed into their intended markets and are expected to produce ratepayer benefits of several hundred million dollars over their lifetimes. Other benefits include increased jobs and economic activity from the manufacture of products in California and a healthy environment as a result of reduced emissions.[9] Appendix D includes additional information about PIER's intellectual property policies and procedures.

The following two tables give a sense of the relative scales of federal and state funded R&D in California. Table 1 lists a selection of the largest state funded research programs, including the level of funding as of 2004/2005 and what IP policies are observed if identified. Note that the University of California serves as the administrator for many of these programs, and already has IP management policies in place that mirror federal policies.

Table 2 is a summary of federal funds spent on R&D in California for fiscal year 2002 through federal research facilities, industrial firms, nonprofits, and state and local government agencies. Clearly, non-state funding drives the research conducted in the state's academic and nonprofit research institutions. Moreover, IP policies and procedures are well-established in these research institutions that are in keeping with federal regulations.

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[8] CCST has conducted two reviews of the PIER program at the request of the Legislature, the California Public Interest Energy Research Independent PIER Review Panel Final Reports of May 2001 and May 2005 respectively. http://ccst.us/ccst/pubs/pier/index.html.

[9] California Energy Commission. 2004 Annual Review of the PIER Program. Volume 1 — Commercial Successes and Benefits. March 2005. CEC-500-2005-055-V1.

Table 1: State Funded R&D

Example of Major State Programs 2004-2005 (Thousands of Dollars)

	Amount	IP Process
PIER *	62,500	Remains Property of Contractor
Caltrans	55,600	Follows State or University Policy
Natural Gas Research*	12,000	Remains Property of Contractor
Child and Family Trust**	17,900	No Identified Policy
Breast Cancer***	14,900	Follows UC Policies
Tobacco-related Disease***	14,200	Follows UC Policies
HIV-AIDS***	9,200	Follows UC Policies
Sustainable Agriculture Research**	7,500	No Identified Policy
Health and Human Services**	9,400	Available for Public Use
Geothermal Resources Development*	2,500	Remains Property of Contractor
TOTAL	205,700	

Total State Funded R&D Approximately $300 Million per year

In addition, $300 Million per year has been allocated for the California Institute for Regenerative Medicine

The state government has also funded specific research programs including the California Institutes for Science and Innovation* (at $410 Million over five years), programs in Caltrans, Cal/EPA and others.**

* Administered by the California Energy Commission.

** Reported in Governor's budget 2004-2005.

*** Administered by the University of California.

Sources: Compiled from numerous sources including the Governor's Budget for 2004-5; communication with the individual agencies and programs referenced; the California Department of Finance; and the Research Administration Group at the University of California Office of the President.

Table 2: Federal Obligations for Research and Development by Agency and Performer: California, Fiscal Year 2002

Federal Obligations for Research and Development by Agency and Performer: California, Fiscal Year 2002 (Thousands of Dollars)

		Performer			
Agency	**Total**	**All FFRDCs***	**Universities & Colleges**	**State & Local Government**	**Other****
Department of Agriculture	115,099	0	34,927	186	79,986
Department of Commerce	85,030	588	10,844	381	73,217
Department of Defense	7,915,109	243,637	323,792	0	73,217
Department of Energy	1,306,156	1,091,931	122,864	272	91,089
Department of Health & Human Services	3,105,359	42,092	1,693,959	6,519	1,362,789
Department of the Interior	99,459	0	5,865	593	93,001
Department of Transportation	27,535	50	3,281	14,361	9,843
Environmental Protection Agency	15,768	0	12,612	615	2,541
National Aeronautics and Space Administration	2,492,779	1,303,480	182,244	2,237	1,004,818
National Science Foundation	523,761	395	459,061	0	64,305
All Agencies	**15,686,055**	**2,682,173**	**2,849,449**	**25,164**	**10,129,269**

* FFRDC = Federally Funded Research and Development Center.

** Other includes Federal Intramural, Industrial Firms and Other Nonprofits.

Notes: Federal R&D obligations are as reported by funding agencies.

Sources: Prepared by the National Science Foundation/Division of Science Resources Statistics. Data compiled from numerous sources; see the section, Data Sources for Science and Engineering (S&E) State Profiles. http://www.nsf.gov/statistics/nsf05301/tables/ca.xls.

2. Ownership of IP Derived from State Funding

Key Points:

- **Ownership of IP is a central issue in establishing IP policy.**
- **Ownership of IP generally resides with those who are best able to manage it; long-standing federal policy allows ownership of IP to reside with the grantee.**
- **IP can be protected in a number of ways: copyright, patents, and trade secrets.**

Ownership of intellectual property resulting from sponsored research is a central issue in establishing an intellectual property policy. The core, long-standing federal policy is grantee ownership. From this primary characteristic many other policy considerations follow. This ownership of the outputs of creative human endeavors (e.g., research articles, patentable inventions, databases, research tools, computer programs) resides with the grantee, and is protected in a number of ways (copyright, patent, trade secret) depending on the intended or potential use of the IP.

In considering the issue of IP ownership, it is important for the state to consider:

- The relative importance of consistency with federal laws and policy,
- Who is best able to manage the resulting IP , and
- The existing financial models for the creation of new products and services.

Clearly, consistency with federal statutes and policy suggests that ownership of IP resulting from state-sponsored research should reside with the grantee. In considering who is best able to manage IP resulting from university research, strong arguments have been made that IP management should occur at a level that is as close as possible to the research itself — and perhaps more importantly — as close to the researchers as possible. This was the conclusion of the California Technology, Trade and Commerce Agency report of 2003, which recommended that the University of California — the recipient of the most research funding from the state — decentralize its technology transfer programs to the local campus level.[10] UC has been decentralizing technology transfer for several years and the process is to be completed by July 2007.

State funding for research supports primarily basic research, and many of the outputs of that research are in the form of the creation of new knowledge, usually expressed in research articles, to which copyright protection is generally applicable. In some instances, however, IP resulting from early stage research is protected by patents, and requires the institutional capacity to invest in filing patent applications before there is any prospect of a return on that investment.

If the state or state agency that is the sources of funds were to manage IP resulting from its sponsorship, an allocation of additional funds would be required to invest in patent filings as the research results emerged from the laboratory. The source of funding and professional staff

[10] Lon Hatamiya, Jeff Newman, and Jessie Szeto, Recommendations on Streamlining the University of California Technology Transfer Process, California Department of Technology, Trade and Commerce (Sept. 19, 2003).

required to provide that technical function at the state level is unknown. Research universities and not-for-profit research institutes, however, have addressed this issue over the last 20 years and have either established fund sources to support patent filings or utilize the royalty stream resulting from past inventions to support the costs of new patent filings.

We find compelling reasons to recommend that ownership of IP arising from state-sponsored research reside with the grantee, based on the need for compliance with federal policies (e.g., the Bayh-Dole Act), as well as consideration of who is best able to manage the IP and most likely to have existing financial models to invest in patent filings. This approach will both provide a policy framework that does not conflict with federal statutes and policy, and recognize the importance of the researchers themselves in helping to manage and advance the IP. It also builds on the existing institutional infrastructure to manage and fund investments in IP protection.

Types of IP that May Be Generated

Any IP model must be developed with consideration for the different kinds of IP which state-funded research may generate. The most common types of outputs are patentable inventions, research tools, computer programs, databases and research articles; the most common IP protections for these outputs are patents, trade secrets, and copyright. These are detailed in Table 3, and described further in Appendix A.

Research Tools and Databases

Particular attention needs to be paid to the treatment and dissemination of research tools and databases. The success of the state's investment in research will depend greatly upon researchers' ability to access data and information, often for multiple purposes. Scientific and technical progress will depend on researchers' ability to access and use information in the public domain and to combine public and proprietary data into new databases, as well as to re-evaluate and reuse existing data. The importance of this kind of access was reaffirmed most recently by the National Academy of Sciences.[11]

Making research tools developed with state funding largely available to other scientists for use in ongoing research is consistent with federal guidelines, in particular those of the National Institutes of Health.[12] A sample of those guidelines concerning research tools can be found in Appendix C. Policies that are consistent with those guidelines should be encouraged by the state.

Creators of IP that falls into the "research tools" category have several options to protect their work. Research tools may include biological material such as cell lines, monoclonal antibodies, reagents, software programs, data and databases, and other inventions and copyrightable works.

Grantees may choose not to file patents on research tools. Alternatively, they may choose to file patents, in which case they have, in turn, a number of other options. They can grant royalty-bearing, nonexclusive licenses to others who wish to use the research tools or, when the research tool needs further development, they can grant exclusive licenses to encourage a company to further develop and commercialize the invention, usually with a condition of broad, reasonable

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[11] "Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health." National Academy of Sciences Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation. (Prepublication Copy — November 2005), p. 4.

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

availability once development is complete. Each of these approaches supports wide availability to the research community for further development and the overall advancement of the science. We recommend that exclusive licenses for purposes other than the development of a research tool, if used, should generally retain rights for the grantee and the research community to continue to use the IP for research purposes.

Table 3: Expected Output from Research and the Applicability of Intellectual Property Protection

Expected Output	Definitions	Applicable Intellectual Property Protection[13]
Patentable Inventions	Discoveries that advance science and enable new useful applications, notably including therapeutics, diagnostic tools or products. Such discoveries are often patented, and licensed in a manner that will promote the development and availability of products embodying the invention. When significant further investments are required to take a promising research result to a viable product, exclusive licensing may be the best mode to benefit the public, by inducing private industry to make the significant investment to further develop the research into a product. In other cases, nonexclusive licenses can encourage widespread development and adoption of new patentable discoveries. For effective technology transfer, more than patents must sometimes be licensed; biological materials and equipment and associated know-how may be transferred through material transfer agreements.	Patent Trade Secret
Research Tools	Inventions that broadly facilitate subsequent research, including both methods (e.g., Polymerase Chain Reaction (PCR) a technique for amplifying DNA to facilitate cloning and sequencing) and products (e.g., specific cell lines, such as embryonic stem cells, DNA clones, or antibodies). This IP may be patented or not, but is best managed through strategies that ensure widespread dissemination and use. Research tools are often shared freely and without any formal agreement; however, if the provider of research tools wishes to control dissemination of the research tool, a material transfer agreement may be used.	Patent Trade Secret Physical Property Right
Computer Programs	Computer programs for a variety of purposes, including analyzing data. Computer programs are automatically protected by copyright law, and may be made available to research communities or the public through open source licensing or dedication to the public domain; if further investments are needed to refine the program to make it more useful, proprietary licensing may be appropriate.	Patent Trade Secret Copyright
Databases	Compilations of data, typically generated from research, sometimes from one source, but often combined from many sources. Original databases are generally protected by copyright law and there have been several legislative bills in recent years seeking to extend this protection. Databases may be shared without restriction, or licensed to research communities, to promote the advancement of science. When developed by private industry or under private funding, databases may be licensed as a commercial asset.	Trade Secret Copyright
Research Articles	Publishable scientific articles protected by copyright law. Although it is common for publishers to request or require researchers to assign copyrights as a condition of publication, published work is widely available to the research community via digital libraries, open licensing, and pre-print servers.	Copyright

[13] See Appendix C for more detailed discussion of these types of intellectual property.

Researchers increasingly need access to large amounts of data, often available in electronic form through databases. As generators and users of databases, researchers are dependent on database information, which must be gathered and entered, updated regularly, with quality controls implemented to be sure the data are accurate and the database remains useful. Databases can be made available for a fee or for free. In addition, many research enterprises maintain "proprietary" databases to which they have dedicated significant resources and which they may or may not make available to others. Even if the research relies on access to a database that is not available for others to use, the results of research conducted with the aid of the database should be widely disseminated.

The state could encourage grantees to make state-funded databases as widely available as possible. However, if a proprietary database is necessary to move a grantee's research forward faster, proprietary databases may be developed for and used in that research.

Moreover, grantees should discuss the research tools they anticipate creating and whether and how they intend to make them available to other researchers, particularly state-funded researchers. Some acceptable approaches might be:

- For biological material, licenses will typically be nonexclusive for the purpose of research. Biological materials may also be placed in repositories to store, reproduce and transmit the materials. (See Appendix C, NIH Guidelines, for an example of a material transfer agreement.)
- For software, internal use licenses will typically be nonexclusive; but if a company will add value and further develop the software, commercialization licenses would generally be exclusive, perhaps for a limited period of time and a specific area or areas of science. Alternatively, software may be made broadly available through open source licensing or affirmatively put in the public domain for use by anyone.
- For data and databases, the state should encourage wide accessibility of public and proprietary data for the benefit of researchers. If a company has proprietary data or databases that will enhance the likelihood of a new product, more restricted access may be appropriate, provided the results of the research can be freely shared.
- For inventions, grantees should license as appropriate for the stage of development of the invention, taking into consideration the requirements for effective diligent commercialization and public availability as quickly as possible.

In all cases, grantees should be obliged to disclose to the state the patentable inventions and other intellectual creations that result from state-funded research. If grantees believe that their creations would be most effectively disseminated and most effectively foster significant ongoing scientific progress through dedication to the public domain or open source licensing, the state should respect this decision. Most importantly, state grantees should be expected to reserve the right to use the technology for their own research and education purposes and to allow other nonprofit institutions to do so as well, even in cases where an exclusive commercial license is granted for the commercial development of a product.

3. Strategies for IP Management

Key Points

- **The federal Bayh-Dole Patent and Trademark Amendments Act of 1980 led to the development of consistent invention policies for federally funded research conducted at universities and in small businesses.**
- **The Bayh-Dole Act confers both rights and responsibilities to recipients of federal research funding.**
- **New IP management strategies are emerging to retain certain categories of new knowledge in the public domain to keep research findings freely available to all. All of these strategies allow ownership of IP to remain with the grantee.**
- **Some private funders are experimenting with licensing agreements that instigate development of products targeted to poor populations located in countries that do not have the market structures to support commercialization.**

In Chapter 2, we discussed ownership of IP, and concluded that, in keeping with long-standing and successful federal policy, ownership of IP generated with state funding should reside with the grantee.

In this chapter, we discuss management of IP. Several strategies for IP management are discussed, in particular, the Bayh-Dole Model, patent pooling, and open access. In addition, we recommend a model for the state to consider, manage, and administer IP.

Research, especially in universities and other nonprofit research institutions, receives funding from many sources, including federal and state agencies, private industry and nonprofit organizations. Ownership of any IP generated by such research, and the details of how it is managed, depends on the source of funding, but generally converges on high-level objectives such as ensuring broad dissemination of research results and managing inventions for the public benefit. Other objectives are discussed in Chapter 5.

The Federal Bayh-Dole Model

Up through the 1970s, agreements on ownership of inventions derived from federally funded research were negotiated individually with each government agency. The results were inconsistencies and high transaction costs that too often contributed to ineffective transfer of university IP to technologies for commercialization. Moreover, many promising federally funded research discoveries were not being transferred into widespread use because IP rights were not being licensed for further development. One result is that by 1980, an inventory of about 28,000 patents developed with federal funding had built up, with less than 5% licensed and developed into useful products. Without strong IP protection, clarity of ownership and the ability to obtain exclusive licenses, companies had little incentive to invest in transforming the research discoveries into marketable products.

The Bayh-Dole Patent and Trademark Amendments Act of 1980 (Bayh-Dole) led to the development of consistent invention policies for federally funded research conducted at universities and in small businesses. It permitted grantees to patent inventions resulting from federally funded research, which they could then license to other entities, including to private firms willing to invest in commercialization.[14] Many research universities and labs began to encourage faculty and other researchers to identify and report discoveries that could be patented for commercial development. Many institutions also established technology transfer offices with their own resources to handle patent prosecution and licensing.

Some critics of Bayh-Dole argue that an unintended consequence of the act was the aggressive use of patenting to protect "upstream" IP, or IP that is the result of early stage research. They note that such early results would more appropriately serve other researchers, and ultimately the public, if broadly disseminated in the public domain.[15] As an outgrowth of those concerns, new strategies for keeping early research results in the public domain have emerged, and are discussed below.

While it is difficult to measure the direct effect of Bayh-Dole on technology transfer, by rationalizing and simplifying the process of moving technologies generated by federally funded research from university laboratories to the private sector, Bayh-Dole is generally considered to have contributed positively to the development of some technologies that may not have been made available to the public in its absence.[16] Appendix B provides additional analysis of the Bayh-Dole Act.

Key Provisions of Bayh-Dole

Bayh-Dole is quite simple in concept and in practice. It allows universities and other research institutions to claim ownership of inventions developed through federal funding. It also creates a number of requirements for universities that elect to own those inventions.

Under Bayh-Dole, those institutions:

- Must file patents on inventions for which they decide to claim ownership.
- Must have written agreements with faculty and staff requiring disclosure and assignment of inventions,
- Must share a portion of the revenues with inventors, and
- Must use any excess revenue to support research and education.

In turn, the Government funding agency:

- Retains non-exclusive right to the invention for its own uses,
- Retains march-in rights. This permits the government to step in and work to achieve the practical application of the invention if the patent holder or licensee has not done so expeditiously, and

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[14] David C. Mowery, "The Bayh-Dole Act and High-Technology Entrepreneurship in U.S. Universities: Chicken, Egg, or Something Else?" Prepared for the Eller Center conference on Entrepreneurship Education and Technology Transfer (U. of Arizona, January 21-22, 2005), pp. 14-15.

[15] Arti K. Rai and Rebecca S. Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine." 66 Law & Contemporary Problems 289 (Winter/Spring 2003).

[16] Jerry G. Thursby and Marie C. Thursby, "University Licensing under Bayh-Dole: What are the Issues and Evidence?" (May 2003) p. 9.

- Requires that any manufacturing that results from inventions made with federal funding occur substantially in the United States.

In many ways, the situation in California today regarding state-funded research resembles the federal situation in the late 1970s prior to the passage of Bayh-Dole: state-level policies are not uniform and do not have a common set of clearly stated objectives. Contracting is possible, but it is complicated. The absence of clear guidance leads to considerable time and costs associated with negotiating the handling of IP stemming from state funded research. The University of California, for example, entered into 900 contracts with 74 state agencies for a total of $220 million in 2003, most of which had to be negotiated individually. UC estimates that if the 900 state awards had been federal awards (or implemented in a streamlined manner similar to federal awards), UC and perhaps also the state would have saved over $1.1 million in streamlined invoicing, record keeping, and administrative issues, including time spent negotiating contract provisions.[17]

Most university research relies on multiple sources of support, and universities must take great care to ensure that researchers do not operate under conflicting terms and restrictions in the ways IP generated in the course of their research is to be handled. Since the vast majority of research funding at most universities and nonprofit research laboratories comes from federal agencies, policies for the management of IP at those institutions are driven primarily by the provisions of Bayh-Dole. One role of technology transfer offices at universities and nonprofit research institutions is to negotiate compromises between all affected parties in such instances. It is not the role of the state agencies to fund technology transfer offices directly, but by streamlining and standardizing state-funded IP policies, the complications and administrative costs associated with managing conflicting obligations can be reduced all around.

Public Domain for Science

Several strategies have emerged to encourage the placement of new knowledge in the public domain. The need for such strategies is predicated on the concern that certain scientific works that traditionally had not been protected, or had no legal mechanism to be protected, are now or soon may be subject to copyright and patent protections that limit their accessibility to other researchers and the public. The primary goal of the public domain movement is to keep research findings — the essential building blocks of knowledge — readily available to everyone.

Several efforts have emerged to describe various strategies to expand open access to scientific works. Research articles, research tools, software, and databases are the kinds of research outputs that are the focus of public domain discussions. The key nonprofit efforts are Creative Commons (and its derivative organization, Science Commons) for authors of copyrightable works and Open Source for software. To date, databases are generally not subject to federal intellectual property protection in the United States, but there are concerns that this may change. Databases may be protected as trade secrets under state law.

As noted earlier, different kinds of legal protections are applied to different kinds of research outputs. The common attribute of both the public domain movement and the intellectual property rules it challenges is that ownership of IP, if retained, should reside with the creator of the knowledge.

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[17] Alan Bennett, "University of California Agreement," University of California, Davis, Transfer Office and Office of the President (Davis, California, 2004), p.1.

Research Articles

Creative Commons is an organization created to focus on individual creators and their copyrights.[18] This group is not against intellectual property. Rather, its philosophy is "some rights reserved," which is incorporated into its trademark.[19] A key innovation is the "creative commons" license, through which the creator of the original work can select the rights he or she wants to retain. The idea is to provide authors control, in an inexpensive and standardized way, to specify exactly how their work may be used and shared.

