



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

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

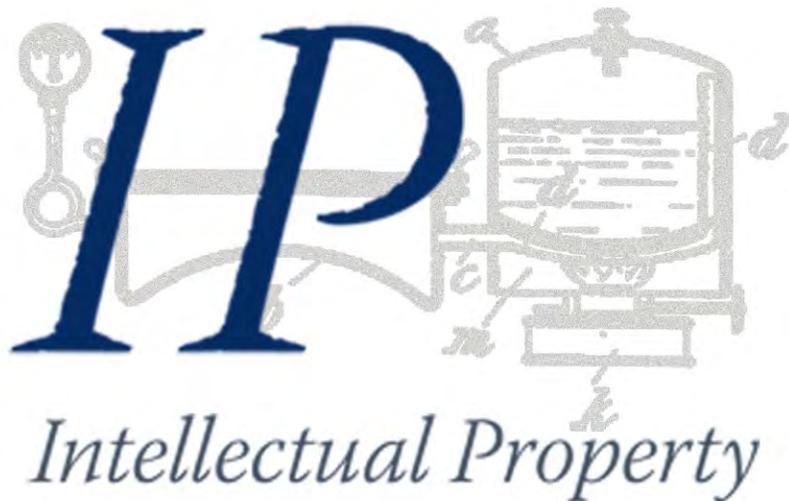
Executive Summary

January 2006

CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY
INTELLECTUAL PROPERTY STUDY GROUP

**CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY
INTELLECTUAL PROPERTY STUDY GROUP**

**POLICY FRAMEWORK FOR INTELLECTUAL PROPERTY DERIVED FROM
STATE-FUNDED RESEARCH:**



**FINAL REPORT TO THE
CALIFORNIA LEGISLATURE
GOVERNOR OF THE STATE OF CALIFORNIA**

EXECUTIVE SUMMARY

JANUARY 2006

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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.

A handwritten signature in black ink, appearing to read 'Karl Pister'.

Karl Pister
Board Chair

A handwritten signature in black ink, appearing to read 'Lawrence Papay'.

Lawrence Papay
Council Chair

A handwritten signature in black ink, appearing to read 'Cornelius Sullivan'.

Cornelius Sullivan
Council Vice Chair

A handwritten signature in black ink, appearing to read 'Susan Hackwood'.

Susan Hackwood
Executive Director

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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.

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.

Consistency with federal statutes and policy suggests that ownership of IP resulting from state-sponsored research also should reside with the grantee.

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.

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.

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.

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.

APPENDICES



In the interests of brevity, we include here only one appendix (Appendix E) from the full report, which contains an additional response to specific provisions in ACR 24 not addressed directly in the body of the report; this appendix includes feedback from selected outside reviewers per the specifications of the ACR.

The full report contains additional appendices intended as resources to supplement the body of the report. They include sections prepared by Study and Working Group members to expand upon key points and relevant examples of IP policies and development.

In the full report, Appendix A explains the different types of intellectual property in greater detail, explaining what each entails and the different kinds of protection that they offer. Appendix B provides greater detail on the Bayh-Dole Act, the federal IP policy used as a reference point throughout this report. Appendix C provides excerpts from guidelines for disseminating research resources arising from National Institutes of Health funded research. We believe that California's role in funding research is comparable in many respects to that of the federal government and federally funded agencies such as the NIH, and hence we find this an applicable model for comparison. Appendix D provides the intellectual property procedures from one of the largest state-funded research program, the Public Interest Energy Research (PIER) program. Appendix F contains the text of ACR 252 and 24.

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.



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
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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.

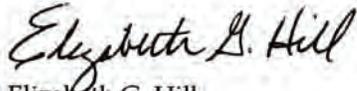
Mr. Lawrence T. Papay

3

December 15, 2005

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,

A handwritten signature in black ink that reads "Elizabeth G. Hill". The signature is written in a cursive style with a large initial "E".

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

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."

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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 Wynne McGrath
State Public Policy Director



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December 8, 2005

Robert P. Feyer
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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

Dr. Susan Hackwood
December 8, 2005
Page 2

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

OFFICE OF THE TREASURERP. 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,

A handwritten signature in blue ink that reads "Juan C. Fernandez".

Juan C. Fernandez, Director
Public Finance Division

Attachment

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.

EXTERNAL 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.

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California Department of Health Services

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State Public Policy Director
Alzheimer's Association

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Public Library of Science

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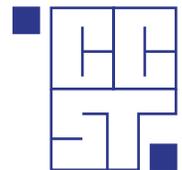
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