

Executive Summary

Policy Framework for Intellectual Property Derived from Stem Cell Research in California:

***Interim Report to the
California Legislature
Governor of the State of California
California Institute for Regenerative Medicine***

August 2005

CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY
INTELLECTUAL PROPERTY STUDY GROUP

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**POLICY FRAMEWORK FOR INTELLECTUAL PROPERTY DERIVED FROM
STEM CELL RESEARCH IN CALIFORNIA:**



**INTERIM REPORT TO THE
CALIFORNIA LEGISLATURE
GOVERNOR OF THE STATE OF CALIFORNIA
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE**

AUGUST 2005

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TABLE OF CONTENTS



LETTER FROM CCST LEADERSHIP1

STUDY GROUP MEMBERSHIP3

PREFACE.....5

EXECUTIVE SUMMARY7

APPENDICES.....17

REVIEWERS19

CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY 21

ADDENDUM.....25

LETTER FROM CCST LEADERSHIP



It is often said that California is the nation's high-tech leader. Certainly, the size of California's science and technology sector, its leading public and private research institutions, and world-renowned high-tech business community bear ample witness to this statement by simple scale and scope. But what drives the state's true leadership position is not just the size of its science and technology sector, the total dollar amount of its research and development activities, or number of patents earned. It is California's willingness to look ahead, take risks, set the standards for performance, and then excel in highly competitive arenas.

The approval by voters of Proposition 71, and the resulting California Institute for Regenerative Medicine (CIRM), is the most recent example of this state taking the lead on an important issue. CIRM is a historic state-funded research and development initiative that far exceeds any comparable state investment in the country. Its goal is to serve a key role in the advancement of stem cell research, a field of exploration and discovery that in many ways is in its early stages, yet holds much promise to increasing our understanding of how cell lines develop and regenerate. The hope is that this research will lead, in time, to therapies and treatments for diseases and conditions that, to date, have been intractable or deadly.

CIRM is faced with many challenges. It is a new organization currently engaged in the process of writing many of its own rules, because there are no precedents for establishing a state-level research institute of this magnitude.

It is not easy to break new ground. CIRM involves a significant investment for California and many interests are at stake. This interim report provides policy recommendations to the California Legislature, the Governor and CIRM about how to address an important infrastructure challenge: establishing a consistent and workable set of intellectual property policies for stem cell research that will best serve the interests of the state, the public and the research community. The analysis and recommendations CCST provides here are an interim step to another unprecedented project, that of designing a comprehensive set of intellectual property policies for the state. CCST's final report on that topic will be completed in December of this year.

In approaching this project, CCST has brought together a team of experts and leaders from the high-tech community representing business and industry, venture capital, academia, and government. These individuals have taken their responsibilities very seriously and have volunteered a tremendous amount of time and effort to the project despite their own significant other commitments. The resulting consensus report reflects a great deal of discussion and review.

It is our hope that the results serve as a useful guide for CIRM as it continues to establish the policies that will guide its work for the next decade and beyond. We also believe that this report will be of use to state legislators and other state leaders as they continue to consider how best to encourage exploration and innovation in California.

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Karl Pister
Board Chair

Handwritten signature of Lawrence Papay in black ink.

Lawrence Papay
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PREFACE



Innovative technologies and their underlying intellectual property (IP) are the fundamental drivers of California's high-tech economy. In general, the way that IP is handled creates the environment in research institutions and in business and industry necessary for risk taking and the investment of capital to translate creative ideas to marketable products, and subsequent attendant benefits. Time-tested models in the private sector and at the federal level show that uniform IP policies create efficiencies in time and money, reduce barriers, and increase opportunities for the development of new products and services.

At the state level, however, a comprehensive and coherent policy does not yet exist either for state-generated works or for 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.

In order to help state policymakers design an IP policy framework appropriate for California's current economy, the Legislature through ACR 252 requested that the California Council on Science and Technology (CCST) conduct an analysis of whether and how to implement a set of consistent statewide policies. This analysis is scheduled for completion in late 2005.