With respect to scientific publishing in particular, the Creative Commons philosophy has some notable successes, particularly in biomedical fields. The Public Library of Science (PLoS) and BioMed Central both emerged in the last few years as alternative models for publishing biomedical research articles in new ways. PLoS, a nonprofit publisher, now publishes six biology related journals; BioMed Central, a for-profit commercial publisher, publishes 130 journals.

Traditional commercial scientific publishing requires authors to sign over copyrights for their articles. In the past, scientists did not challenge these requests, as the journals were an essential and the most prestigious vehicle for career advancement and to share their research results with colleagues and the larger scientific community. Information technology dramatically changed the ability to share information, and the dynamic between scientists and publishers began to change, with scientists asserting more control over the use and availability of their works.

PLoS and BioMed Central have emerged as viable alternatives for publishing in biomedical fields. Public domain publishing has progressed more slowly in other fields, due to a variety of factors including the size and internal culture of the field. Authors assert Creative Commons Attribution Licenses on their works.[20] By doing so, they retain copyright on the work, but irrevocably license the work to any third party to redistribute and use the work, subject to the condition that proper attribution be given whenever the work is reproduced or redistributed. By retaining copyright, authors and/or their representatives retain the right to enforce the terms of the license, but not the right to dictate how or by whom the work is used.

Another new organization is emerging that is derivative of Creative Commons. Less than a year old, Science Commons will have three main projects: publishing, licensing, and data. The publishing project will focus on using legal and technical experts to help researchers make the best use of new communications technologies. The licensing project will explore ways of combining IP rights (such as patent pooling and other rights-bundling methods) to advance certain research fields. Huntington's Disease research is being used as a case study to explore a range of legal and institutional issues related to licensing. The data project involves engagement in a variety of hot issues around the potential application of intellectual property protections for databases. Science Commons will build a case study around integrating a web of data, papers, tools and policy to aid research into brain disease.

Software

Software is protected by copyright. It may be made available to research communities or the public through open source licensing or dedication to the public domain.

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[18] see http://creativecommons.org/about/licenses/.

[19] Ibid.

[20] See http://creativecommons.org/licenses/by/2.5/.

Open source licensing began in 1985. The Open Source Initiative describes the basic idea behind open source as follows: When programmers can read, redistribute, and modify the source code for a piece of software, the software evolves. People improve it, people adapt it, people fix the bugs. And this can happen at a speed that, if one is used to the slow pace of conventional software development, seems astonishing.[21]

The open source community, which has built momentum over the last 20 years in the technical cultures that created the Internet and World Wide Web, asserts that such a rapid evolutionary process produces better software than the traditional closed model, in which only a very few programmers can see the source. Efforts are now underway to insert this philosophy into the commercial environment.

Databases

Databases are generally not subject to federal intellectual property protections in the U.S. Therefore, the issue with databases is not infringement, but accessibility. There are many examples in the research community, however, of scientists making research databases available to other researchers. Many are concerned about efforts underway to allow databases to be protected under federal law, and therefore available only at a cost and on certain terms. Many complex issues arise, such as cost and the terms of use; what restrictions or requirements funders may impose, and institutional policies for sharing and access. With software, some of the concerns are alleviated by using open source licenses, but those provisions are not yet standard with databases.

Patent Pooling

This approach comes into play when there may be complementary patents owned by several institutions that, if pooled and subject to coordinated or collaborative development efforts by several groups, result in new standards for a field or dramatic innovations that otherwise would not occur or would occur much more slowly.

Patent pooling has been examined by the U.S. Patent and Trademark Office.[22] A patent pool is an agreement between two or more patent owners to license one or more of their patents to one another or third parties. A patent pool may also be "an aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool." [23]

Historically, patent pooling has played an important role in the development of some industries, for example, sewing machines over 100 years ago, early aircraft, and early radio and television. In these examples, patent pooling was important in enabling the development of standards in infant industries.

There are, however, other examples where patent pools are used in anticompetitive ways that actually slow warranted technological progress. Theoretically (based on examples), the owner of a complementary patent has an incentive to induce technological competition against its complement, either by lowering its royalty rate below the short-term profit maximizing

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[21] http://www.opensource.org/.

[22] Jeanne Clark, et al., "Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?" U.S. Patent and Trademark Office (December 5, 2000).

[23] Ibid. p. 4.

rate, or by inventing around the complement. Alternatively, owners may choose to participate in a patent pool as a mechanism to fix prices. One example of the latter is a Federal Trade Commission complaint against Summit and VISX, in which the companies were charged with unlawful price fixing to protect their market positions and profits.[24] Neither serves the best interests of the public.

There is a tension, therefore, between pooling of patents, which affords a certain right to exclude others from making, using or selling a patented invention, and antitrust laws, which prevent the creation of monopolies. Ensuring that patent pools are carefully monitored to encourage innovation, industry and competition is an oversight function that requires a highly qualified professional infrastructure.

In considering the use of patent pools, the state must carefully assess the potential for procompetitive and anticompetitive actions. Moreover, it must consider how unilateral state actions could affect the viability of patents in larger commercial markets. In short, unanticipated consequences need to be considered.

For example, if patent pooling were required within a particular sector and only among a set of state funded institutions in California (even though similar lines of research may be occurring elsewhere), then those patents, researchers and institutions would be at a severe disadvantage relative to other researchers and other markets in the country and in the world. Although California is a large market in and of itself in many sectors, the potential is great for asymmetry to develop between institutions doing state-funded research. They would be disadvantaged due to onerous IP requirements.

Another consequence would be the expense of establishing a sophisticated mechanism — likely within state government — to know which IP is amenable to patent pooling, securing patent pooling agreements, and the shopping the patents around to potential commercial partners. Although an IP tracking function could be accomplished with the state relatively inexpensively (and is discussed in Chapter 6), the business development function needed for patent pooling requires a set of skills that generally are found primarily in venture capital firms or in industry and funded by private sources.

Additional Models for Managing IP: Experiments with Licensing Agreements

In addition to the Bayh-Dole Act, which serves as the model for managing IP derived with federal funding, other groups have invested in exploring other models, with a particular focus on experimenting with licensing agreements.

While it is the study group's belief that the federal model is the most appropriate for the state to consider, two privately funded programs mentioned in the amended ACR 24 merit examination. They are the International AIDS Vaccine Initiative (IAVI) and the Grand Challenges in Global Health Initiative. Both have initiated new strategies for IP that "commit funding recipients and entities seeking to commercialize research to ensure that resulting therapies and products are accessible and affordable to designated low-income populations." [25]

While these private organizations are substantially different from federal or state agencies, they offer some interesting points of commonality and differences with regards to their IP policies.

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[24] Ibid. p. 10.

[25] See ACR 24 (Appendix F).

A significant commonality between these private initiatives and federal policies is that the grantee owns all IP generated with funding from these sources. The experimentation begins with the licensing strategies used to move new knowledge to products that benefit the public.

International AIDS Vaccine Initiative

The International AIDS Vaccine Initiative (IAVI) is a not-for-profit organization operating in 23 countries. Since its inception in 1996, IAVI has invested more than $100 million in AIDS vaccine development.[26] Funding comes from the Bill & Melinda Gates Foundation; the Rockefeller, Starr and Sloan Foundations; the World Bank; Becton, Dickinson & Co.; the European Union; and the governments of Canada, Denmark, Ireland, the Netherlands, Norway, Sweden, the United Kingdom, and the United States. IAVI manages a portfolio of R&D projects that focus on new concepts for vaccine development. The funds are dedicated to supporting research on difficult technical problems that impede the translation of basic research into easily usable products and therapies. If an AIDS vaccine is developed with IP-derived from IAVI support, it will be made affordable in developing countries.

One of IAVI's goals is to support projects that bridge the gap between fundamental research and product development efforts, with a focus on applied research and vaccine design — not the early basic research. The focus is on moving beyond basic research to translating those discoveries into useful products in areas where commercial markets do not exist, yet where the need is great. To make headway in those difficult markets and on seemingly intractable and complex applied research questions, IAVI seeks to harness the necessary global talent and infrastructure.

A second goal is to identify key research questions that are not being funded elsewhere, and create new research consortia, involving many institutions, that would not otherwise occur. IAVI identifies key researchers in wide ranging institutions — academic institutions (sometimes several of them) and industry — to work on those issues. A current example, begun in 2002, is the Neutralizing Antibody Consortium, which has made progress towards understanding the large scientific challenge of designing immunogens for eliciting broadly neutralizing antibodies against HIV. This consortium started with four member institutions; it now includes eight, and may soon grow more and include international institutions. Other research questions are being identified, with plans to begin new consortia to work on complex problems.

The IP derived from IAVI funding is owned and managed by the grantees, as in the Federal Bayh-Dole policy. The individually negotiated IP licensing agreements require that vaccines developed using IP derived with IAVI funding must be provided in poor countries at a reasonable price, as based on the income level of the country and other factors.

IAVI envisions that its funding is supporting research and development that will bridge the gap between the basic research and the proofs of concept that overcome the large technical challenges that currently exist. The IP associated with the proofs of concept will then be licensed by industry, which will play its traditional role in product development and commercialization of the vaccines. After licensing the IP, the cost of development will be incurred by industry, and in poor countries, those vaccines would be delivered at reasonable prices. The initiative does not, however, establish restrictions in other markets for the vaccine or for use of the licensed IP for other applications.

[26] The International AIDS Vaccine Initiative — http://www.iavi.org.

Grand Challenges in Global Health Initiative

The Grand Challenges in Global Health Initiative is a $482 million effort supported by the Bill and Melinda Gates Foundation, the Wellcome Trust in the United Kingdom, and the Canadian Institute for Health Research. The $450 million in funding from the Gates Foundation includes $200 million managed by the Foundation for the National Institutes of Health (FNIH). FNIH was established by Congress to maximize the resources available to the NIH and to provide flexibility necessary to address promising new research areas. FNIH also facilitates public-private partnerships.

The Grand Challenge was launched in 2003 with the goal of instigating the development of research projects that would apply innovation in science and technology to the greatest health problems of the developing world. The key focus of this challenge is to improve global health technologies. Forty-three grants, for a total of $436.6 million, were announced in late June. These grants involved scientists in 33 countries.[27]

Projects target technologies, as opposed to fundamental research, which is funded by NIH or private foundations. Some projects will improve on existing technologies; others will attempt to develop entirely new technological approaches. The range of projects include developing low-cost technologies for formulating vaccines that do not require refrigeration, and single-dose vaccines; new strategies for HIV vaccines; and new, low cost diagnostics for serious diseases. Of the initial grants, nearly all represent new consortia of academic, nonprofit, and for-profit institutions.

The Grand Challenge handles IP through a new concept called a "global access strategy." It does not have an IP policy per se. Instead, IP is dealt with in the terms and conditions of each grant award. Grantees must develop a global access plan that specifies how current and newly generated IP will be managed so as to facilitate access of new products and therapies to those most in need in the developing world. Each grantee must develop its own response to the objectives of the global access strategy. The strategy describes the thought processes of members of the consortia receiving the grant about developing a usable product, producing a product maturation plan, criteria for selecting research and commercial partners, and other issues.

The global access strategy is innovative in that it is causing grantees to push the envelope in thinking about how to eventually develop licensing agreements that enable access by poor countries. To date, most grantees are still developing their global access plans and other documents, such as project management charters, so it is not possible to point to an existing "model" per se. The Gates Foundation and the FNIH, which will each manage about half of the grants, realize the uniqueness of this approach, and anticipate an iterative process with the grantees over time while the global access strategies are developed. Through that process, many lessons will be learned and best practices will emerge.

In many ways, these initiatives are quite innovative in the ways that they focus primarily on how IP, particularly patents, is licensed and used. As with other IP schemes, ownership will reside with the grantee. In addition, most other aspects of IP management in these initiatives are consistent with the general principles put forward in this report:

- Ownership of IP resides with the grantee,
- To the greatest extent possible, create incentives for commerce,

[27] The Grand Challenges in Global Health Initiative — http://www.gatesfoundation.org and http://www.fnih.org.

- Encourage timely publication of results to diffuse knowledge widely, and
- Require diligent development of IP into products that benefit the public.

All of these alternatives — public domain for science, patent pooling, and experimentation with licensing — show a range of creative and innovative approaches to handling IP that warrant further exploration and public discussion. These efforts have succeeded in catalyzing principal investigators, business managers, and technology transfer executives and managers to begin thinking in new ways about managing IP.

Over time, as these alternatives evolve and develop track records, case studies to examine strengths, weaknesses, and lessons learned would shed light on the long-term viability of these approaches. As promising as some of these recent approaches may be, there has not yet been any significant opportunity for the commercialization of intellectual property created using them. We feel, therefore, that it is too soon to recommend to the state wholesale adoption of the processes used in any of these initiatives.

Instead, we recommend that the state, given the basic and early applied nature of the research it funds, has goals much more aligned with federal agencies than with private or public charities. Therefore, consistency with the objectives the Bayh-Dole Act would provide the best incentives to researchers to develop new knowledge and protect it, and to commercial entities to license IP, invest the financial resources required to develop it, and commercialize new products and applications.

4. Return on Investment

Key Points

- **Return on the government's investment in research was debated extensively at the federal level prior to and following the passage of the Bayh-Dole Act in 1980, and continues to be a subject of discussion today by federal agencies.**
- **Those who invest in R&D can expect that a substantial fraction of the social return to their investment will not accrue personally to them.**
- **There are substantial spillovers between scientific research and innovation, as well as substantial lags.**
- **The principal benefits of R&D have long been understood to be long-term and to manifest in a variety of ways, few of which benefit the originators of the research directly financially.**
- **In considering a set of IP policies, it is important to understand that the reward system that motivates researchers depends in large part upon their ability to share some or all of their research, in order to obtain recognition.**
- **In any scenario other than the extremely rare "blockbuster" invention, and regardless of the state's IP policies, state-funded innovations and the revenues generated from them cannot realistically be expected to have any significant direct effect on the state's revenues.**
- **The desire for substantial financial return to the state in the form of royalties should be balanced with the need to create incentives for the much greater commercial investment that is necessary to develop and commercialize useful products.**
- **Bayh-Dole policies require that grantee's net licensing revenue be used only for research and education.**

The state's return on its investment in research emerged as an issue in discussions about ACR 252 and ACR 24. Fortunately, these kinds of discussions are not new, and the state can benefit from the lessons learned at the federal level a generation ago.

Return on the government's investment in research was debated extensively at the federal level prior to and following the passage of the Bayh-Dole Act in 1980, and continues to be a subject of discussion today by federal agencies. These discussions may prove to be of value to the state as it considers how to maximize the state's return on investment, both directly and indirectly.

The Economics of Science and Return on Investment on R&D

An understanding of the economics of science will help state policymakers develop policies governing the administration of IP. One key goal of any statewide policy would be to streamline regulatory procedures and facilitate the development of IP, in particular the high-tech IP for which California is known. It is, however, a challenge to design policies around long-term

processes such as the eventual return on investment for R&D. Despite the lengthy delays between initiating basic research and the economic impact of its results, the economic impact of science nonetheless is held to be reliable and hence the issue has been extensively studied at the federal level, both for government-sponsored and privately funded research. As one report prepared by the Congressional Budget Office notes, "At the very least, effective innovation policy requires an awareness of the ways in which government policies… may affect private sector innovation." [28]

In general, research on the return on investment in R&D focuses on two main issues.

- What is the return on investment (ROI) in various types of R&D as measured by its effects on aggregate output (e.g., economic growth)?
- To what extent can the person or institution conducting the research directly capture the benefits generated by the research?

There has been considerable interest in the second issue, particularly with recent highly-publicized discussions surrounding Proposition 71 and the appropriate policy framework for the California Institute for Regenerative Medicine. However, the second issue is contingent upon the first; the actual potential range of benefits needs to be understood before determining how to effect distribution of these benefits in any given sector.

Defining return on investment for R&D

The United States emerged from World War II with a strong respect for science and an imperative to understand better how to foster its development and its potential impact on the economy.[29] A key early approach by Nobel Laureate Robert Solow sought the answer by process of elimination, asking how much growth cannot be explained by other, easier to measure factors, such as capital investment, workforce education, natural resources, economies of scale, etc.[30] Later analyses offered still more detailed decompositions of the sources of growth; an analysis of economic growth over a 40 year period published in 1974 concluded that 26.7% was due to growth in the labor force, 14.7% was due to growth in physical capital, 10.6% was due to capturing economies of scale, 12.0% was due to greater educational attainment, 27.0% was due to advances in knowledge (R&D), and 9.2% to all other factors.[31] Many refinements and extensions in this analysis have been conducted. Scherer[32] was among the first to point out that some of the growth attributed to capital investment probably reflects advances in knowledge because some knowledge necessarily must be embodied in investment to influence output. He tried to measure the growth effects of R&D, in particular, and found that roughly half of the growth in labor productivity is due to R&D. While there are many other refinements, these basic conclusions remain roughly accurate — somewhere between 25% and 50% of economic

[28] Congressional Budget Office, Federal Support for R&D and Innovation: A CBO Study (United States Congress: CBO), April 1984, p.3.

[29] Paula E. Stephan, "The Economics of Science," Journal of Economic Literature Vol XXXIV (September 1996), p. 1199.

[30] RM Solow, "Technical Change and the Aggregate Production Functions," Review of Economics and Statistics 39(3) (1957), pp. 312-20.

[31] Edward F. Denison, Accounting for United States Economic Growth 1929-1969 (The Brookings Institution: Washington, D.C.) 1974. pp. 124-149.

[32] Scherer, Frederic M. 1982. "Inter-Industry Technology Flows and Productivity Growth."Review of Economics and Statistics, vol. 64, no. 4 (November), pp. 627-634.

growth is due to advances in knowledge. By implication, the social returns on investment in R&D (by some estimates from 30% to over 100%[33]) are much greater than the social returns on investment in physical capital, while the return on investment in human capital (education) fall in the middle.

Who captures the benefits from R&D?

The most important economic fact about R&D spending by the government or the private sector is that much of it cannot be appropriated, or controlled exclusively by one individual and/or research institution for maximum benefit. Even with broad and strong IP protections, competitors can "invent around" many innovations at a far lower cost than the cost of the original innovation. And, in the case of patents, IP rights are of limited duration, and may be freely copied by competitors after the patents expire. One example is the production of popular and effective drugs by generic drug companies once a patent initially held by another company that developed and commercialized the drug expires. Hence, those who invest in R&D can expect that a substantial fraction of the social return to their investment will not accrue personally to them.

However, researchers are not motivated solely by the prospect of direct financial or market-based success. The past few decades have seen an important recognition of the fact that a non-market reward system has evolved in science that provides other incentives for scientists to pursue R&D which may ultimately benefit others more than them.[34] This comes in the form of peer recognition for being the first to communicate an advance in knowledge

Economics research is full of hundreds of papers that estimate the private and social returns to R&D both in general and with respect to specific technologies. Many studies, such as the one conducted by the Congressional Budget Office,[35] focus on a downstream industry in a vertical chain, and estimate the returns for the downstream firms on (1) their own R&D, (2) the R&D of their competitors, and (3) the R&D of their suppliers. As noted above, the results of this research vary substantially in the magnitude of the estimates, but the ubiquitous qualitative finding is that R&D by other firms is roughly as important to a firm's profitability and productivity as its own R&D. Moreover, the results differ dramatically by industry. The drug industry, for example, has a very high private return to R&D compared to most others; however, it also derives substantial benefit from federally supported basic research in biomedicine.[36]

As to basic research in universities, this, too, has been studied extensively. A useful 1996 survey of this research[37] found that the social return on investment on basic research is roughly three times the ROI on physical capital investment, and that about 11% of products and 9% of production processes in the private sector could not have been developed without a long delay in the absence of relevant university research. While the limitations inherent in cost-benefit approaches for evaluating the contribution of basic research have been made clear,[38] overall the

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[33] Charles I. Jones and John C. Williams, "Measuring the Social Return to R&D," The Quarterly Journal of Economics, MIT Press, vol. 113(4), pages 1119-1135.

[34] Stephan, p. 1201.

[35] Congressional Budget Office, p. 90

[36] Congressional Budget Office, p. 59.

[37] Stephan, p. 1227.

[38] Paul David, David Mowery, and W. Edward Steinmueller, "Analyzing the Economic Payoffs from Basic Research," Economics of Innovation and New Technology 2(1) 1992: pp. 73-90.

consensus is that there are substantial spillovers between scientific research and innovation, as well as substantial lags.

During the period that new knowledge is systemized and diffused, it is likely to be applied commercially near where it is discovered. Social scientists have documented the advantages of this "geographically localized knowledge" to the research productivity and market success of firms located near the great research centers.[39] Indeed, the very best academic scientists are often directly involved in commercialization of their discoveries through participation as principals or consultants to firms newly established for that purpose.[40] In California, such "geographically localized knowledge" is especially evident, with scores of leading companies in biotechnology, pharmaceuticals, medical devices, energy, hardware, software, instrumentation and other sectors, located near major research universities and institutes.

The bottom line is that the principal benefits of R&D have long been understood to be long-term and to manifest in a variety of ways, few of which benefit the originator(s) of the research directly financially. In fact, the traditional "pipeline" concept used to track R&D from basic research through applied development has long since become suspect for being too simplistic.[41] And because basic research often provides answers to unposed questions, researchers (particularly in a nonprofit environment) often find it more effective to shift goals during research;[42] this can make it challenging to establish a direct cause-and-effect relationship between basic research and total social return on investment.

In considering a set of IP policies, it is therefore important to understand that the reward system that motivates researchers depends in large part upon their ability to share some or all of their research, in order to obtain recognition. While on the surface it may appear illogical to suppose that a researcher would prefer the recognition of his or her peers over direct financial reward from his research, two factors must be considered. First, recognition as an effective motivator has been well documented. Second, this recognition can in fact lead to direct financial rewards in the form of higher salaries, more grants, and consulting fees.[43] Hence, direct return on investment is frequently a less significant factor as a motivator for researchers, and is more important to private, for-profit industries.

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[39] See particularly Jaffe, Adam B, "Real Effects of Academic Research," Amer. Econ. Rev., Dec. 1989, 79(5), pp. 957-70; Jaffe, Adam B , Trajtenberg, Manuel & Henderson, Rebecca, "Geographic Localization of Knowledge Spillovers as Evidenced by Patent Citations," The Quarterly Journal of Economics, MIT Press, vol. 108(3), pp. 577-98; Mansfield, Edwin, "Academic Research Underlying Industrial Innovations: Sources, Characteristics, and Financing," Rev. Econ. Statist., Feb. 1995, 771(1), pp.55-65; and Zucker, Lynne G & Darby, Michael R & Brewer, Marilynn B, "Intellectual Human Capital and the Birth of U.S. Biotechnology Enterprises," American Economic Review, American Economic Association, vol. 88(1), pp. 290-306.

[40] Zucker and Darby (1996) and Zucker, Darby, and Armstrong (1998). These "star" scientists' involvement appears to play a major role in determining which firms utilizing breakthrough discoveries will be most successful. Interestingly, these scientists often publish more and better science during the period of their academic involvement, apparently due to the greater resources which result from their commercial activities.

[41] Congressional Budget Office, p. 90.

[42] Stephan, p. 1205.

[43] Peter Howitt, "The Economics of Science and the Future of Universities," The 16th Timlin Lecture, February 16, 2000 (U. of Saskatchewan) p.9.

State Revenues from IP

Some who are concerned about state expenditures in this period of tight budgets have proposed that the state seek to maximize its revenues from state-funded inventions, with the goal of either recovering the cost of the research or helping to solve the state's fiscal problems. In any scenario other than the extremely rare "blockbuster" invention, and regardless of the state's IP policies, state-funded innovations and the revenues generated from them cannot realistically be expected to have any significant direct effect on the state's revenues for the immediate future. In addition, the costs of protecting and maintaining IP rights are significant, and would decrease the net gain from an individual profitable patent.

Most significant is the risk that requiring short-term financial returns to the state will likely compromise much larger societal and financial returns in the longer term, e.g., discouraging or compromising commercial development or innovations necessary for society and the state to benefit ultimately through maximal economic activity.

Defining "Return on Investment"

The state may benefit from IP generated with its funding in several ways.

In the near term, economic benefits will most likely accrue to the state from its investment in research through retention and recruitment of high-quality research personnel and enhanced business activity in support of research institutions and programs. In some cases, state funding can be used to leverage additional research funding from federal and private sources. Both of these benefits align with the intent of ACR 252 to encourage participation of small businesses and promote collaboration between commercial concerns and nonprofit organizations, including universities.

Regarding benefits from new discoveries, the primary IP derived from state-funded research in this early period will be either published articles, or research tools or inventions that have promise, but for which much more development funded by venture capital and companies will be required to determine their optimal use and commercial viability. To the extent that state policies encourage the diligent use of IP to develop new products, then competition and economic activity will occur.

Figure 1a shows a typical model for research output at a nonprofit research institution. Figure 1b shows two models for revenue distribution. Variations occur in each type of institution, but the path of outputs suggests the complexity of the interactions between researchers and any net revenues downstream.

Analyses show that research investment has spawned the establishment of many new companies in California, which in turn supports the state's economic growth. For example, a 2004 report by the state's biomedical industry prepared for the California Healthcare Institute (CHI)[44] by PriceWaterhouseCoopers found that California universities and research institutes have spun off 732 companies. These companies bring significant jobs, tax revenues, new products, and intellectual and scientific capital to the state. According to this report, the 2,600 biomedical companies in California generate over 230,000 jobs, making the biomedical industry a leading employer in the state. The jobs in this sector pay an average salary of $67,000 per year, thereby contributing substantially to income tax revenues to the state. These companies

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[44] California Healthcare Institute, California's Biomedical Industry: 2004 Report (http://chi.org/home/template5.php?pid=34&subSel=3&subSel=3) p.11.

From Research to Commercial Product: Typical Research Output at a Non-Profit Research Institution

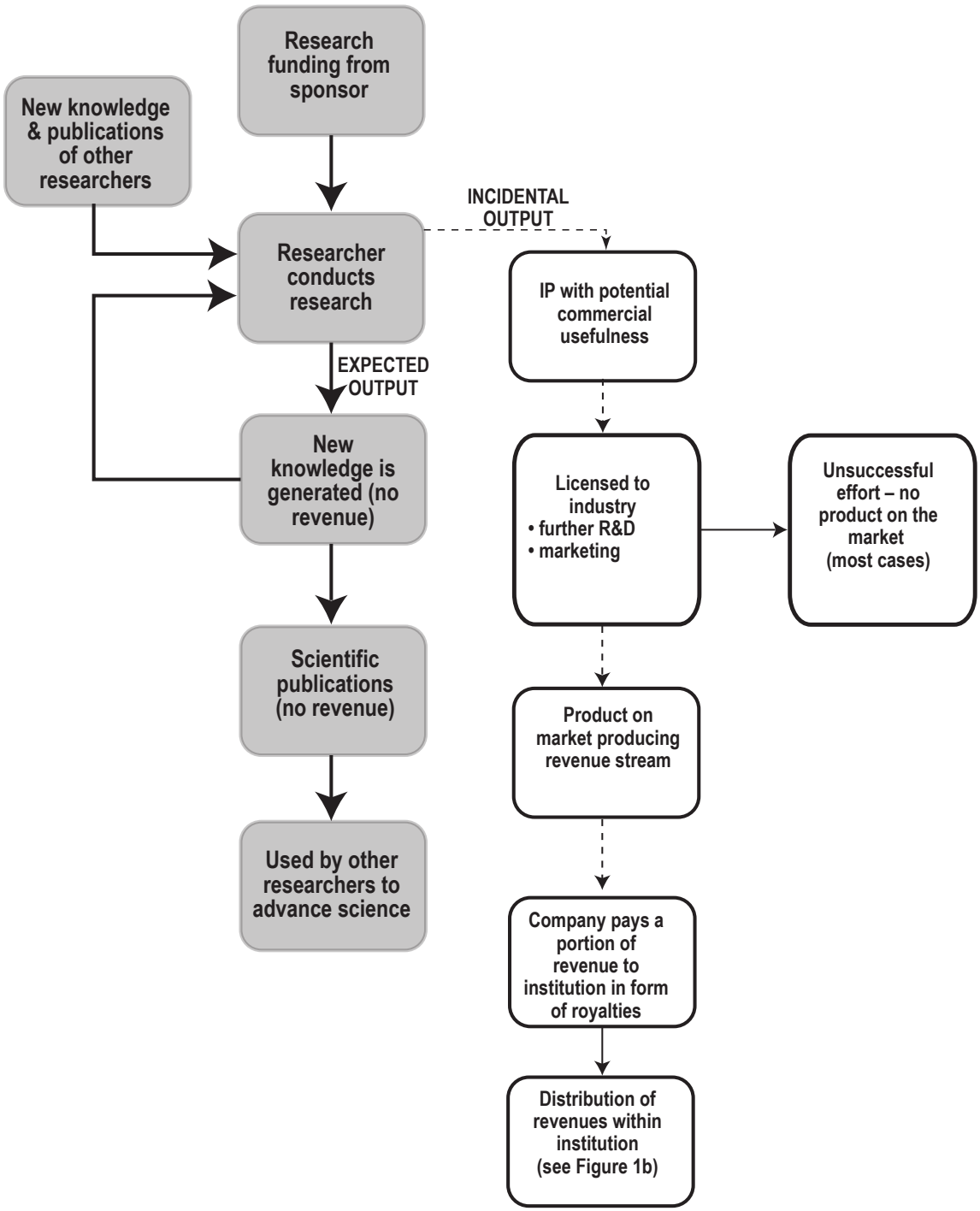

Figure 1a: From Research to Commercial Product. This figure illustrates the typical pathway for knowledge generated by research at a nonprofit research institution (left) and the steps following the incidental production of IP with commercial usefulness (right).

Models for Revenue Distribution

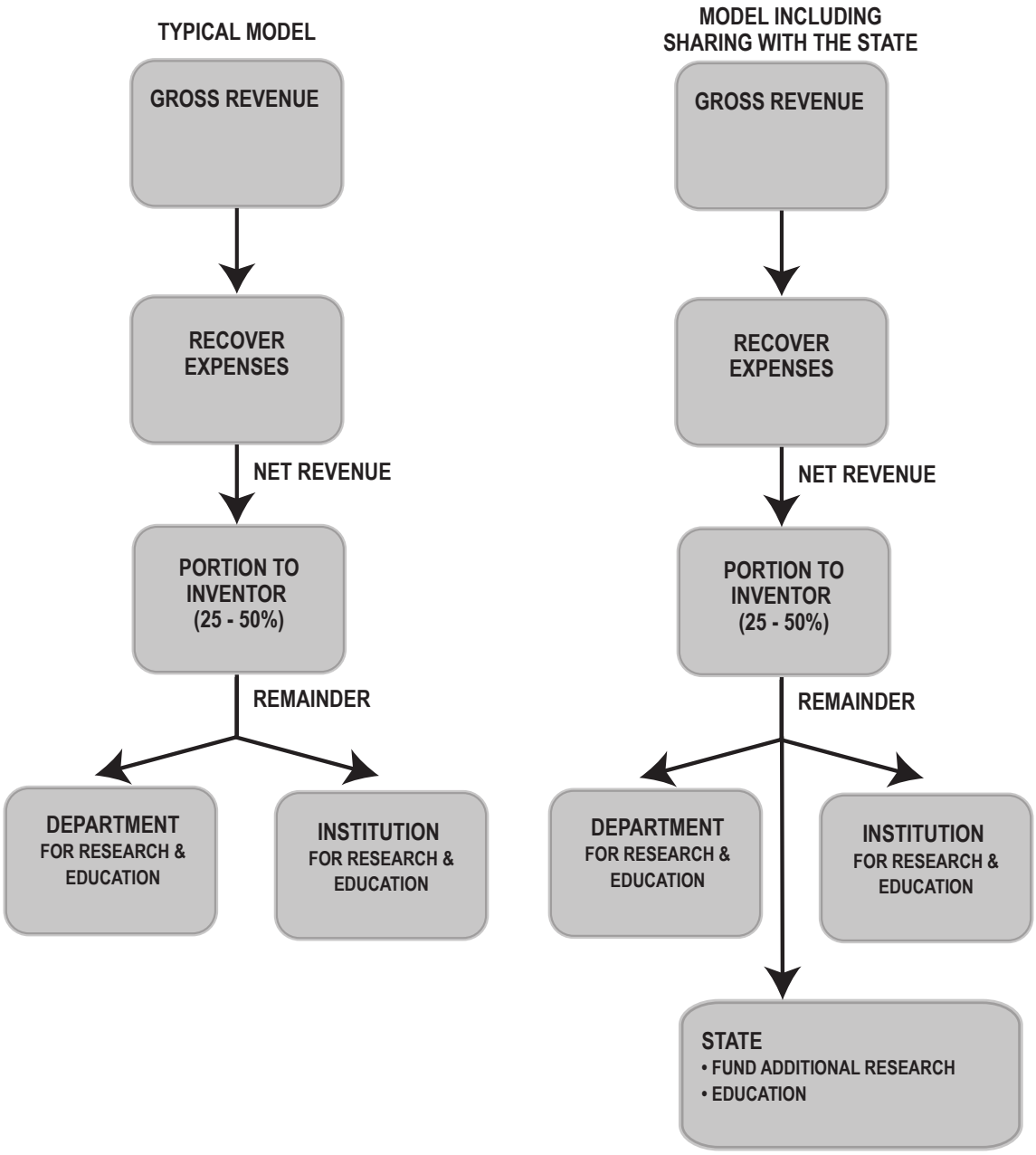

Figure 1b: Models for Revenue Distribution. At left is a typical model for revenue distribution at a university or other nonprofit research institution. At right is a potential variation of this model including the state as a beneficiary of the net revenue.

generate $32.3 billion in worldwide revenues, and on average invest 48% of those revenues back into research and development activities. These companies also attract further investments to California, with over $4 billion coming from alliances with big pharmaceutical companies, and $2.1 billion from venture capital.

Royalty Revenues and Revenue Sharing

The desire for substantial return on investment, in particular if that in turn drives high royalty rates on early stage research products, should be balanced with the need to create incentives for the much greater commercial investment that is necessary to develop useful treatments and therapies.

At least in the near term, and possibly in the longer term (10-15 years), the primary output derived from much state-funded research and development will be either research articles, or research tools or inventions that have some promise, but for which much more research funded by venture capital and companies will be required to determine their optimal use and commercial viability.

Requirements for royalty revenue sharing may have negative impacts on both nonprofit and for-profit grantees. Revenue sharing imposed by the state on its nonprofit grantees may act as a disincentive to invest the effort and cost necessary to secure patent protection, find an appropriate licensee, and ultimately transfer a promising technology to the commercial sector for the development of treatments and drugs that prove beneficial to the general public. In addition, for nonprofit grantees, a royalty sharing requirement could, depending on how it is administered, prevent them from maximizing the impact of state funding by using it to leverage

The Cohen-Boyer Patents: An Unusual Success Story

Stanford researcher Stanley Cohen and UC San Francisco researcher Herbert Boyer invented the fundamental technology used widely to catalyze research and commercialization in the exciting new field of DNA cloning, also known as recombinant DNA. DNA Cloning is a method to splice DNA from two or more sources, which becomes incorporated into a single recombinant molecule. It also is used to produce drugs such as insulin, for diabetes; erythropoietin, a protein that stimulates the production of red blood cells and is used in the treatment of anemia; tissue plasminogen activator, a clot-dissolving enzyme used to prevent damage to heart muscle following a heart attack; and human growth hormone.

Stanford University, which managed the three basic DNA cloning patents on behalf of the two universities, granted a total of 478 non-exclusive licenses. The licenses contained reasonable royalty rates (e.g., 1/2% on end-product sales). The licenses' non-exclusivity and reasonable pricing discouraged circumvention of patent rights and spurred further research, development and innovation in the research field. Royalties on the patents exceeded $255 million, which has been used to support research and education at both universities.

This example, however, is a highly unusual amount of royalty returns — a so-called "blockbuster" that defines the exception rather than the rule. The ultimate benefits were both the development of a powerful new research tool and additional funding for research and education.

federal funds, since federal funding rules require them to use net royalties for education and research purposes. Royalty revenue sharing imposed on its for-profit grantees could discourage their participation in state funding altogether.

In addition, income on royalties from licenses is not guaranteed, and is often modest. For example, a study of University of California inventions over two decades (1975-1995) showed that only 1 in 400 inventions could be expected to bring in over $1 million in licensing revenue over its entire life.[45] In addition, according to a recent national Association of University Technology Managers (AUTM) survey, universities, on average, produce one commercially significant invention for every $2.5 million of research funding.[46] As noted in the insert box, the Cohen-Boyer patents resulted in a much larger revenue stream, but that invention is considered a quite rare "blockbuster."

Looked at another way, in a typical year, state research funding is about $300 million, which could be expected to produce 120 inventions, out of which 0.3 inventions could be expected to bring in over $1 million over its entire lifetime. Alternatively, one invention every three years could be expected to bring in over $1million in its entire lifetime.

The issue of whether or not to require recipients of research grants to compensate the state in the event they realize income from the commercialization of IP created under state funding was explored by the state-funded Breast Cancer Research Program (BCRP), administered by the University of California. The BCRP considered the advantages and disadvantages of a number of approaches,[47] ultimately deciding not to impose any kind of compensation requirement, preferring instead to encourage maximum participation in the program.

It should also be noted that at the federal level, after considerable debate on this topic, the NIH decided that the single most important goal for biomedical research was the rapid development and commercialization of products, and that direct financial considerations should be secondary.

Instead, the state should focus on providing incentives for commercial investment and development of new technologies within the state of California. That strategy will potentially contribute the largest economic impacts in the near term through job creation.

Reinvestment into Research

This issue is closely tied to revenue sharing, as the flow of revenue first needs to be determined before consideration can be given to how much can be reinvested in research. The state's potential nonprofit grantees, based on Bayh-Dole requirements, already have policies in place that require net licensing revenue to be used only for research and education. The federal government imposes this as a condition of its funding to nonprofits. As with IP ownership, consistency with the requirements of other providers of research funding will allow state grantees to leverage such funds where available and appropriate, and avoids the necessity, expense and administrative burden of isolating state-funded research activity.

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[45] "Considerations in Developing an Intellectual Property Model for Research Grants Awarded by the California Institute for Regenerative Medicine," University of California, The Burnham Institute, Stanford University, and University of Southern California (2004) p.3.

[46] AUTM Licensing Survey: FY 2002, Ed. Ashley J. Stevens (Association of University Technology Managers, 2003).

[47] Charles L. Gruder, "Options for Requiring For-profit Grantees to Compensate the State," University of California Special Research Programs (1994).

It should be noted that reinvestment into research based on any revenue flow back to the state would be most effectively guaranteed if the revenue were either returned directly to the state or to a special research account managed by the state (similar to the Breast Cancer Research Account), as opposed to the state's general fund.

5. Objectives for State IP Policies

Key Points

- **Through its support of research, the state's mission is to make grants with an ultimate goal of enabling researchers to discover and develop new knowledge that will ultimately find its way into new products that benefit the public.**
- **The primary objectives of the state's IP policies should be to maximize its effectiveness in supporting this mission.**

Research universities and other nonprofit research institutions will be the primary participants in conducting research funded by the state, although some research will be conducted by industry. To succeed, the state must provide an attractive source of research support to talented scientists who are the most likely to produce the most important research. One attraction is to ensure that the state's policies do not differ dramatically from the prevailing research and academic policies that enable those researchers to make and receive credit for significant contributions at the frontiers of science.

Through its support of research, the state's mission is to make grants with an ultimate goal of enabling researchers to discover and develop new knowledge that will ultimately find its way into new products that benefit the public. The primary objectives of the state's IP policies should be to maximize its effectiveness in supporting this mission. Examples of such objectives might be:

- *Support the open dissemination of research results and transfer of knowledge, where appropriate.* As noted earlier, *w*idespread dissemination of research results is essential for the advancement of science and the development of practical application. For instance, universities preserve the rights of their researchers to freely publish their research results.
- *Ensure that discoveries and research tools that are useful for further research are made broadly available to the research community.* Accessibility of research tools ranging from cell lines to reagents to software programs is essential for the advancement of research.
- *To the extent possible, preserve the ability for grantees to leverage non-state funds in their related research.* Ideally, the state's IP policies would not conflict with the obligations associated with other sources of research funds. Under federal funding, for example, a nonprofit recipient of funds generally retains ownership of its inventions and must ensure that any net proceeds from licensing the inventions be used to support further scientific research and education. Any state policy to the contrary would prevent a grantee from fully leveraging federal funds.
- *Encourage practical application of state-funded research results for the broad public benefit.* The ultimate goal of the state is to provide public availability of scientific advances. This goal cannot be accomplished without industry involvement. In the pharmaceutical and biotech industries, where a tremendous investment is required to take a drug through development and regulatory hurdles, companies usually require

exclusive access to a promising new discovery in order to justify such an investment. Such exclusive access is achieved through use of the patent and licensing system. Other types of research results can be made broadly available on a nonexclusive basis. Attention should be paid, however, to not encouraging exclusive licensing of upstream research results that would, in all likelihood based on historical examples, advance research more significantly by remaining in the public domain. The Cohen-Boyer patents for recombinant DNA technology and the subsequent non-exclusive licensing strategy provide a model that should be explored for its applicability to other settings.

- *Accelerate the transition of discoveries from research to commercially available products, preventive measures, diagnostics, and treatments.* The state's IP policies need to be crafted with this fundamental premise in mind. It will be important to avoid introducing any policies that would slow down, inhibit, or prevent this transfer process. This approach is consistent with that of the NIH, which has affirmed that the primary consideration in government-funded biomedical research needs to be accelerating research into the development and commercialization of diagnostics and therapies.
- *To the extent possible, balance existing investments with state investments such that each receives appropriate return.* As noted elsewhere in this report (Figures 1a and 1b), the state could apply other models and formulae to determine how any revenue stream is directed.
- *Promote collaboration between commercial entities and nonprofit research institutions.* Close collaboration between such entities is often critical to bridge the gap between early stage discoveries and products. Collaboration with California-based companies is to be encouraged to help achieve some level of economic return to the state. The location of the firm, however, should not be the major criterion.
- *Encourage private investors to invest in further research and development of new technologies resulting from state-funded research.* Venture capital investment plays a critical role in the development of IP after initial research and before late-stage R&D which is more generally funded by private industry.
- *Minimize costs of administering policies.* To minimize costs and administrative burden, the state should strive for a uniform and streamlined process for administering its grants and resulting IP. For example, permitting grantees to administer inventions in accordance with their established policies (to the extent such policies are consistent with the state's objectives) would relieve the state of this administrative effort and expense.
- *Be mindful of the time delay and private investment needed before significant benefits accrue to the state.*

6. How Should California Handle IP Generated with State Funding?

Key Points

- **If the state chooses to handle IP generated with its funding, it should use a mechanism that preserves the state's rights and minimizes the costs of doing so.**
- **An office within a single agency could serve four functions: track IP generated by state employees; track IP that emerges through research funding; monitor the use of that IP; and collect and manage any revenues that the state may receive.**

The Legislature's request to CCST to develop recommendations for IP policy suggests that the state has an interest in handling IP developed with its funding. We note in Chapter 2 that ownership of IP should reside with the grantee, and subsequent management of it should also occur as close as feasible to the grantee. That generally means that active IP management occurs within the grantee's institution.

If, however, the state chooses to play an oversight role, we propose a mechanism that both preserves the state's rights, and minimizes the costs of providing state oversight of its own IP.

The major criticism of the 2000 auditor's report was that in the absence of statewide policies, an idiosyncratic agency-by-agency approach to handling IP developed. The result was great unhappiness on the part of those who entered into contracts with the state, a burdensome reporting process, and no clear understanding about the value of the state having IP rights. California agencies must deal with IP related issues such as the collection of potential royalties, return on investment, and California's desire to sell IP to entrepreneurs for further development of California industries. Such an approach is confusing, expensive, and internally inconsistent, resulting in high costs and inefficiencies for grantees and contractors.

These inefficiencies have occasionally significant repercussions. For example, the state is missing opportunities to leverage federal funds towards state goals related to homeland security, energy, and disaster mitigation. The Department of Energy (DOE) and NASA fund several large laboratories in the state of California, including the Lawrence Berkeley National Laboratory, the Lawrence Livermore National Laboratory, the Sandia National Laboratories/ California, the Stanford Linear Accelerator Center, the NASA Ames Research Center, and the Jet Propulsion Laboratory. The combined R&D expenditures for these and other federal facilities in California total about $5 billion a year.[48] However despite the significant opportunities for the state to make use of these facilities, conflicts in contracting policies between federal and state agencies are major limiting factors in the successful negotiation of contracts between the two bureaucracies.

California is a leader in technological advances and is a forerunner on projects that most DOE and NASA laboratories are currently working on. If there were not conflicting federal and state regulations, California could more easily take advantage of the knowledge and expertise

[48] California Council on Science and Technology, California's Federal Laboratories: A State Resource. Sacramento: January 2006, p.1.

of the labs on topics of interest that could directly affect and benefit California. Unfortunately, an opportunity to leverage federal funds towards state goals is being missed.

With respect to IP developed by state employees it seems reasonable for the state to generally insist on ownership and control of that IP. The kinds of IP to be protected would be, for example, trademarks, copyright of materials created by employees in state agencies, or databases containing information needed by the state.

With respect to IP generated by research performed elsewhere with state funding, the role of the state in asserting ownership of that IP is less clear. At the federal level, this discussion played out over 25 years ago. The result, as noted elsewhere, was the Bayh-Dole Act: ownership resides with the grantee and management occurs in the research institution, with some constraints.

For both of these categories (state-generated and state-funded IP), at the very least, a rationale can be established for the state to oversee and keep track of the IP its funding generates.

If the legislature decides that the state should play such a role, we recommend the establishment of an office within a single agency that would serve four functions: track IP generated by state employees; track IP that emerges through funding of research; monitor the use of IP; and collect any revenues that the state may receive.

The alternative is to enter into a contract with a private firm to provide those services to the state, in much the same way as the state hires other kinds of expertise. Fortunately, because of its vibrant high-tech and biotech communities, California is home to many companies with deep expertise in IP matters that would enable the state to track and monitor its IP efficiently and effectively. Such firms may also even have the networks to increase the use of IP to benefit the public.

A third alternative exists; the University of California already manages several state research programs, and has well-established IP management capabilities. The state could explore the possibility of contracting with UC to provide this service to the state.

If the state chooses to establish its own office, we recommend establishing only one office within state government, rather than an office in each agency that is assigned a set of related duties. Combining those functions in one office, rather than distributing a smaller function across each agency, will enable the hiring of professional staff with the requisite skills in IP policy, technology transfer, the law to track and monitor IP effectively, and will provide for consistent treatment of IP across state agencies.[49]

IP Oversight Functions

The first function of such an office (or contractor) would be to track IP generated by state employees. Such a tracking function would assist the state in determining which creations warrant IP protection and what kind of protection. Knowing what IP exists also allows the state to examine those outputs that might be commercialized, with a possible financial return to the state.

[49] An exception to this recommendation is IP developed with CIRM funding. In our interim report, we recommend a similar tracking function to reside within CIRM. Our assessment is that the amount of funding over ten years, the relatively narrow technical field of the research to be funded (that is, stem cell-related, not information technology, agriculture, or other fields), and the range of IP generated in that timeframe, warrants a special role for CIRM to track that IP.

The second function would be to track IP generated by state-funded research. The purpose would be to know what knowledge has been created, how it is being protected, and if there are co-funders for the research (e.g., federal or private). This office could set up a database that tracks IP by category of protection, date of creation, owner of IP, and research institution. Other kinds of information that would be interesting to know are other sources of funding on the research project (to ensure compliance with other rules and regulations), and licensing agreements. This minimal tracking function would be a substantive improvement over the current situation.

A third function would be to monitor the way IP is being used. If, by monitoring IP, the state can determine that due diligence is not being performed to develop or license IP, it can assert "march-in rights" similar in intent to those given to the federal government under Bayh-Dole.

March-in rights are a mechanism within the Bayh-Dole Act that enables the government to step in under certain circumstances and require the grantee to license to responsible applicants on reasonable terms. If the contractor fails to do so, the government may grant such license itself. These rights were intended to be used when the government could demonstrate that an invention was not being diligently developed.

This provision of Bayh-Dole was quite controversial initially, causing many companies to be extremely wary of accepting federal funds or licensing inventions created under federal funds. However, industry has come to participate more willingly since, in the 25-year history of the act, the federal government has never invoked the clause, despite several requests for it to do so. [50, 51] Therefore, there are no precedents at the federal level to guide state action if it were to assert march-in rights. The absence of a case where the government has exercised its march-in rights can be viewed as a positive statement for the overall policy, namely that the inventors and institutions are motivated and effective in moving IP into the commercial market place.

The state can choose to establish a similar policy that allows march-in rights if it finds that IP created with its funding and licensed to a commercial entity is not being developed in a timely way. March-in rights could be triggered if, for example, a licensee or corporate grantee has not taken, within a reasonable time, effective steps to achieve practical application in a particular field of use.

Such a policy could be instituted whether or not there is an office to oversee IP, but the kind of office we suggest here would be the likely place to provide that function for the state. However, since the state has no track record in this area, it is quite possible that industry will exhibit the same kind of reluctance to participate as it did in the early years of Bayh-Dole.

The fourth function that a state office could play is to collect and manage royalty revenues the state may receive from its IP.

As noted elsewhere in this report, we do not recommend that the state require royalty returns from its grantees except in those "blockbuster discoveries" where the returns exceed a predetermined limit. Nevertheless, if the state determines that royalty revenue sharing is not counter to the state's broader mission and is the best way to satisfy public expectations, some tactics to do so are explored here.

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[50] http://ott.od.nih.gov/Reports/March-in-Norvir.pdf; http://ott.od.nih.gov/Reports/March-in-xalatan.pdf.

[51] http://ott.od.nih.gov/Meeting/Senator-Birch-Bayh.pdf

Before requiring that a portion of royalties be returned, the state should:

- Permit grantees to recover all direct expenses incurred in pursuing patent protection and licensing opportunities.
- Begin royalty revenue sharing only when certain thresholds have been passed, e.g., net revenues exceeding $500,000/year to the licensor, to avoid the administrative inefficiency of dealing with marginal amounts of money and to help grantees offset the cost of the risks they take in technology that is ultimately unsuccessful, thereby providing an incentive to take such risks.
- Allow grantees to share any licensing income with inventors, in accordance with their established institutional policies. This requirement is dictated under federal funding regulations, and serves as an incentive for the inventor to participate in the time-consuming process of obtaining patent protection and to help a potential licensee fully utilize a technology. Furthermore, many institutions have employment agreements/contracts under which they are required to share such income according to pre-established formulas.
- Enable grantees to fulfill their other mandatory obligations. For example, when an invention includes a co-inventing/co-owning institution, and the grantee is managing the invention on behalf of both parties, it may be legally obligated to share a specified portion of any income it receives with the co-inventor/co-owner.
- Direct any shared revenues that are returned to the state be used to fund further research and education, which is consistent with the objectives of the state and with the mission of nonprofit research institutions. This use of revenues minimizes potential conflicting requirements with Bayh-Dole for nonprofits that also have federally funded research in similar areas.

7. Recommendations for the State's IP Policies

Key Points

- **The state's IP policies need not be identical to those of the Bayh-Dole Act, but its provisions should not conflict with that Act in ways that would lead to confusing, conflicted, or convoluted funds-management administration by institutions, ultimately impeding the conduct of research.**

As the state develops its IP policies, consideration should be given to the likely and fairly frequent circumstance where state funds for research would be leveraged with federal funds. At a minimum, the state should recognize that existing institutional policies are driven by Bayh-Dole. To minimize confusion and maximize the return on grant funds, the state's policies should be consistent with Bayh-Dole.

This is not to say that the state's policies need be identical to Bayh-Dole, but its provisions should not conflict with Bayh-Dole in ways that would lead to the creation of confusing, conflicting, or convoluted funds-management administration by institutions, ultimately impeding the conduct of research.

Consistency between federal and state policies would avoid conflicts in determining ownership and royalties from cumulative research results involving related projects, possibly supported by a variety of funding sources. In addition, the state should avoid adopting a set of IP policies that make the prospective financial returns for inventions made with state grants less attractive than those for comparable federal grants. A likely unintended consequence could be that the best researchers and institutions would favor types of research funded by the latter.

We recommend, therefore, four general principles for the state's IP policy:

- The policy is consistent with the Federal Bayh-Dole Act. This principle can play out in many ways that are of benefit to the public. In particular, ownership of IP resides with the grantee, which is required to diligently develop the technology for the public benefit. In addition, the balance of any net royalties must be used to support research and education activities.
- The policy creates incentives for commerce in California from state-funded research to the greatest extent possible.
- The policy encourages timely publication of results to diffuse knowledge widely, and provides guidance on the kinds of data that are desired to be placed in the public domain or available under open source, Creative Commons, or other broad-use licenses, including software and special databases.
- Requires diligent commercialization of IP-protected technology into products that benefit the public.

With these principles in mind, we recommend that the state develop IP policies that accomplish the following:

1. Permit grantees to own IP rights from state-funded research.

To encourage the greatest participation in state-funded research, by both for-profit and nonprofit entities, grantees should be permitted to own IP that they create in projects fully or partially funded by the state. From a grantee's perspective, this avoids "fractionating" the research results from a given researcher/laboratory. This approach is consistent with the Bayh-Dole Act and with the requirements of most other funding entities, thus allowing grantees to leverage federal and other funds (where available and appropriate) and avoiding the administratively burdensome need to isolate state-funded research to prevent conflicting obligations from the use of third party funding. However, the state should retain the ability to step in and require grantees to license to responsible applicants on reasonable terms — so-called "march-in" rights — if grantees do not show diligence in developing and applying the technology, and another party is willing and able to do so (see recommendation 5 below).

2. Where appropriate, require that grantees (institutions, individuals, or both) provide a plan describing how IP will be managed for the advancement of science and California public benefit.

Although such a plan is not customary for research grants, public calls for accountability with respect to certain kinds of research suggest that developing a plan may at times be a political necessity.

Due to the national (and international) nature of the research in research universities and not-for-profit and for-profit institutions, it is not realistic to expect that every state-funded discovery or invention will be licensed and developed exclusively in California. Indeed, if this is a requirement for state funding, researchers and California will be placed at a severe competitive and economic disadvantage. However, it would be advisable to incorporate a section of the grant application that asks potential grantees to explain how the work is expected to benefit the state of California and how specific IP management strategies will attempt to direct commercialization opportunities to the state. Evaluating these potential contributions should be at the discretion of the granting agency.

3. Grant basic research funds without requiring that grantees commit to providing a revenue stream to the state. If, however, a revenue stream develops over time, revenues will be reinvested in research and education.

The state must take care not to create financial burdens that discourage or impede the rapid development of new products for the public good. Direct revenue sharing — even if acceptable to licensees —would take years to benefit the state, and would run contrary to the terms of most federal funding, which specifies that excess revenues can only be used to support research and education. Further, the total amount of such shared revenue is likely to be miniscule compared to the state's research budget — far too small a benefit to risk alienating potential high-quality commercial partners. There are multiple examples of the negative effects that policies requiring direct revenue sharing at the federal level have had on the technology transfer process. We believe that a state IP policy that seeks to benefit the state by revenue sharing would not be appropriate and could well have the unintended consequence of decreasing, rather than increasing, the long-term economic benefits to the state.

We do not recommend the state focus on royalty revenues as a significant financial return because history shows that this expectation will not be met and the cost of administration will likely exceed the returns. However, in those exceptional cases where the licensing royalties are large (for example, with net revenues to the licensor greater than $500K), we recommend the state policy include a revenue sharing agreement between the institution owning the IP and the state agency, with an agreed fraction of the returns going to the agency to support further research within their charter.[52]

4. Generally, make state-developed research tools widely available to other researchers.

In any licensing of state-funded inventions, especially those that are useful in future research activities, it should be made clear that grantees should be expected not only to reserve their own right to use the invention for research and educational purposes, but to also reserve the right to share their state-funded research tools with as few encumbrances as possible, especially for use in other state-funded research.

Grantees should ensure that third party agreements, e.g., for access to research materials, preserve their ability to broadly share research tools and data, and to publish freely as appropriate.

In their grant applications, as part of their IP management plan (see recommendation 2, above), applicants should be expected to provide a plan describing how IP will be managed to ensure that research tools will be made broadly available for the further advancement of science. This is consistent with the NIH guidelines for its research proposals.

5. Require diligent efforts to develop state-funded IP into applications and products that benefit the public.

Inventions made under state funding should be promptly reported to the state by the office in the grantee's institution responsible for such matters. As discussed above, where an industry investment is required to develop a product, companies usually require exclusive access in order to justify such an investment. This is usually achieved through use of the patent system. To preserve the ability to secure the patent protection necessary for exclusive access, the state must be able to receive invention reports in confidence. In addition to initial invention reports, in order to monitor the diligent development of state-funded inventions, the state should require periodic (every 3-5 years) reports on IP utilization as well.

Exclusive commercial licenses issued by the grantee for the commercialization of state-funded research should include a provision requiring the recipient of the license to diligently develop the licensed invention. Such a provision permits the grantee to terminate the license if the licensee is unwilling or unable to move a technology forward in an appropriate and timely manner. Since diligence terms are case-specific, it is important that the state not impose any specific parameters in this area.

If a grantee chooses not to move forward with commercial development or use of a state-funded invention, it should be required to notify the state and provide it the opportunity to do so, either through an exclusive license to the grantee's interest in the technology or by permitting the state to take title to the invention, but only to the extent that the grantee is

[52] With respect to CIRM, the revenue sharing agreement would be between the institution owning the IP and CIRM, with an agreed fraction of the returns going to CIRM to support further research.

legally able to transfer title — e.g., if federal funds are used to create the invention, the grantee is usually prohibited by law from transferring title. This kind of transfer is generally referred to as a reversionary right.

6. Retain within the state Bayh-Dole-like "march-in" rights if the owner of IP is not undertaking appropriate steps to transfer technology to benefit the public.

The state may want to consider retaining the right to step in if it is clear that effective steps are not being taken within a reasonable time to achieve practical application of state-funded IP. Such rights could include the state's ability to require the grantee to grant a license to a responsible applicant on reasonable terms. However, great caution should be taken with implementing such a right. At the federal level, such "march-in" rights are similarly provided to the federal government, but with a process of checks and balances. Early on, industry was concerned about the uncertainty introduced by the federal "march-in" rights and showed a great deal of reluctance to invest in federally-funded inventions. While some still express concern over this issue, it has been largely mitigated by the fact that the federal government has not yet exercised this right.

7. Leave license particulars to the owner who is in the best position to judge how best to ensure that discoveries are made widely available through commercialization or otherwise.

The state should avoid overly prescriptive policies for IP derived from state-funded research. In general, each piece of IP is unique and grantees are in the position to know how their IP could be commercialized, and have the expertise to negotiate deals with the private sector with the goal of successful commercial development. Moreover, grantees are in a position to monitor licensees to ensure that they are being diligent in their efforts to develop useful products.

8. Reserve the right to use IP by or on behalf of the state for research or non-commercial purposes.

The state should receive a non-exclusive, royalty-free license to all state-funded IP to practice and have practiced on behalf of the state for research or non-commercial purposes. The license should include the right to allow other state-funded researchers to use such IP in their state-funded research activities. This is consistent with policy at federal agencies (e.g., NASA).

9. Establish and maintain state-administered functions to track all IP generated through state funding.

In order to effectively keep track of IP generated through state-funded research, it will be essential to establish a database to track it and an office to collect and update the information. Such a database would be a useful source of information to other state-funded researchers, and to companies interested in commercial development of the IP. A small state office or a contractor to the state would be the logical repository for tracking IP generated through research that it funds. The state could require that all grantees report regularly about the IP generated with state funds in a form that can be readily introduced into a database. This would enable the state to more accurately inform the state of all the benefits derived from research it funds. The state may wish to contract out this responsibility, but the office should remain under the state's jurisdiction.

Conclusion

The state has an important role in funding research. The key role of state funding for research is to generate knowledge by stimulating researchers to work on research questions that, when better understood or solved, may benefit the state. The state, therefore, plays an important role in identifying what those questions are in many sectors, and in providing appropriate incentives for the state's best researchers to work on finding answers to those questions.

The state also needs to ensure that the researchers and their institutions have incentives to do the research, and that commercial firms also have incentives to license that IP and invest their own funds to develop new products. One key way to create such incentives is to be cognizant of the federal policies in place that currently drive research, and build state policies that are consistent with those policies. By doing so, the state will be better able to leverage its smaller, strategic dollars, create significant alliances with other funding partners, and attract the best researchers to work on state problems.

California remains a place where high-quality research, entrepreneurship and innovation occurs on a large scale. Careful attention to the way that state policies for IP create incentives for researchers and commercial partners will help California continue to play that important role in the nation's research and economic life.

Appendix A: Types of intellectual property

James Pooley and Katherine Nolan-Stevaux

Different forms of intellectual property are used to protect diverse discoveries. This appendix offers a brief primer on patent, trade secret, and copyright protection, focusing specifically on how each relates to biological, biotechnological, or pharmaceutical discoveries, and illustrates how some discoveries may be protected by combinations of different intellectual property regimes.

Patents provide exclusive protection for inventions for a limited time period. For twenty years from the application date, a patent holder may exclude others from making, using, or selling the patented material. Patents enable protection of human-made inventions that are novel, useful, and inventive compared to what is publicly available. Consequently, research tools in biology, chemistry, engineering, and computer science are often patented. To obtain a patent, an inventor must file an application with the United States Patent and Trademark Office, which will determine whether the invention meets the patentability requirements, and if so, will issue the patent. In return for full public disclosure of the invention in the body of a patent, the inventor obtains the right to exclude others from practicing the invention. Thus, during the life of a patent, no one else may make, use, sell, or offer for sale any product or method that is covered by that patent. Once the patent expires, anyone may use the invention without restriction. For example, after a patent on a pharmaceutical drug expires, generic drug companies may manufacture and sell generic versions of the drug.

Patents are commonly used to protect biological, biotechnological, or pharmaceutical research tools. Although genes as they exist in the human body may not be patented, upon isolation from an organism, they are appropriate patentable subject matter in many countries. Accordingly, substances purified or isolated from nature, such as human hormones like insulin, and substances created in the laboratory, such as the cholesterol lowering drugs called statins, are frequently patented. In addition, living materials, such as cultured cell lines or stem cells, may be patented once isolated from their natural environment. Even the research methods by which such cell lines are isolated may be protected through patenting. Although patenting an invention can be expensive, many view the exclusive rights to the invention as worth the cost.

In contrast to patents, **trade secrets** exist as long as the information remains secret. Any information or invention that provides actual or potential value to its holder qualifies for trade secret protection, provided that such information is not generally known or easily discoverable. In order for an invention to acquire trade secret status, the inventor must undertake reasonable efforts to keep the invention secret. For example, documents describing the trade secret should be marked confidential, kept in a secure location, and access to that location should be restricted. Individuals with access to the trade secret should sign confidentiality and non-disclosure agreements in order to preserve the trade secret. Anyone who uses improper means to obtain a trade secret will be liable to the owner. However, others may independently discover a trade secret without incurring liability, if they do not employ improper means. In such a scenario, as long as the invention remains secret, it remains a trade secret; however, once the invention becomes publicly available, trade secret protection ends. Thus, the scope of trade

secret protection may be broad and potentially permanent, but unlike patents, trade secrets do not provide exclusive protection.

Trade secret law may protect biological or pharmaceutical research at select times in a research program. Prior to the publication of a patent application, trade secret protection enables an inventor to ensure that the invention is not disclosed publicly. However, once the application is published, trade secret protection ends and, if the patent issues, the invention will benefit from patent protection. If the invention is not patentable or the inventor elects not to seek patent protection, trade secret law may protect the invention indefinitely or until patentable research tools have been generated using the trade secret. For example, prior to publishing their own results, researchers may agree to share a mouse model of Alzheimer's disease with an academic laboratory subject to a material transfer agreement (MTA), requiring the receiving researchers' assurance that no for-profit research will be conducted using the mice and that none of the research will be shared with for-profit institutions. Researchers receiving materials under an MTA sign confidentiality and non-disclosure agreements designed to ensure that the invention remains a trade secret.

Unlike patent and trade secret protection, which focus on protecting ideas and information, **copyright** protects original expression recorded in a tangible medium. Copyright protection lasts longer than patent, extending 70 years beyond the life of an individual author, or, for institutional authors like companies, either 95 years from publication or 120 years from creation, whichever is shorter. Although most commonly associated with protection of literary, dramatic, or musical works, including scientific publications, copyright also protects aspects of computer software. Essential functional components of software may not be copyrighted, but creative elements, such as a novel search mechanism, are eligible. Unlike patents, which require government review and validation, copyright protection begins at the moment of creation (although copyrights can be registered with the federal government to ensure robust remedies for infringement). Similar to trade secret, copyright does not provide protection against independent development by others. However, copyright differs from both patent and trade secret by providing a fair use exception, which enables some copying of a "work" subject to the nature of the use, the type of work, the amount of the work used, and the effect of the copy on the market for the original work.

In terms of biological, biotechnological, or pharmaceutical inventions, copyright often protects tools used in bioinformatics, or the use of mathematical, statistical, and computing methods to solve biological problems. In the post-genomics era, bioinformatics includes analyses of gene products (e.g., comparison of gene expression profiles), descriptions of protein interactions in cells or organisms, and analyses and comparisons of sets of experiments, such as the effort to assemble gene expression profiles from different human tumors to identify new genes involved in cancer initiation and progression. Copyright may protect aspects of the software tools used for the analysis of these complex problems and the websites through which researchers access such information from databases.

Recent developments in biology illustrate how patent, trade secret, and copyright converge to protect particular aspects of new technologies. For example, gene expression profiling experiments require the use of multiple inventions protected by different intellectual property approaches. First, the products of active genes, or transcripts, are isolated from tissues or cell lines. Both the method of isolation as well as the cell line may be patented. Second, these transcripts are washed over a DNA gene chip, upon which portions of every gene in a given organism is affixed, with the transcripts binding specifically to their respective gene. Patents may protect the manufacturing method for the DNA chip and the isolated genes spotted

on the chip. In addition, trade secret may protect the organization of the genes on the chip, the selection of specific portions of the genes fixed on the chip, and the types of internal controls employed. Third, a patented machine scans the chip, translating binding patterns into raw data, and computer software transforms the raw data into a list of genes, in order of their level of activity. Different software may be employed to identify clusters of genes with similar activity patterns. Aspects of these computer programs may be protected through either patent or copyright. Fourth, a researcher may compare this dataset with a database of similar gene expression profiles, again employing software that may be in part both patented and copyrighted. In addition, the database may be proprietary, using trade secret protection to protect its contents. Thus, biological research today often employs multiple types of intellectual property to protect distinct parts of a research program.

Appendix B: The Bayh-Dole Act

Wendy Streitz and Richmond Wolf

Background

Prior to the 1980 passage of The Patent and Trademark Law Amendments Act (P.L. 96-517 and P.L. 98-620), better known as the Bayh-Dole Act, there was no consistent federal policy concerning ownership of inventions made through the use of federal funds. Agreements on ownership of inventions were negotiated individually with each federal agency, resulting in inconsistencies and high transaction costs. By 1980, the government held title to approximately 28,000 patents, of which fewer than 5% were licensed to industry for the development of commercial products. Congress passed the Bayh-Dole Act with a primary objective of promoting public benefit from government-funded research, or in the Act's own words, to "use the patent system to promote the utilization of inventions arising from federally supported research or development." It was anticipated that, not only would the public benefit from the availability of goods and services that would otherwise be unavailable, but the U.S. economy would benefit as well. It was also anticipated that a uniform federal policy would substantially reduce the transaction costs of awarding research contracts and grants.

Elements of Bayh-Dole

The Bayh-Dole Act originally applied to nonprofit organizations and small businesses; it was extended to include large businesses by a February 18, 1983 Presidential Memorandum. Under the Bayh-Dole Act, recipients of government contracts and grants may take title to inventions they make with the use of federal funds in return for a commitment to diligently pursue the timely development of those inventions into products and services that can benefit the public. To provide further incentive for diligence, grantees may retain any income received through their commercialization of a government-funded invention.

Some important elements of Bayh-Dole are:

- The Bayh-Dole Act applies to all federal grantees, including universities, small businesses, industry, research foundations, etc.
- Grantees may own inventions they make with the use of federal funding.
- Grantees must disclose such inventions to the federal funding agency and report annually on the utilization of each invention.
- Grantees must notify the federal government in a timely manner if they choose not to pursue rights in an invention so that the federal government may maintain the rights. In the event that the federal government declines its rights, the inventor(s) may petition the government to have the rights assigned to them.
- The federal government retains a nonexclusive, nontransferable, royalty-free license to practice the invention for use by or on behalf of the government.
- To ensure diligence, if the grantee does not pursue patent protection within certain time limits, the federal government can take title to the invention.

- To ensure diligence, if the grantee does not take reasonable steps to achieve practical application of the invention, the federal government can exercise a march-in right to enable another party to make use of the patent rights.
- The Act is silent on copyright issues.

In the case of a nonprofit grantee, the following also apply:

- Title may not be transferred to a third party except under very limited circumstances.
- To ensure that federally funded inventions contribute to the economic development of the U.S., products that are sold in the U.S. must be substantially manufactured in the U.S.
- Reasonable efforts must be made to license to small businesses. This requirement fosters regional economic development, supports the formation of new companies, and strengthens existing small businesses.
- Net royalties received by the grantee must be shared with the inventor(s). This provides an incentive for researchers to actively participate in the technology transfer process and promotes further innovation.
- The balance of any net royalties must be used to support research and education activities.

Conflicts with Federal Funding

Although most research institutions receive research funding from a number of sources, the vast majority comes from the federal government (e.g., in a recent fiscal year at a major west coast research institution, less than one% of all extramural research sponsors were federal government organizations, but the funding from these federal government organizations accounted for over 70% of total extramural research funding at the institution). Since Bayh-Dole applies if *any* amount of federal funds is used in the creation of an invention, there is a very good chance that an invention made at a university will fall under Bayh-Dole. This could happen through the existence of a co-inventor who receives federal funds, or from an unanticipated convergence of separately funded research projects in a lab.

If a research institution were to accept research funds with obligations that conflict with Bayh-Dole (e.g., with title going to the sponsor) and federal funds were to become involved in the creation of an invention, the institution would be in the untenable position of either violating federal law or breaching a legal agreement with the other sponsor. To prevent such a situation from occurring, research institutions generally do not accept funding that conflicts with the requirements of Bayh-Dole. In the rare case that a research institution does accept such funds, it must put processes in place to rigorously ensure that no federal funds become involved in the research. Not only is this administratively burdensome, it can entail limiting funding opportunities for an entire lab as well as limiting with whom a research may and may not collaborate.

The following are some of the areas of potential conflict with Bayh-Dole. If a research agreement were to contradict any of these elements, the research funding could very well be less attractive than funding from another source.

- Title to inventions — Nonprofit organizations are generally prohibited from transferring title to inventions made under Bayh-Dole.

- Use of net royalties — Use of net royalties by nonprofit organizations for any purpose other than research or education is prohibited under Bayh-Dole.
- Sharing royalties with inventors — Nonprofit organizations are required to share net royalties from federally-funded inventions with their inventors.
- Government purposes licenses — The federal government retains a non-exclusive license to practice federally-funded inventions for use by or on behalf of the government; any licenses to other sponsors must be subject to the government's rights.
- Reversionary rights — If the grantee chooses not to pursue an invention or if it does not file patents within certain time limits, title to federally funded inventions can revert to the government. The government also has the right to take title if the grantee is not taking reasonable steps to achieve practical application of an invention. Any rights granted to other sponsors must be subject to the government's rights.

Resources

The Bayh-Dole Act: http://straylight.law.cornell.edu/uscode/html/uscode35/usc_sup_01_35_10_II_20_18.html.

"The Bayh-Dole Act: A Guide to the Law and Implementing Regulations", COGR Brochure, October 1999: http://straylight.law.cornell.edu/uscode/html/uscode35/usc_sup_01_35_10_II_20_18.html.

"University Technology Transfer: Questions and Answers", COGR Brochure, October 1999: http://www.cogr.edu/docs/BayhDoleQA.htm.

Appendix C: Excerpts from Guidelines for Disseminating Research Resources Arising Out of NIH-Funded Research[53]

Definition of Research Tools

The definition of research tools is necessarily broad, and it is acknowledged that the same material can have different uses, being a research tool in some contexts and a product in others. In determining how an NIH-funded resource that falls within the definition should be handled, Recipients should determine whether: (1) The primary usefulness of the resource is as a tool for discovery rather than an FDA-approved product or integral component of such a product; (2) the resource is a broad, enabling invention that will be useful to many scientists (or multiple companies in developing multiple products), rather than a project or product-specific resource; and (3) the resource is readily usable or distributable as a tool rather than the situation where private sector involvement is necessary or the most expedient means for developing or distributing the resource. Recipients should ensure that their intellectual property strategy for resources fitting one or more of the above criteria enhances rather than restricts the ultimate availability of the resource. If Recipient believes private sector involvement is desirable to achieve this goal, Recipient should strategically license the invention under terms commensurate with the goal.

Use of Simple Letter Agreement

Recipients are expected to ensure that unique research resources arising from NIH-funded research are made available to the scientific research community. The majority of transfers to not-for-profit entities should be implemented under terms no more restrictive than the Uniform BioMaterial Transfer Agreement (UBMTA). In particular, Recipients are expected to use the Simple Letter Agreement provided below, or another document with no more restrictive terms, to readily transfer unpatented tools developed with NIH funds to other Recipients for use in NIH-funded projects. If the materials are patented or licensed to an exclusive provider, other arrangements may be used, but commercialization option rights, royalty reach-through, or product reach-through rights back to the provider are inappropriate.

Similarly, when for-profit entities are seeking access to NIH-funded tools for internal use purposes, Recipients should ensure that the tools are transferred with the fewest encumbrances possible. The Simple Letter Agreement may be expanded for use in transferring tools to for-profit entities, or simple internal use license agreements with execution or annual use fees may be appropriate.

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[53] Department of Health and Human Services, National Institutes of Health, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research, Resources: Final Notice, Federal Register Vol. 64, No. 246 (December 23, 1999) pp. 72090-72096, http://ott.od.nih.gov/pdfs/64FR72090.pdf.

Simple Letter Agreement for the Transfer of Materials

In response to RECIPIENT's request for the MATERIAL [insert description] the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.

2. THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.

3. The MATERIAL will be used for teaching or not-for-profit research purposes only.

4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching or not-for-profit research purposes only.

5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.

6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties which may arise from its use, storage or disposal of the Material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider.

7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.

8. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested, the amount will be indicated here:

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

Provider Information and Authorized Signature

Provider Scientist:

Provider Organization:

Address:

Name of Authorized Official:

Title of Authorized Official:

Certification of Authorized Official: This Simple Letter Agreement has has not [check one] been modified. If modified, the modification are attached.

(Signature of Authorized Official) (Date)

Recipient Information and Authorized Signature

Recipient Scientist:

Recipient Organization:

Address:

Name of Authorized Official:

Title of Authorized Official:

Signature of Authorized Official

Date:

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

(Recipient Scientist) (Date)

Ensuring Consistent Obligations

Recipients must ensure that obligations to other sources of funding of projects in which NIH funds are used are consistent with the Bayh-Dole Act and NIH funding requirements. Unique research resources generated under such projects are expected to be made available to the research community. Recipients are encouraged to share these Guidelines with potential co-sponsors. Any agreements covering projects in which NIH funds will be used along with other funds are expected to contain language to address the issue of dissemination of unique research resources. Examples of possible language follow. The paragraphs are presented in a "mix and match" format:

The project covered by this agreement is supported with funding from the National Institutes of Health. Provider agrees that upon publication, unpatented unique research resources arising out of this project may be freely distributed.

In the event an invention is primarily useful as a research tool, any option granted shall either be limited to a non-exclusive license or the terms of any resulting exclusive license shall include provisions that ensure that the research tool will be available to the academic research community on reasonable terms.

Provider agrees that Recipient shall have the right to make any materials and inventions developed by Recipient in the course of the collaboration (including materials and inventions developed jointly with Provider, but not including any Provider materials (or parts thereof) or Provider sole inventions available to other scientists at not-for-profit organizations for use in research, subject to Provider's independent intellectual property rights.

Subject to Recipient's obligations to the U.S. government, including 37 CFR Part 401, the NIH Grants Policy Statement, and the NIH Guidelines for Obtaining and Disseminating Biomedical Research Resources, Recipient grants to Sponsor the following rights:

Limiting Exclusive Licenses to Appropriate Field of Use

Exclusive licenses for research tools (where no further research and development is needed to realize the invention's usefulness as a tool) should generally be avoided except in cases where the licensee undertakes to make the research tool widely available to researchers through unrestricted sale, or the licensor retains rights to make the research tool widely available. When an exclusive license is necessary to promote investment in commercial applications of a subject invention that is also a research tool, the Recipient should ordinarily limit the exclusive license to the commercial field of use, retaining rights regarding use and distribution as a research tool. Examples of possible language include:

Research License means a nontransferable, nonexclusive license to make and to use the Licensed Products or Licensed Processes as defined by the Licensed Patent Rights for purposes of research and not for purposes of commercial manufacture, distribution, or provision of services, or in lieu of purchase, or for developing a directly related secondary product that can be sold. Licensor reserves the right to grant such nonexclusive Research Licenses directly or to require Licenses on reasonable terms. The purpose of this Research License is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the Licensed Patent Rights, however, Licensor shall consult with Licensee before granting to commercial entities a Research License or providing to them research samples of the materials.

Licensor reserves the right to provide the Biological Materials and to grant licenses under Patent Rights to not-for-profit and governmental institutions for their internal research and scholarly use.

Notwithstanding anything to the contrary in this agreement, Licensor shall retain a paid-up, nonexclusive, irrevocable license to practice, and to sublicense other not-for-profit research organizations to practice, the Patent Rights for internal research use.

The grant of rights provided herein is subject to the rights of the United States government pursuant to the Bayh-Dole Act and is limited by the right of the Licensor to use Patent Rights for its own research and educational purposes and to freely distribute Materials to not-for-profit entities for internal research purposes.

Licensor reserves the right to supply any or all of the Biological Materials to academic research scientists, subject to limitation of use by such scientists for research purposes and restriction from further distribution.

Licensor reserves the right to practice under the Patent Rights and to use and distribute to third parties the Tangible Property for Licensor's own internal research purposes.

Appendix D: Intellectual Property Procedures for the Public Interest Energy Research (PIER) Program

Intellectual Property
Policies and Procedures
Public Interest Energy Research (PIER) Program
California Energy Commission

Prepared for the California Council on Science and Technology
By Esteban Soriano

Managed by the California Energy Commission (CEC), the Public Interest Energy Research (PIER) Program is funded by the collection of a surcharge on retail electricity sales. Beginning in 1996, $62.5 million has been collected annually to ensure a continuation of public interest research, development and demonstration projects. In 2004 the PIER research partners included universities (14%), small and large businesses (30%), utilities (21%), nonprofit organizations (19%), national labs (12%) and the state (4%).[54] Below is a summary of how the CEC has handled intellectual property with respect to the PIER program.

Executive Summary

Since 1999, the California Energy Commission (CEC) has had in place a standard intellectual property (IP) policy for research contracts awarded as part of its Public Interest Energy Research (PIER) program. In general:

1. All data produced by a contractor is the property of the contractor, subject to the Energy Commission retaining a no-cost, non-exclusive, non-transferable, irrevocable, royalty-free, worldwide, perpetual license to use said data.
2. Patent rights for subject inventions is the property of the contractor, subject to the Energy Commission retaining a no-cost, nonexclusive, nontransferable, irrevocable, royalty-free, worldwide perpetual license to use the invention for governmental purposes.
3. Copyrightable work first produced under a research agreement with the PIER program is owned by the contractor, subject to the contractor granting the Energy Commission a royalty-free, no-cost, nonexclusive, irrevocable, nontransferable, worldwide, perpetual license to produce, translate, publish, use or dispose of said copyrightable work.

In consideration of the Energy Commission providing PIER program funding to a contractor, the contractor must agree to pay the CEC royalties for all project-related products and rights, as follows:

1. 1.5% of the sales price, for a 15-year period.
2. The contractor may do an "early buyout" of royalty payments by paying the CEC two times the amount of funds that were drawn down by the research project.

[54] California Public Interest Energy Research Independent PIER Review Panel Report, California Council on Science and Technology, March 2004.

There is some flexibility in the application of these policies and procedures. The PIER program contracts officer has the authority to decide whether or not the royalty payment clause should be applied to a specific contract. PIER program research contracts that involve joint funding or funds from the U. S. Department of Energy are governed by the different intellectual property policies of that federal agency. Finally, the CEC has negotiated a separate intellectual property agreement (that impacts royalty payments) with the University of California (UC) Office of the President for any PIER program research undertaken by the UC.

In summary, it is the policy of the CEC that for PIER program research awards, any intellectual property generated by a contractor (data, inventions, patents, copyrighted materials, etc.) remains the property of the contractor. The CEC claims no ownership or percentage interest in the IP. Instead, in general, the CEC requires a no-cost, perpetual license to use said IP and the annual payment of royalties for any products that have been commercialized as a result of that intellectual property.

Current CEC staff, and the former PIER program manager, report that several products developed under the PIER program IP policy/contract terms have gone to market and the CEC has begun receiving modest annual royalty payments.

Initial Efforts to Establish an IP Policy for the PIER Program

As the PIER program launched in 1999, program management recognized the importance of setting into place a policy on any intellectual property developed by a contractor working on a PIER program research initiative. According to then PIER program manager Dr. Terry Surles, CEC staff held a series of discussions in late 1999 and early 2000, looking for consensus on the issue of the CEC holding any stake in IP emanating from PIER program funded research. Staff did not reach consensus on how a sharing of IP would be accomplished. The end result was a decision to allow the contracting entity to retain all rights to intellectual property (proprietary data, patents, copyrightable material, "commercializable" technology/equipment, etc.) it developed. In exchange for these rights, the contractor would have to provide the CEC with a cost-free license to use the IP for government purposes and would pay the CEC royalties for products brought to market and sold.

The chair of the current PIER Independent Review Panel (IRP), Carl Weinberg, was a member of the initial IRP in place during the 1999-2001 period. He notes that the initial panel, too, looked at the question of potential CEC interest in the ownership of intellectual property developed during the course of PIER program funded research. After discussions with PIER program staff, the first IRP concluded its discussions without agreement among panel members on what advice to provide the CEC with respect to IP ownership interest. CEC deputy director Ron Kukulka was part of those initial CEC discussions and reports that staff ultimately crafted contract standard terms and conditions language regarding intellectual property and "patterned it generally after" the IP policies of the New York State Energy Research Development Authority (NYSERDA) and the Electric Power Research Institute (EPRI).

Three PIER Program IP Policies

The CEC has developed standardized contract terms and conditions for use in developing PIER program research award contracts. Three versions of contract terms and conditions have been developed. The first contract template is referred to as "standard" terms and conditions. A second set of terms and conditions has been negotiated with the University of California and is applied to all contracts involving the UC. A third set of terms and conditions has been developed

for use in those contracts that are jointly funded with, or use funds from, the U.S. Department of Energy (DOE). All three contract versions, along with their own specific appendices and exhibits, appear on the CEC website and are easily accessible for review by prospective bidders and others.

For the standard contract template, the issue of intellectual property is detailed in Exhibits "D," "E," and "H." In general, language in these exhibits stipulates that the contractor retains the rights to proprietary data, intellectual property, copyrightable materials, and discoveries that may be patented. The contractor has some obligations to specific activities and timelines with respect to identifying such material, providing descriptions to the CEC, and applying for patents and copyrights. Contractors agree to provide the CEC with a no-cost, irrevocable, royalty-free license to use/access the data, material, or invention for "government purposes." If a product or item is commercialized and goes to market, the contractor agrees to pay the CEC 1.5% royalty of gross sales for a period of 15 years. In such a situation, during the first two years that a royalty is being generated, the contractor has the option to "buyout" the long-term royalty payment process by making a lump sum payment to the CEC equal to twice the amount of funds that were actually drawn by the contractor during their research contract with the PIER program.

For the UC contract template, intellectual property, licensing rights, and royalty payments are described in Exhibits "E," "H-1," "H-2-A," H-2-B," and "H-2-C." In general, for PIER program research projects contracted with the UC (and not with the DOE research labs managed by the UC), the UC retains all rights to data, copyrightable materials, discoveries, and inventions. It has agreed to provide the CEC with a no-cost, nonexclusive, nontransferable, irrevocable, perpetual, royalty-free, worldwide license to "use or have practiced such rights for or on behalf of the State of California for governmental purposes." In consideration of the CEC providing funding to the UC, the UC will pay the CEC a portion of either net revenues or net royalties. Net royalty payments commence when the net royalty calculations are positive and are calculated at 10% of the net royalty payments received by the UC as a result of licensing to others. If the licensee is a UC institution, the UC will pay the CEC an annual amount of 1.5% of net revenues of the sales of the licensed product.

For the DOE contract template, the U.S. Department of Energy, five DOE national laboratories, and the CEC have produced a "jointly development model agreement." The issues of intellectual property, patent rights, inventions, and royalties are covered in Appendices "B" and "D." With respect to intellectual property and inventions, the DOE allows the contractor to "elect to obtain the entire right, title, and interest throughout the world." The DOE does require that any invention derived from research projects supported in whole or jointly with DOE funding must be substantially manufactured in the United States unless domestic manufacture is not commercially feasible. Contracts involving the DOE also contain provisions for the payment of net royalties for the sale of inventions or products derived from the intellectual property "first reduced to practice" in the conduct of the research project. The CEC PIER Fund will be paid an amount equivalent to 15% of total annual net royalties received by the contractor/sponsor resulting from the sale or assignment of each invention, copyrighted project work, or other intellectual property right and these payments will continue for 15 years or until copyright protection expires, whichever occurs first.

Comparison to NYSERDA and EPRI Intellectual Property Policies

The PIER program's contract terms and conditions have elements that are very similar to those of NYSERDA (New York State Energy Research Development Authority), as indicated by CEC senior administration. The issue of intellectual property, data, and inventions is

detailed in Article VIII, Sections 7 and 8 of NYSERDA's standard research contract template (also available on its website). NYSERDA contract language allows the contract to "elect to retain the entire right, title and interest throughout the world to each Subject Invention of the contractor conceived or first actually reduced to practice in the performance of the work under the agreement." Similar to the language of PIER program contracts, NYSERDA retains a non-exclusive, non-transferable, irrevocable, paid-up license for itself. It goes further by extending this paid-up license requirement to the "State of New York and all political subdivisions and other instrumentalities of the State of New York."

The terms of California's Electric Power Research Institute's (EPRI) standard research contracts differ significantly from those of the PIER program in several important areas. First, EPRI states that due to the funding it provides and its tax-exempt status, "EPRI will generally take ownership of all intellectual property rights that arise in connection with the work performed under the contract." In general, contractors are NOT granted any license rights to intellectual property in the contract. EPRI indicates that it is most interested in commercializing the results of its research and will work to develop licensing agreements with the contractor after or concurrently with the research contract. Further, for any background intellectual property owned by a contractor and necessary to practice the foreground technology being developed under an EPRI contract, EPRI requires that the contractor grant EPRI, on a royalty-free or reasonable royalty basis, a non-exclusive, worldwide license to practice the background technology or intellectual property application, including the right to sublicense.

EPRI owns all rights to data generated by the research it supports and to all inventions developed by the contractor or subcontractors working on a research contract. EPRI will assign intellectual property rights through the granting of licenses and, in exchange, EPRI receives consideration in the form of license fees, royalty payments, and commitment to a commercialization project agreement.

In general, the PIER program's standard terms and conditions for its research contracts are closely aligned with the way NYSERDA treats the ownership of and access to intellectual property and the copyrighted material, inventions, patents, and commercialized products derived from IP. PIER program IP policies are vastly different from those of EPRI, for EPRI insists on maintaining all rights to IP, while the CEC assigns those rights to the contractor in exchange for royalty payments.

PIER Program's IP Policy in Practice

While there is specific language describing IP policies in the contract terms and conditions for PIER program research projects, the treatment and application of IP policy is flexible. As noted in the above narrative, variations of IP policy have been negotiated with the University of California and the U.S. Department of Energy (along with five DOE energy laboratories). Within the standard terms and conditions template, the CEC contracts officer can decide whether or not to include any of the terms of Exhibit E which cover background intellectual property or even whether or not to include the royalty payments provisions for a specific contract, depending on its appropriateness. Former PIER program manager Terry Surles indicates that a "large" number of PIER research contracts are "one of" in nature; that is, specific contract language, including the handling of intellectual property and specific provisions relating to royalties, have been negotiated separately for individual contracts. In so doing, CEC contract officers have been able to be sensitive to the needs of contracting organizations as well as the specific commercialization prospects of individual research initiatives.

Lessons Learned

The history of the development of intellectual property policies and practices for the PIER program within the CEC is an example of the difficulty in reaching consensus on the issue of ownership of intellectual property first reduced to practice by a contractor in a research project funded by a government entity. In theory, there can be many stakeholders involved in the issue, including the government agency providing the research contract, the ratepayers or taxpayers who provided the initial capital, the contracting entity, the state as an entity, the actual researcher or author or team generating the IP, the researcher or author or team of any background IP used to help develop the foreground IP, and so on. In this particular case, it proved difficult for initial CEC and PIER program staff to develop consensus on CEC ownership of IP and, instead, the CEC opted to grant the contractor full ownership rights in exchange for a no-cost, perpetual option by the CEC to the IP and for royalty payments for any commercialization and licensing activity of the intellectual property.

This is an approach similar to the way NYSERDA and DOE handle IP developed in research that they sponsor. These organizations, too, make no claims to IP ownership and instead seek concessions and benefits via royalties and use/licensing fees.

References

1. For the terms and conditions of PIER program research contracts, including exhibits discussing intellectual property, go to: http://www.energy.ca.gov/contracts/index.html#piergeneralinf.

2. For the terms and conditions of NYSERDA program research contracts, including exhibits discussing intellectual property, go to: http://www.nyserda.org/Funding/stdforms.asp.

3. For the terms and conditions of EPRI research contracts, including discussing IP issues, go to: http://www.epri.com/corporate/discover_epri/epri_facts/contractors/business_epri.html.

Appendix E: Additional Response to ACR 24

CCST's study group began this project in early 2005 in response to ACR 252. The study group's goal was to provide legislators a framework for intellectual property policy. With the passage of Proposition 71 in November 2004, ACR 24 was subsequently authored in the spring of 2005 requesting CCST to consider the disposition of IP derived from stem-cell research funding. In August 2005, the study group released an interim report in response to the April 24, 2005 version of ACR 24.

As the study group completed its work on that interim report, ACR 24 had not yet been finalized and CCST knew that ACR 24 could potentially be subject to change. However, in keeping with its original commitment and timeline to produce an interim report by late June/early July, the study group completed its deliberations and the report underwent external peer review by late June. As the report was going into production, the Senate Health Committee added several amendments on July 13 that requested the study group to expand the scope of the project to address some additional concerns.

While we recognize the importance of the amendments in the revised ACR 24, upon further consideration, they do not affect the study group's key conclusions and recommendations for the state's intellectual property policy as set forth both in the interim report or in this final report.

This appendix provides brief comments on the amendments, some of which are not directly related to the substance of the report or are beyond the original scope of the project to address IP policy.

Amendments to ACR 24 as of July 13, 2005

Whereas, A number of organizations funding biomedical research, including the Bill and Melinda Gates Foundation and the International AIDS Vaccine Initiative, have successfully implemented intellectual property policies that commit funding recipients and entities seeking to commercialize research to ensure that resulting therapies and products are accessible and affordable to designated low-income populations.

This issue was addressed in the Addendum of the Interim Report, August 2005. It is given additional consideration in Chapter 3 of the final report, in the section on "Additional Models for Managing IP: Experiments with Licensing Agreements."

Resolved, That the Legislature requests the study group to develop general guidelines or criteria to define how the state can achieve maximum public benefit from research funded under Proposition 71.

The interim report provided an overview of California's potential return on investment from IP generated by CIRM-funded research (see Section 5 of that report). That analysis provides background and context for the typical generation of revenues and benefits from biomedical research, and offers guidelines for the disposition of revenues from IP generated by CIRM-funded research.

In addition, Chapter 4 of this final report includes additional discussion of return on investment, with a more lengthy discussion of the ways that economists measure return on investment.

It is not possible, even with more time and with additional resources, to do justice to the much more complex issue of how an entity, such as a state, can achieve maximum benefit from research funded under proposition 71. The definition of maximum benefit (monetary and otherwise) and the determination as to how the state can achieve it are broad subjects in need of further, scholarly investigations in several areas over a long period of time.

Resolved, That the Legislature requests that the options and recommendations identified by the study for Proposition 71-funded research reflect the constraints posed by the use of tax-exempt bonds for research and represent options and recommendations that are consistent with the goal and intent of using tax-exempt bonds to fund the research, including options and recommendations for achieving accessibility and affordability of treatments, products, and therapies resulting from Proposition 71 funded research.

CCST consulted on two occasions with Orrick, Herrington & Sutcliffe, LLP, the bond counsel retained by the State Treasurer's Office, in order to assess the scope of the issues involved in the use of tax-exempt versus taxable bonds. CCST also heard the testimony from the State Treasurer's Office, Orrick, Herrington & Sutcliffe, LLP, and Legislative Council at the Joint Informational Hearing on October 31.

The ultimate disposition of the ability of the state to use taxable or tax-exempt bonds to fund stem-cell research will depend upon decisions yet to be rendered by the U.S. Internal Revenue Service. The decision about which options to present to the IRS must be made by key stakeholders, and CCST does not have the expertise to provide an opinion on those legal and political matters. Orrick Herrington provide additional information in their letter later in this appendix.

The report's recommendations about the ownership and management of IP, however, would appear to be consistent with the use of tax-exempt bonds, since no direct return of intellectual property or its licensing revenue to the state is anticipated or required. As noted earlier, this proposed strategy is consistent with federal policies, in particular, the Bayh-Dole Act.

Given the financial and tax ramifications of bond financing, full consideration of this issue, and consideration of other potential mechanisms to utilize a portion of licensing revenue to meet state expectations and needs is beyond the scope of this committee's charge. Key stakeholders, with the assistance of tax, bond, and financing experts within or contracted by the Treasurer's Office and the State Attorney General's Office, need to develop a range of options, which they must then consider thoroughly for their fiscal and political impacts before submission to the IRS for a ruling.

Resolved, That the Legislature requests that the California Council on Science and Technology establish a review group to include representatives of bond counsel firms, the Legislative Analyst, the Treasurer, consumer and public interest groups, and foundations engaged in funding biomedical research to review and comment on the study and options and recommendations for generating public benefit from commercialization of technology developed with Proposition 71 funds prior to their release, and that the council compile those comments in the report.

The study group incorporates a broad range of experts involved with the creation of and administration of IP policy in a variety of institutions.

The study group's interim and final reports have been reviewed by external reviewers (Appendix I) and the CCST board and council (Appendix J) in accordance with CCST's peer review procedures. In addition, representatives of the groups requested by ACR 24 were asked to review the final report. As with other reviewers, their comments were considered, as appropriate, in the final report.

The final report reflects the input and expertise of both the study group members and those who reviewed the report. As with the interim report, we anticipate that the final report will attract commentary from the groups and organizations listed above as well as others. It is our hope and intent that the document serves as an important starting point for additional discussion. We look forward to constructive commentary, analysis, and alternative options for the state to consider from other groups.

In response to this provision of ACR 24, CCST solicited reviews from members of the groups described. Responses received are included here, which include the following:

- Elizabeth G. Hill, Legislative Analysts Office
- Jackie Wynne McGrath, State Public Policy Director, Alzheimer's Association
- Robert P. Feyer, Orrick, Herrington & Sutcliffe, LLP
- Juan C. Fernandez, Director, Public Finance Division, State of California, Office of the Treasurer

Only one, from the Legislative Analyst, requires a detailed response.

LAO

60 YEARS OF SERVICE

December 15, 2005

Mr. Lawrence T. Papay, Council Chair
California Council on Science and Technology
1130 K Street, Suite 280
Sacramento, California 95814-3965

Dear Mr. Papay:

As you know, Chapter 111, Statutes of 2005 (ACR 24, Mullin), directs a study group convened by the California Council on Science and Technology (CCST) to develop general guidelines to define how the state can achieve maximum benefit from research funded under Proposition 71. Assembly Concurrent Resolution 24 also directs our office, among others, to review and comment on the study group's options and recommendations concerning the commercialization of technology developed with Proposition 71 funds. We received a copy of the study group's "Policy Framework for Intellectual Property Derived from State-Funded Research" on November 29, with a request for our comments by December 8. This letter contains our comments in fulfillment of ACR 24.

We note that the Policy Framework report makes little reference to research funded under Proposition 71 *per se*, but rather focuses on intellectual property (IP) developed by state-funded research more generally. We further note that the study group released a separate "interim" report ("Policy Framework for Intellectual Property Derived from Stem Cell Research in California") in August 2005, which does focus on Proposition 71-funded research. We understand that CCST means for the interim report to be viewed as its response to ACR 24, while the most recent report (that we have been asked to review) primarily responds to earlier legislation (Chapter 190, Statutes of 2004 [ACR 252, Mullin]). Finally, it is our understanding that these comments are to be appended to the most recent report when it is officially released in January 2006.

Because ACR 24 directs us to review the study group's options and recommendations concerning Proposition 71-funded research, and because it is primarily the interim report (rather than the report you have asked us to review) that appears to respond to ACR 24, we have expanded our review to both reports. Given the limited time permitted for our review, we have focused our review on a few key issues.

Both reports generally assert that the state can best ensure public benefit from sponsored research by promoting fiscal and other incentives for researchers and others

Legislative Analyst's Office
California Legislature
Elizabeth G. Hill • Legislative Analyst
925 L Street, Suite 1000 • Sacramento CA 95814
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to commercialize IP. More specifically, the interim report recommends that the California Institute for Regenerative Medicine (CIRM) permit grantees considerable freedom in the ownership of IP rights and income derived there from. At the same time, it recommends certain protections for state interests, such as requiring grantees to provide a plan describing how the state will benefit from CIRM-funded IP, and permitting CIRM to intervene if an IP-owning grantee is not promoting benefits to the public.

Both reports also downplay the likelihood that the state could achieve a significant income stream from state-funded IP. The interim report asserts that "regardless of CIRM's IP policies, CIRM-funded innovations and the revenues generated from them cannot realistically be expected to have any significant effect on the state's revenues for the immediate future" (p. 33). This theme is repeated more broadly in the Policy Framework report. In general, that report urges that the state not treat funding for state-sponsored research as "venture capital" that would produce a significant revenue stream to the state. Moreover, both reports recommend that any state revenue derived from such research be reinvested in education and research.

In our opinion, these recommendations and findings, while plausibly argued in the report, lack sufficient data and analysis to substantiate them. For example, CCST acknowledges that it did not attempt to prepare an independent fiscal analysis comparing (1) the revenues that the state might derive from royalties, patents, and other forms of IP revenue-sharing agreements with (2) revenues the state could derive from the economic expansion CCST asserts would accompany expedited commercialization of new products if the state did not pursue IP-related revenues. Nor does the report adequately document the University of California's current policies and effectiveness in garnering IP revenues based on current research efforts. Absent this kind of information and analysis, we cannot evaluate these recommendations.

Beyond these findings and recommendations about revenue-sharing, the Policy Framework report asserts that "it is not possible...to do justice to the much more complex issue of how an entity, such as a state, can achieve maximum benefit from research in any particular area" (p. 81). Assembly Concurrent Resolution 24 asked that the study group address that specific question with regard to Proposition 71.

In other respects, the reports do offer assistance to the Legislature in considering how IP derived from Proposition 71-funded research should be treated. The reports offer an articulate argument in favor of state restraint in this area, which could contribute toward a fuller debate of this issue. Similarly, the reports include useful definitions of IP, summaries of relevant federal law, and other information that can help inform legislative decision-making in this area.

Thank you for the opportunity to offer comments. This is an important frontier of state policy that, by definition, has not been well established.

Sincerely,

Elizabeth G. Hill

Elizabeth G. Hill
Legislative Analyst

cc: Dr. Stephen Rockwood, Co-Chair
Dr. Alan Bennett, Co-Chair

Study Group Response to the LAO

We commend the LAO for its careful review of the draft report, with a particular focus on ACR 24's request for comments on the issues related to Proposition 71. The LAO correctly notes that the study group's primary response to ACR 24 can be found in the interim report released in August 2005; supplemental information about ACR 24 is found in Appendix F.

Comment 1: Page 2, para 2. The LAO raises substantive issues about the usefulness to the state of "independent fiscal analysis comparing 1) the revenues that the state might derive from royalties, patents, and other forms of revenue-sharing agreements with 2) revenues the state could derive from the economic expansion CCST asserts would accompany expedited commercialization of new products if the state did not pursue IP-related revenues."

Response 1: We concur with the LAO's suggestion for an independent fiscal analysis of the issues described, and agree that such information would be an important resource for the state. That kind of activity, however, falls outside of the scope of work CCST was requested to perform by ACR 252 and the expertise of the study group members who were selected on the basis of their knowledge of IP issues.

A detailed fiscal analysis of the kind suggested by LAO would require more time, more financial resources and different kinds of expertise than were assembled to examine IP policies for the state. We support the conduct of a comprehensive, independent, and rigorous study that can be performed over an extended period of time and examines a variety of economic models. We advise against a study that could be done quickly and without adequate resources.

In the absence of such a detailed California-specific study, annual reports by the Association of University Technology Managers (AUTM) include economic models that project royalty revenues earned by universities to jobs created, total economic activity and tax revenues generated. [55]

Comment 2: Page 2, para 2. The LAO comments that the report does not adequately document the University of California's current policies and effectiveness in garnering IP revenues based on current research efforts.

Response 2: An examination of a specific research institution's policies and relative effectiveness in securing IP revenues was not within the charge of the study group, which was to recommend to the state policies that would apply to IP derived from state-funded research.

We refer readers, however, to recent report from the Association of University Technology Managers.[56] It shows in detail the licensing revenue garnered by California institutions, licenses and options executed, start-up companies formed, U.S. patent applications filed and issued, and total research spending. We include a brief summary of licensing revenue here, with the caveat that the sources of research funding for each institution varies widely .

California Research University	Licensing Revenues 2004
California Institute of Technology	$ 9,886,087
Stanford University	$47,272.397
University of California system	$74,275,000
University of Southern California	$ 3,213,486

[55] Association of University Technology Managers. http://www.autm.net/surveys/.

[56] AUTM U.S. Licensing Survey: FY 2004.

Comment 3: Page 2, para 3. "…the Policy Framework report asserts that 'it is not possible …to do justice to the much more complex issue of how an entity, such as a state, can achieve maximum benefit from research in any particular area.' "

Response 3: The LAO's review of the draft report revealed a lack of clarity in language in Appendix F. The language has been changed to reflect the exact language of ACR 24, "how the state can achieve maximum benefit from research funded under Proposition 71."

alzheimer's association

the compassion to care, the leadership to conquer

December 13, 2005

Annzell Loufas, Director
Sacramento Office of the California
Council on Science and Technology
1130 K Street, Suite 280
Sacramento, CA 95814

Dear Ms. Loufas:

Thank you for giving the Alzheimer's Association the opportunity to review and comment on the California Council on Science and Technology report: *Policy Framework for Intellectual Property Derived from State-Funded Research: Final Report to the California Legislature, Governor of the State of California.*

Following are the comments of Lynn Pasahow, who is a volunteer with the Alzheimer's Association and a former Board Member for the Bay Area Chapter. He specializes in Intellectual Property matters in his law practice of Fenwick and West LLP:

> The proposal in the report is to generally follow the current federal model under the Bayh-Dole act, because:
>
> - The federal system has proven itself as achieving the right mix of goals: getting technology used; economic development; and financial return to appropriate stakeholders (generally, the academic institution performing the sponsored research).
> - The federal system has recognized the special needs to make sure research is promptly publicized (usually through publication), that research tools are made widely available, and that a reservation of "march-in" rights ultimately assures that the sponsor (federal or state) can assure the technology is being made available).
> - Often state money is intermixed with federal money in sponsoring research, and a radically different state system would be a logical problem.
> - Anything else would require major new infra-structure and probably would not work as well.
>
> I think the report has the right answers.

Again we appreciate the opportunity to weigh in on this complex and important issue.

Sincerely,

Jackie McGrath

Jackie Wynne McGrath
State Public Policy Director

921 Eleventh Street, Suite 601 • Sacramento, California 95814 • Phone (916) 447-2731 • Fax (916) 447-2741 • www.caalz.org

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December 8, 2005

Robert P. Feyer
(415) 773-5886
bobfeyer@orrick.com

Dr. Susan Hackwood
Executive Director
California Council on Science and Technology
1130 K Street, Suite 230
Sacramento, CA 95814

Re: Report on Intellectual Property Policies

Dear Dr. Hackwood,

You have provided us with an advance copy of the Final Report of the Council's Intellectual Property Study Group regarding a Policy Framework for Intellectual Property Derived from State-Funded Research.

Our involvement in this topic derives from our firm's role as the Bond Counsel to the State Treasurer's Office in connection with the proposed issuance of State general obligation bonds under the Stem Cell Research and Cures Bond Act, approved as part of Proposition 71 at the November 2004 statewide general election.

We have consulted with task force members, at their request, about the technical legal issues involved in the issuance of tax-exempt bonds to finance scientific research, as is contemplated by Proposition 71. As we told these members, and have testified in public on other occasions, the implementation of intellectual property policies for bond-funded research grants or loans can, depending on a great many variables, affect the ability to issue bonds on a tax-exempt basis. We would expect to obtain an advance "private letter ruling" from the Internal Revenue Service before the State issues tax-exempt bonds under the Stem Cell program which could be impacted by intellectual property concerns. We are optimistic (although we cannot provide any assurances at this time) that methods could be developed which would allow for favorable rulings from the I.R.S., although this will depend on what IP policies are ultimately adopted by the California Institute for Regenerative Medicine or the State.

Even if some portion of tax exempt bonds would be precluded because of the inability to obtain a favorable I.R.S. ruling, we believe there are techniques for the issuance of taxable bonds which would provide funding for scientific research at costs which would not be significantly higher than the cost of tax-exempt bonds. Ultimately, therefore, we believe the State should implement IP policies without regard to potential impacts on the issuance of bonds.

We have no substantive comments on the Report itself.

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ORRICK

Please feel free to contact me or my partner, Perry Israel, if you have any further questions on these matters.

Very truly yours,

Robert P. Feyer

DOCSSF1:856242.1

STATE OF CALIFORNIA

Philip Angelides, Treasurer

OFFICE OF THE TREASURER
P. O. BOX 942809
SACRAMENTO, CA 94209-0001

December 8, 2005

Dr. Steven Rockwood
Co-Chair
Intellectual Property Study Group
California Council on Science and Technology
1130 K Street, Suite 280
Sacramento, CA 95814

Dear Dr. Rockwood:

Thank you for the opportunity to review the California Council on Science and Technology's "Policy Framework for Intellectual Property Derived from State-Funded Research" (the Report), which is intended to help the Legislature and the Governor establish intellectual property policy for the State.

The State Treasurer's Office (STO) reviewed the Report as it relates to bond financing of the state-funded research, particularly the Stem Cell Research and Cures Act of 2004. The STO does not offer any comments with respect to the rest of the document since it covers a subject matter outside the normal scope of duties of the STO. Those familiar with medical research and intellectual property issues are better suited to comment on such matters.

Your disclosure in Footnote 3 on page 19 is accurate. California's stem-cell bond initiative is the first of its kind in the nation and will require clarification regarding intellectual property rights and the tax structure of the bond. Given the unique nature of the stem cell bonds, we anticipate requesting clarification on certain tax rules as they apply to bond-funded medical research from the Internal Revenue Service in advance of a bond issuance.

It is the view of this office that the debate over state-funded intellectual property and the resulting policy should focus on cultivating a research environment that benefits all Californians. Accordingly, any such policy should recognize that some return on investment should accrue to the State. The Treasurer's position on this matter is best described in the letter he wrote to Dr. Zach W. Hall, President of the California Institute for Regenerative Medicine. A copy of the letter is attached for your reference and should be made part of our official comments on the Report.

Again, thank you for giving the STO the opportunity to review the Report.

Sincerely,

Juan C. Fernandez, Director
Public Finance Division

Attachment

G:\Stem Cell Prop 71\letter to CCST final.doc

CCST and the study group wish to express their gratitude to each of the above agencies and organizations that provided the above comments.

Resolved, That the Legislature requests that the California Council on Science and Technology complete its study by November 1, 2005 and report its options and recommendations for generating public benefit from commercialization of technology developed with Proposition 71 funds to the health committees of the Senate and Assembly no later than January 1, 2006 for consideration in developing further policies in this area.

This interim report, responsive to ACR 24, was released on August 23, 2005. It was released prior to November 1 because the study group completed its initial analysis. To date, it has been one source of information for CIRM as it continues its process of developing IP policies. The final report with recommendations for the state of California, as requested by ACR 252, will be released in January 2006 as originally scheduled.

Appendix F: Legislative Requests Assembly Concurrent Resolutions 252 and 24

BILL NUMBER: ACR 252 CHAPTERED, RESOLUTION CHAPTER 190
FILED WITH SECRETARY OF STATE SEPTEMBER 14, 2004
ADOPTED IN SENATE AUGUST 26, 2004, ADOPTED IN ASSEMBLY AUGUST 18, 2004
INTRODUCED BY Assembly Member Mullin, JULY 8, 2004
Assembly Concurrent Resolution No. 252 — Relative to the California Council on Science and Technology.
LEGISLATIVE COUNSEL'S DIGEST
ACR 252, Mullin. California Council on Science and Technology.

This measure would request the California Council on Science and Technology to create a study group, as specified, on how the State of California should treat intellectual property created under state contracts.

WHEREAS, California is home to many of the world's top research universities, national laboratories, and leading-edge high technology companies that generate significant intellectual property; and

WHEREAS, It is in the interest of the state to ensure that the results of state-funded research are promptly protected and developed; and it is in the interest of the state to facilitate, promote, and enhance technology transfer programs that will facilitate the transfer of technology into the marketplace for the public benefit; and

WHEREAS, The State of California supports the establishment of government-university-industry partnerships to develop leading-edge research results that would encourage economic development through growth of small business, development of emerging industries, and creation of jobs within the state; and

WHEREAS, The Bureau of State Audits Report, "State-Owned" Intellectual Property, November 2000, stated that policies and guidelines should be established to assist state agencies in determining how best to administer state-owned intellectual property so that it can be utilized in the best interests of the public; and

WHEREAS, The Legislature supports the use of efficient models to develop and streamline infrastructures, policies, and processes for the management of intellectual property developed under state funding in order to stimulate economic development in the state similar to the approach used by the federal government; and

WHEREAS, A comprehensive intellectual property policy can foster major technological developments; and

WHEREAS, In this time of fiscal crisis, it is necessary for the state to create public-private partnerships; and

WHEREAS, The California Council on Science and Technology has a proven record of accomplishment in providing timely, impartial analyses of complex issues for the legislative and executive branches of government, including energy research in the Public Interest Energy Research Program, Critical Path Analysis of California's Science and Technology Education System and Nanoscience and Nanotechnology: Opportunities and Challenges in California; now, therefore, be it

Resolved by the Assembly of the State of California, the Senate thereof concurring, That the Legislature requests the California Council on Science and Technology to create a special study group to develop recommendations to the Governor and the Legislature on how the state should treat intellectual property created under state contracts, grants, and agreements, including, but not limited to, the following:

(1) Promoting the utilization of intellectual property arising from state-supported contracts, grants, and agreements.

(2) Encouraging maximum participation of small business firms in those state-supported awards.

(3) Promoting collaboration between commercial concerns and nonprofit organizations, including universities.

(4) Ensuring that the intellectual property created by nonprofit organizations and small business firms is 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 that intellectual property made in the state by California and United States industry and labor.

(6) Ensuring that there are mechanisms in place that allow the state to obtain certain minimal rights in state-supported intellectual property to meet the needs of the state and protect the public against nonuse or unreasonable use of that intellectual property.

(7) Minimizing the costs of administering policies in this area; and be it further

Resolved, That the Legislature requests the California Council on Science and Technology, upon creation of the study group, to work with its sustaining institutions, state agencies, including the office of the Attorney General, and other organizations, to complete this study. Members of the study group are to include, but are not limited to, the following:

(1) The Department of General Services.

(2) Experts in contract and licensing with the state and federal governments.

(3) Research and development practitioners.

(4) Experts in technology transfer.

(5) Individuals representing the public interest; and be it further

Resolved, That the Chief Clerk of the Assembly transmit copies of this resolution to the Attorney General and the Department of General Services.

BILL NUMBER: ACR 24 CHAPTERED
BILL TEXT
PASSED THE ASSEMBLY SEPTEMBER 7, 2005
PASSED THE SENATE SEPTEMBER 6, 2005
AMENDED IN SENATE AUGUST 30, 2005
AMENDED IN SENATE AUGUST 16, 2005
AMENDED IN ASSEMBLY APRIL 21, 2005

INTRODUCED BY Assembly Member Mullin
FEBRUARY 22, 2005
Relative to the California Council on Science and Technology.
LEGISLATIVE COUNSEL'S DIGEST
ACR 24, Mullin. California Council on Science and Technology.

This measure would request the California Council on Science and Technology to expand the scope of its study group on how the State of California should treat intellectual property created under state contracts to include contracts, grants, and agreements developed under Proposition 71 of the November 2, 2004, general election and to study and report to the Legislature on how the commercialization of technology developed with the investment of taxpayer dollars could generate a public financial benefit. It would also request the council to establish a review group to review and comment on the study.

WHEREAS, California is home to many of the world's top research universities, national laboratories, and leading-edge high technology companies that generate significant intellectual property; and

WHEREAS, It is in the interest of the state to ensure that the results of state-funded research are promptly protected and developed; and

WHEREAS, The commercialization of technology developed with the investment of taxpayer dollars in the form of contracts, grants, and agreements could generate some public benefit, including, but not limited to, state revenues, favorable pricing, revenue sharing, and reinvestment into research; and

WHEREAS, It is in the interest of the state to facilitate, promote, and enhance technology transfer programs that will facilitate the transfer of technology into the marketplace for the public benefit; and

WHEREAS, The Legislature supports the use of efficient models to develop and streamline infrastructures, policies, and processes for the management of intellectual property developed under state funding in order to stimulate economic development in the state similar to the approach used by the federal government; and

WHEREAS, The voters approved the passage of Proposition 71, California Stem Cell Research and Cures Act, which establishes the California Institute for Regenerative Medicine to regulate stem cell research and provide funding, through grants and loans, for this research and research facilities; and

WHEREAS, The passage of Proposition 71 heralds a new era for the future of medicine and the way diseases are treated; and

WHEREAS, Proposition 71 contemplates that the state will receive public benefits from the commercialization of research funded with Proposition 71 dollars in the form of patent royalties and license revenues; and

WHEREAS, Provisions of the Internal Revenue Code governing the use of proceeds of tax-exempt bonds significantly limit the state's ability to directly receive economic benefit in the form of royalties and license revenues from research funded under Proposition 71; and

WHEREAS, The people of the state should derive a substantial public benefit from the commercialization of state-funded research; and

WHEREAS, There are currently no general guidelines or standards defining public benefits derived from research funded by the state; and

WHEREAS, Receipt of economic benefit in the form of favorable pricing on therapies and treatments developed with Proposition 71 funds may be achievable using tax-exempt bonds for research; and

WHEREAS, A number of organizations funding biomedical research, including the Bill and Melinda Gates Foundation and the International AIDS Vaccine Initiative, have successfully implemented intellectual property policies that commit funding recipients and entities seeking to commercialize research to ensure that resulting therapies and products are accessible and affordable to designated low-income populations; and

WHEREAS, Use of tax-exempt bonds for research under Proposition 71 is fiscally prudent for the state and is consistent with taxpayers' expectations in approving Proposition 71; and

WHEREAS, The development of innovative technologies is fundamental to the California economy; however, lack of understanding about the research enterprise and technology transfer, as well as lack of clarity concerning the role of the state government, if any, in developing intellectual property into marketable products make it difficult for the state to design an effective intellectual property policy; and

WHEREAS, The Legislature approved Assembly Concurrent Resolution No. 252 of the 2003-04 Regular Session, which requests the California Council on Science and Technology to establish a study group to develop recommendations to the Governor and the Legislature on how the state should treat intellectual property made under state contracts, grants, and agreements; and

WHEREAS, The scope of the study does not include the contracts, grants, and agreements developed under Proposition 71; now, therefore, be it

Resolved by the Assembly of the State of California, the Senate thereof concurring, That the Legislature requests the California Council on Science and Technology to expand the scope of the study group on how the state should treat intellectual property created under state contracts, grants, and agreements, to include contracts, grants, and agreements developed under Proposition 71; and be it further

Resolved, That the Legislature requests the study group to study how the commercialization of technology developed with the investment of taxpayer dollars in the form of contracts, grants, and agreements could generate some public benefit, including, but not limited to, state revenues, favorable pricing, revenue sharing, and reinvestment into research; and be it further

Resolved, That the Legislature requests the study group to develop general guidelines or criteria to define how the state can achieve maximum public benefit from research funded under Proposition 71; and be it further

Resolved, That the Legislature requests that the options and recommendations identified by the study for Proposition 71-funded research reflect the constraints posed by the use of tax-exempt bonds for research and represent options and recommendations that are consistent with the goal and intent of using tax-exempt bonds to fund the research, including options and recommendations for achieving accessibility and affordability of treatments, products, and therapies resulting from Proposition 71-funded research; and be it further

Resolved, That the Legislature requests that the California Council on Science and Technology establish a review group to include representatives of bond counsel firms, the Legislative Analyst, the Treasurer, consumer and public interest groups, and foundations engaged in funding biomedical research, to review and comment on the study and options and recommendations for generating public benefit from commercialization of technology developed with Proposition 71 funds prior to their release, and that the council compile those comments in the report; and be it further

RESOLVED, That the Legislature requests that this report and the interim version of it released by the council be viewed as an informational and preliminary tool and as such not be the only source used in the development of intellectual property policy or guidelines by the California Institute for Regenerative Medicine regarding contracts, grants, and agreements made pursuant to Proposition 71, and that further consideration be given to the significant policy, legal, and fiscal issues associated with development of intellectual property policy and guidelines under Proposition 71; and be it further

Resolved, That the Legislature requests that the California Council on Science and Technology complete its study by November 1, 2005, and report its options and recommendations for generating public benefits from the commercialization of technology developed with Proposition 71 funds to the health committees of the Senate and Assembly no later than January 1, 2006, for consideration in developing further policies in this area; and be it further

Resolved, That the Chief Clerk of the Assembly transmit copies of this resolution to the Attorney General, the Department of General Services, and to the author for appropriate distribution.

Appendix G: Intellectual Property Study Group

CO-CHAIRS

ALAN B. BENNETT
Associate Vice Chancellor for Research, University of California, Davis
Executive Director, Public Intellectual Property Resource for Agriculture

Alan Bennett currently serves as the associate vice chancellor for research at the University of California, Davis where he is responsible for technology transfer, strengthening research-based alliances with industry and supporting technology-based economic development in the Sacramento/Davis region. He also serves as the founding executive director of the Rockefeller Foundation-supported Public Intellectual Property Resource for Agriculture (PIPRA); an organization comprised of 25 universities dedicated to the collective management of intellectual property to support broad commercial innovation as well as humanitarian uses of technology in agriculture. From 2000-2004, Bennett served as the executive director of the University of California Systemwide Office of Technology Transfer and Research Administration. He earned B.S. and Ph.D. degrees in plant biology at UC Davis and Cornell University, respectively; and joined the UC Davis faculty in 1983.

STEPHEN D. ROCKWOOD
Executive Vice President
Science Applications International Corporation (SAIC)

Stephen Rockwood is an executive vice president and a former member of the Board of Directors of SAIC. He has over 35 years experience leading scientific research activities including the direction of technical projects and the formulation and analysis of national science policy issues.

He served as a captain in the U.S. Air Force supporting laser weapons research and anti-ballistic missile programs, and later spent 15 years at Los Alamos National Laboratory leading research activities in laser development, isotope separation, fusion energy, computational sciences and nuclear science. Rockwood has since held several executive positions with SAIC.

Rockwood earned a B.S. in physics and mathematics in 1965 from Grinnell College. He received a M.S. in physics in 1967 and a Ph.D. in physics in 1970 from the California Institute of Technology.

MEMBERS

SUSAN V. BRYANT
Professor of Developmental and Cell Biology, and
Dean, School of Biological Sciences
University of California, Irvine

Susan Bryant obtained her undergraduate degree at King's College and her Ph.D. at St. Mary's Hospital Medical School, University of London. She moved to the U.S. to study regeneration as a postdoctoral fellow at Case Western Reserve University, and was recruited as the first woman on the faculty in biology at the University of California, Irvine.

In 2001 she was elected a fellow of the American Association for the Advancement of Science. Along the way, she has held several leadership positions, including program director at National Science Foundation, assistant vice chancellor for plans and programs and department chair at UC Irvine, culminating in being appointed dean of the School of Biological Sciences in 2000. In 1987, she was

awarded one of the first UC Irvine Pacesetter Awards for contributions to women at UC Irvine, and in 2005, she was elected a fellow, the highest honor bestowed, by the Association for Women in Science.

RONALD W. COCHRAN
Laboratory Executive Officer
Lawrence Livermore National Laboratory (LLNL)

As laboratory executive officer, Ronald Cochran assists the laboratory director and associate directors in representation of LLNL, internally and externally. Responsibilities for this position also include oversight of the congressional affairs operational area. Prior to his current position, Cochran served as deputy associate director for Laser Programs and deputy associate director for the Advanced Processing Technology Program. He held a position in the Department of Energy, Office of the Secretary as director of the New Production Reactor Program, and as special assistant to the deputy secretary. He also served as deputy manager in the Department of Energy's Albuquerque Operations Office, providing administrative oversight of two national laboratories.

Cochran earned a B.S. in metallurgical engineering from the University of Tennessee and an M.S. in metallurgical engineering from Ohio State University. Professional organization memberships include the American Society for Metals, the American Association for the Advancement of Science, and the American Nuclear Society.

LAWRENCE B. COLEMAN
Vice Provost for Research
University of California

Lawrence B. Coleman is the vice provost for research, University of California and professor of physics at the University of California, Davis. He served as chair of the University-wide Academic Senate in the 1999-2000 academic year following a year as vice chair of the UC Senate. Arriving at Davis in 1976, he was promoted to associate professor in 1982. While at the UC Davis, he has held the positions of chair, Davis Division of the Academic Senate; director, The Internship and Career Center; acting vice provost of academic programs and dean of undergraduate studies; and acting associate vice chancellor of academic programs.

Coleman's previous affiliations include: postdoctoral research investigator, Department of Physics, University of Pennsylvania, 1975-1976 and research fellow, Department of Physics, University of Pennsylvania, 1970-1975. Coleman received a Ph.D. from the University of Pennsylvania in experimental condensed matter physics, and a B.A. in physics from The Johns Hopkins University.

CYNTHIA CURRY
Senior Staff Counsel, California Department of General Services
Office of Legal Services

Curry is a senior staff counsel with the State of California, Department of General Services, Office of Legal Services. She has been with the state for 10 years, and her main area of practice is contract law, with an emphasis in information technology.

MICHAEL D. GOLDBERG
General Partner
MDV-Mohr, Davidow Ventures

As a general partner at MDV, Goldberg leverages valuable entrepreneur and investor experience from his more than 20 years of work in the life sciences industry including biotechnology, pharmaceuticals, health services and healthcare information technology.

Prior to joining MDV, Goldberg was managing director of Jasper Capital and co-chair of the California Research and Cures Coalition. He has also held senior management and operations roles including serving as chairman of OnCare, an oncology practice management company he founded in 1995. Until 1999, he also served as OnCare's chief executive officer. Previously, Goldberg was founder and chief executive officer of Axion Inc., a cancer-focused healthcare service company he started in 1987 and sold to Bristol-Myers Squibb in 1996. Goldberg received a B.A. from Brandeis University and an M.B.A. from Stanford Graduate School of Business.

GINGER L. GRAHAM
President and Chief Executive Officer
Amylin Pharmaceuticals, Inc.

Ginger L. Graham is president and chief executive officer of Amylin Pharmaceuticals, Inc. Graham is the former group chairman, Office of the President, for Guidant Corporation located in Indianapolis, Indiana. From 1993 to 2000, Graham was president and CEO of Advanced Cardiovascular Systems, and with the creation of Guidant in 1994, she became president of the Vascular Intervention business group. Graham started her career with Eli Lilly and Company and served in a number of management positions. Her diverse career path gave her the opportunity to work in a variety of industries including agriculture, cosmetics, pharmaceuticals, investment banking and medical technology.

Graham received a Bachelor of Science degree in agricultural economics from the University of Arkansas. She also holds a Master of Business Administration degree from Harvard University.

WAYNE C. JOHNSON
Vice President, Worldwide University Relations
Hewlett-Packard

Wayne C. Johnson is the vice president for Hewlett-Packard Company's worldwide University Relations. He is responsible for higher education programs in research, marketing and sales, recruitment, continuing education, public affairs and philanthropy.

Johnson joined HP in July 2001 from Microsoft's University Relations Department. From 1967 to 2000, he held a variety of positions at the Raytheon Company in Lexington, Massachusetts, including national sales manager for Wireless Solutions, manager of International Financing and Business Development in Wide Area Surveillance Programs, manager of Administration and Strategic Planning, and manager of Program Development and Operations for Technical Services. He was an adjunct professor of Management at Boston University from 1977 to 1999.

Johnson received his B.A. from Colgate University, Hamilton, New York, and his M.B.A. from Boston College's Carroll School, Boston, Massachusetts.

KATHARINE KU
Director, Office of Technology Licensing
Stanford University

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 such as biotechnology and semiconductor inventions, software, medical instrumentation, etc. From 1994-98, Ku was also responsible for Stanford's Sponsored Projects Office, which handles research contracts and grants for the university. Prior to 1991, Ku was vice president, business development at Protein Design Labs (PDL), Inc. Prior to PDL, Ku spent 12 years at Stanford in various positions, was a researcher at Monsanto and Sigma Chemical, administered a dialysis clinical trial at the University of California, and taught chemistry and basic engineering courses.

Ku has been active in the Licensing Executive Society (LES), serving as vice president of the Western Region, trustee, and various committee chairs. She recently received the AUTM Bayh-Dole Award for her efforts in university licensing. Ku has a B.S. in chemical engineering from Cornell University, an M.S. in chemical engineering from Washington University and is a registered patent agent.

MEYYA MEYYAPPAN
Director, Center for Nanotechnology
NASA Ames Research Center

Meyya Meyyappan is director of the Center for Nanotechnology as well as senior scientist at NASA Ames Research Center. He is a founding member of the Interagency Working Group on Nanotechnology (IWGN) established by the Office of Science and Technology Policy. The IWGN is responsible for putting together the National Nanotechnology Initiative.

Meyyappan is a fellow of the Institute of Electrical and Electronics Engineers (IEEE) and the Electrochemical Society. In addition, he is a member of American Society of Mechanical Engineers, Materials Research Society, American Vacuum Society and American Institute of Chemical Engineers. For his work and leadership in nanotechnology, he has been awarded NASA's Outstanding Leadership Medal and the Arthur Flemming Award by the Arthur Flemming Foundation and George Washington University. For his contributions to nanotechnology education and training, he has been awarded the 2003-2004 Engineer of the Year award by the San Francisco section of the American Institute of Aeronautics and Astronautics (AIAA). In 2004, he was honored with the President's Meritorious Award for his contributions to nanotechnology.

ROGER G. NOLL
Morris M. Doyle Centennial Professor in Public Policy, Department of Economics, and Professor of Political Science (by courtesy), School of Humanities and Sciences
Stanford University

Roger G. Noll is the Morris M. Doyle Centennial Professor of Public Policy in the Department of Economics at Stanford University. He also has a long affiliation with the Brookings Institution in Washington, D.C., where he has been a senior fellow, a visiting fellow, and a non-resident senior fellow. He served as a member of the California Council on Science and Technology from 1995-2000, and is now a fellow.

Noll holds a Ph.D. in economics from Harvard University and his distinguished career includes service as director of the Public Policy Program at Stanford and visiting positions at the University of Michigan and the University of California, San Diego. Noll has won a Guggenheim Fellowship, the Book Award of the National Association of Educational Broadcasters, and the Distinguished Service Award of the Public Utilities Research Center. He received the 1994 Rhodes Prize for Undergraduate Teaching from Stanford University.

JAMES POOLEY
Partner
Milbank, Tweed, Hadley & McCloy LLP

James Pooley is a partner in Milbank's Intellectual Property Group, specializing in the litigation and trial of patent, trade secret, copyright, and technology-related commercial litigation, in state and federal courts, and before the International Trade Commission. Pooley has practiced in Silicon Valley since 1973, establishing a national reputation as trial counsel in some of the most difficult and high visibility cases involving intellectual property. His successful patent infringement defense of Adobe Systems was recognized by the National Law Journal as the only IP case among its Top Defense Verdicts of 1997, and a record settlement for ESS Technology in a software copyright case led to his being honored as a 2003 Lawyer of the Year by California Lawyer Magazine.

He is a director and officer of the National Inventors Hall of Fame and of the American Intellectual Property Law Association, where he will become president in 2007. Mr. Pooley graduated from Columbia School of Law as a Harlan Fiske Stone Scholar in 1973, and holds a Bachelor of Arts, with honors, from Lafayette College.

PAMELA SAMUELSON
Professor, School of Information Management and Systems, and School of Law
University of California, Berkeley

Pamela Samuelson is a professor at the University of California at Berkeley with a joint appointment in the School of Information Management and Systems and the School of Law. She is also co-director of the Berkeley Center for Law and Technology. Since 2002, she has also been an honorary professor at the University of Amsterdam. Professor Samuelson holds a B.A. and M.A. from the University of Hawaii and a J.D. from Yale University.

From 1997 through 2002, Samuelson was a fellow of the John D. & Catherine T. MacArthur Foundation. She is also a fellow of the Association of Computing Machinery. In 2001, she was appointed to a UC Berkeley Chancellor's Professorship for distinguished research, teaching and service for her contributions to both Boalt Hall and the School of Information Management and Systems.

ROBERT SPINRAD
Retired Vice President, Technology Strategy
Xerox Corporation

Bob Spinrad built his first computer in 1953 out of discarded telephone switching equipment. Playing with his creation sparked a life-long fascination with information technology and its effects on our lives. Spinrad worked as a senior scientist at Brookhaven National Laboratory before joining Xerox in 1968, where, over the years, he held various engineering, programming and research management positions. He last served as vice president, technology strategy.

In addition to other work for these organizations, Spinrad has also served in various advisory roles at Harvard, Stanford, the Massachusetts Institute of Technology, the University of California, the Jet Propulsion Lab, EDUCOM, the Council on Foreign Relations, the National Science Foundation, the National Academy of Sciences, the National Academy of Engineering, the National Research Council, the Council on Library and Information Resources, Lawrence Livermore National Laboratory, the Defense Department's Advanced Research Projects Agency, Bell Labs, the International Institute for Applied Systems Analysis, Digital Pathways, Inc., The Information Society and the McGraw-Hill Encyclopedia of Science & Technology.

Spinrad holds a Ph.D. from the Massachusetts Institute of Technology and M.S. and B.S. degrees from Columbia. He is also a licensed professional engineer (New York).

RICHMOND WOLF
Investment Analyst
Capital World Investors

Richmond Wolf is an investment analyst for Capital World Investors, a venture capitol firm and is the former director of the Office of Technology Transfer at the California Institute of Technology (Caltech), a nonprofit university that also manages the Jet Propulsion Laboratory (JPL) for NASA. He is responsible for the management of the intellectual property portfolio developed at Caltech and JPL, which includes over 2000 issued and pending patents. Wolf has experience working with start-up companies from Caltech and JPL in areas of business and product development, and he was a co-founder of two companies, WebEventBroadcasting and Xen Golf. Wolf is a member of the board of directors of Alexandria Real Estate Equities (NYSE:ARE). He is or has been an observer to the board of directors of Agorare Global, Oraxion, Insert Therapeutics, Aonex, Nanotechnica, Wavestream, and Vasgene, and he is or has been a member of the advisory board of ITU Ventures, Oak Grove Systems, the Los Angeles Regional Technology Alliance, and the Egg Factory. Wolf is a graduate of Princeton University cum laude, received a Ph.D. from Caltech, and he is also a registered patent agent.

JULIE MEIER WRIGHT
President & CEO
San Diego Regional Economic Development Corporation

Julie Meier Wright has served as president and chief executive officer of the San Diego Regional Economic Development Corporation (EDC) since August 1997. EDC is the premier business development organization for the greater San Diego region.

Prior to coming to San Diego, Wright served as California's first Secretary of Trade and Commerce and a member of Governor Pete Wilson's Cabinet from 1991 to 1997. In 2003, she served on gubernatorial candidate Arnold Schwarzenegger's Economic Recovery Council. She currently serves as a senior advisor to the California Budget Education and Action for Reform project and a member of the California Council for Regional Leadership. Prior to her time in public service, she spent 25 years in executive marketing and public affairs positions in the private sector, including 14 years with TRW Inc., now a part of Northrop-Grumman.

Wright holds a Bachelor of Arts degree in Criminology from the University of Maryland. She has completed the Stanford University Advanced Management College, the Stanford Financial Seminar, and a special program on competitiveness at Harvard University.

Appendix H: Intellectual Property Working Group

ELLEN R. AURITI
Executive Director, Academic Legislative Affairs and Research Policy, Office of Research
University of California Office of the President

Ellen R. Auriti is the executive director of research policy and legislation in the Office of Research at the University of California. The Research Policy Unit of the Office of Research provides coordination and guidance on systemwide research policy issues, working with the university's campuses and with other units within UCOP on developing and revising systemwide research policies and guidelines, developing university positions on public policies and proposals affecting research, and coordinating with campuses regarding significant legislative and regulatory changes affecting research.

Ellen received a B.A. from Yale University, and a J.D. from UC Berkeley's Boalt Hall School of Law. Prior to joining the University of California, Ellen was an attorney with Morrison & Foerster in San Francisco.

HALL P. DAILY
Assistant Vice President, Government & Community Relations
California Institute of Technology

Hall P. Daily is the assistant vice president of government & community relations at the California Institute of Technology in Pasadena, California. He came to Caltech in 1987 as assistant director of public relations after a 15-year career in journalism. Prior to his association with Caltech, Daily was an editor and reporter for The Associated Press, the San Jose Mercury News and the Pasadena Star-News.

Daily represents Caltech on the Association of Independent California Colleges and Universities and serves as treasurer of its executive committee. In addition, he represents the state's private universities and colleges on the statewide GEAR UP implementation task force. Daily currently serves as board vice president of El Centro de Accion Sociale in Pasadena, and board member of the Pasadena Police Activities League. In addition, he serves on the convening committee of Pasadena: City of Learning.

WILLIAM J. MCLEAN
Former Director, Combustion Research Facility
Sandia National Laboratories

William J. McLean is former director of the Combustion Research Facility (CRF) at Sandia National Laboratories in Livermore, California. The CRF is a U.S. Department of Energy, Office of Basic Energy Sciences, User Facility dedicated to advancing the science and technology of combustion and related energy systems. He is also responsible, under Sandia's Energy and Critical Infrastructure Strategic Business Unit, for overall program management of Sandia's Energy Efficiency research programs. He maintains close association with the U.S. Department of Energy (DOE) research programs sponsored by the Office of Science and Office of Energy Efficiency and Renewable Energy.

McLean received his undergraduate and graduate education in mechanical engineering at the University of California, Berkeley and was associate professor of mechanical engineering at Cornell University before joining Sandia twenty-five years ago.

BARBARA L. MORROW
Vice President-General Counsel
California Healthcare Institute (CHI)

Barbara L. Morrow joined CHI in September 2002 as vice president-general counsel. Morrow was vice president-legislation of the Civil Justice Association of California (CJAC), a coalition of businesses, individuals, and local government groups, where she oversaw the lobbying program. In that position, Morrow managed a wide range of civil liability and procedural issues, including product liability, arbitration, protective orders, summary judgment law, the unfair competition law, class actions, punitive damages, toxic torts, and construction defect law. Prior to joining CJAC, Morrow served as a legislative aide to Assemblyman Tom Bordonaro (R-Santa Barbara). From 1990-1996, Morrow was in-house counsel to Yamaha Motor Corporation in Cypress, California, where she focused on product liability litigation on a nationwide basis. Morrow holds a bachelor's degree in business administration from Georgia State University and juris doctor degree from Whittier College School of Law.

KURT C. OLSEN
Director of the California Legal and Patent Center
Sandia National Laboratories

Kurt C. Olsen is the principal attorney for Sandia National Laboratories in Livermore, California. He specializes in intellectual property licensing, and manages the patent department.

Working with the staff of Senators Jeff Bingaman (D-New Mexico) and Pete Domenici (R-New Mexico), Olsen developed concepts for protecting know-how in cooperative research and development agreements (CRADAs). Know-how protection was adopted in the Technology Transfer Act of 1989 (15 USC 3710a(c)(7)). His concept for waiver of government licenses to summon private risk capital investment was sponsored by Senator Bingaman and became law in 2000 (15 USC 3710a(b)(6)).

Olsen's early patent work was on computerized speech recognition at Bell Telephone Laboratories in Murray Hill, New Jersey. His undergraduate degree is in mechanical engineering from the University of Colorado, and his law degree is from Cleveland Marshall College.

SALLY O'NEIL
Manager, Industrial Contracts Office
Stanford University

Sally O'Neil manages the Industrial Contracts Office team. In this position, she handles sponsored research agreements, consortium agreements, and master agreements and negotiates and administers agreements for sponsored research with industrial sponsors, including intellectual property, licensing, and publication provisions, for engineering, H&S, and medical schools. She also serves as liaison between the Office of Sponsored Projects and Office of Technology Licensing. She is responsible for specific departments within the School of Medicine, and Engineering.

She earned a B.A. in English (Oberlin College), an M.A.T. in English (University of Chicago), and M.J. (University of California, Berkeley), and a J.D. (University of Santa Clara). O'Neil is a member of the State Bar of California, American Bar Association, and Santa Clara County Bar Association.

VALERIE D. PURNELL
Associate Director, State Governmental Relations
University of California Office of the President

As associate director of the University of California's Office of State Governmental Relations, Valerie Purnell is one of two senior lobbyists representing UC before the legislative and executive branches of California government. Purnell shares the tasks of identifying policy issues relevant to UC, devising the legislative strategies necessary to achieve the university's objectives, and analyzing the intent and potential effect of proposed legislation on the university.

Prior to taking her current position in 1994, Purnell worked for five years with Children Now. There she held the positions of principal lobbyist, media spokesperson, and later, director of external relations. In addition to her work in education, Purnell has had more than twelve years experience as a health policy advocate having worked for organizations such as Health Access, and the public interest law firm, Public Advocates, Inc.

Purnell received her law degree from the University of California, Hastings College of the Law, studied medical sociology at the University of California, San Francisco, and received her undergraduate degree from Pitzer College of the Claremont Colleges.

HEATHER RICHMAN
Associate Director of Government Relations
Stanford University

Heather Richman is the associate director of government relations at Stanford University with her focus being on state issues. She joined the Stanford team in 2004 after working over five years for U.S. Senator Charles Schumer (D-NY) on appropriations, tax and budget issues. Prior to her time in Washington, DC, Richman worked for U.S. Senator Barbara Boxer in her San Francisco office.

KRISTIN SOARES
Associate Vice President of External Relations, Office of State Government Relations
University of Southern California

Kristen Soares, associate vice president of USC External Relations, State Government Relations, represents USC in public policy arenas involving education, research and public service. Based in Sacramento, she works directly with members of the Legislature and officials in the executive branch to stimulate government actions that enhance the university's ability to carry out its mission. She is also responsible for coordinating these activities with USC's Federal Relations Office. Soares has been with USC since 1998 having served as assistant vice president of external relations and director of state government relations. Ms. Soares is a member of the Association of Independent California Colleges and Universities (AICCU) Executive Committee and the Policy Council for the California Chamber of Commerce.

WENDY STREITZ
Director, Policy, Analysis and Campus Services
University of California Office of Technology Transfer

Wendy Streitz is director of the Policy, Analysis, and Campus Services Unit, Office of Technology Transfer at the University of California. Prior to joining the University of California, she served as associate director, Intellectual Property and Technology Transfer at Auburn University. Streitz has a BSE from Harvey Mudd College and an MSEE from Johns Hopkins University. She has spent twelve years in industry in the field of signal processing.

VERONICA VILLALOBOS
Vice President for Public Affairs
Association of Independent California Colleges and Universities

Veronica Villalobos is currently the Vice President for Public Affairs for the Association of Independent California Colleges and Universities (AICCU) and has held that position since June of 2001. She advocates on behalf of 75 nonprofit, WASC accredited colleges and universities in the legislative and regulatory arenas. Ms. Villalobos received her B.S. from Santa Clara University and her M.P.P. from the University of Southern California.

Appendix I: Reviewers

The California Council on Science and Technology adheres to the highest standards to provide independent, objective and respected work. All work that bears the council's name is reviewed by council members and fellows. In addition, the council seeks peer review from external technical experts. The request for rigorous peer review results in a protocol that ensures the specific issue being addressed is done so in a targeted way with results that are clear and sound.

In all, this report reflects the input and expertise of nearly 50 people in addition to those in the study and working groups. Reviewers include experts from academia, high-tech industry, government agencies, national laboratories, venture capital firms, nonprofit organizations, and private foundations.

We wish to extend our sincere appreciation to the external reviewers who have agreed to be listed below and to the many others who requested not to be identified. Their expertise and diligence in reviewing this report has been invaluable, both in rigorously honing the accuracy and focus of the work and in ensuring that the perspectives of their respective areas of expertise and institutions were taken into account. As is customary with peer review, specific comments are not attributed to individuals, but their comments were an important part of the process of producing this report. Without the insightful feedback that these reviewers generously provided, this report could not have been completed.

We also wish to extend particular appreciation to the California State Attorney General's Office for consulting with the study group throughout the preparation of this report.

GEORGE CUNNINGHAM
Chief, Genetic Disease Branch
California Department of Health Services

HELEN DOYLE
Public Library of Science

ROBERT P. FEYER
Orrick, Herrington & Sutcliffe LLP

ELIZABETH G. HILL
Legislative Analyst

MOLLY HOLMAN
Executive Director, Intellectual Property
Amylin Pharmaceuticals

EDWARD K. KAWAHARA
Principal Consultant, California Economic Strategy Panel
California Labor and Workforce Development Agency

GUSTAV A. KOEHLER
Principal Consultant
Time Structures

JACKIE WYNNE MCGRATH
State Public Policy Director
Alzheimer's Association

DAVID MEARS
Director, Research Administration
University of California Office of the President

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Appendix J: California Council on Science and Technology

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