After the passage of ACR 252 in September 2004, a major new initiative passed in the November 2004 elections that held significant ramifications for IP policy in California. Proposition 71, the Stem Cell Research and Cures Initiative, calls for awarding \$3 billion over the next ten years to fund stem cell research and creation of the California Institute for Regenerative Medicine (CIRM). The Independent Citizens Oversight Committee (ICOC), which has been charged with establishing CIRM and implementing Proposition 71, is faced with many significant challenges, including that of establishing policies for the appropriate administration of IP generated through CIRM-funded research. Because CCST had already undertaken the task of developing IP policy recommendations for the state requested by ACR 252, many in the state felt that the Study Group assembled by CCST also would be the most effective body to advise the ICOC and CIRM on developing a sound and coherent set of IP management policies.

Consequently, legislators authored ACR 24, which requests that CCST expand the scope of the Study Group to include contracts, grants and agreements developed under Proposition 71.^{*} This interim report is a response to the original draft of ACR 24 as amended in April 2005. In mid July, several additional amendments were added to ACR 24 with new directives for the Study Group. These are addressed in an addendum at the end of the report.

^{*} ACR 24 of the 2005-06 Regular Session, (Mullin), Amended 4/21/05.

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.

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. Five of the members are associated with CCST as 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. The two 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, from private foundations, government agencies, academia, venture capital firms, and high-tech industry, both biotechnology and other.

This is an interim report (August 2005) intended primarily to advise CIRM as it develops its IP policies. CCST's final report to the Legislature is scheduled for completion in December 2005. Given the urgency of launching the new CIRM, we focus in this report on IP policy issues that are particular to the unique circumstances of CIRM's creation and implementation. The following analysis and recommendations, while intended to be consistent with those under development for our final report, should not be construed as a comprehensive set of guidelines for the state of California.

EXECUTIVE SUMMARY



Proposition 71, approved by California’s voters in November 2004, requires that the Independent Citizens Oversight Committee (ICOC) of the California Institute for Regenerative Medicine (CIRM) set intellectual property (IP) standards that “balance the opportunity of the state of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements.”¹

The purpose of this interim report is to discuss the likely benefits associated with IP created under CIRM funding, describe some existing models for handling IP, and suggest some approaches to the treatment of IP that benefit CIRM and the state. This report provides brief background on the federal Bayh-Dole Act, special considerations about biomedical research, kinds of intellectual property, and California’s return on its investment. It then discusses factors that CIRM will need to consider in the establishment of its IP policies, and presents specific recommendations.

In formulating CIRM’s policies to handle intellectual property, ICOC members and state leaders must realize that this field of research is in its very early years. A significant portion of the funding that CIRM will give out will support basic research; the output of this basic and applied science will largely be research tools, databases of scientific data, research publications, and most important, a step forward in the understanding of the science, paving the way for additional research. A small number of research discoveries may lead to therapeutic or diagnostic technologies, and it is impossible to discern in advance which discoveries have this potential. In all likelihood, the development of effective therapies from CIRM-sponsored research is at least ten to twenty years away.

In the life sciences, the development of a new drug or FDA-approved treatment from a research finding typically takes at least a decade, and it takes private investments in excess of several hundred million dollars in the development process to bring a product to market.

In response to the high degree of public interest in the implementation of Proposition 71 and numerous policy discussions that have unfolded in the months since its approval, we urge CIRM and the state to proceed with caution and not to set overly prescriptive policies for IP derived from stem cell research. We conclude that some Californians have unrealistically optimistic expectations about the likely financial returns to the state from its investment in stem cell research, especially in the short run.

Stem cell research has been promoted as holding a great deal of promise for California. Taxpayers’ return on investment is one issue that figured prominently in literature used to promote Proposition 71 prior to the election and in subsequent discussion of its administration.² In turn, legislators have proposed that CIRM’s IP policy should seek to generate substantial new revenues for the state, new funds for further research by CIRM, and favorable pricing for

¹ Health & Safety Code §125290.30(h)s.

² <http://www.voterguide.ss.ca.gov/propositions/prop71-title.htm>.

therapies derived from CIRM's research. We find that these proposals, and the statements and studies on which they are based, including the economic impact analysis that was released during the campaign by the proponents of Proposition 71, are based on unrealistic assumptions about the potential economic impact of CIRM's research program.³ In particular, although the amount of funds that will be focused on stem cell research – about \$300 million per year for 10 years – is substantial, it must be put in the context of the nearly \$14 billion annually in federally funded research in the state's institutions of higher education, private research institutes and national laboratories, and \$45 billion annually in industry funded R&D.⁴ All interested parties must be mindful of overestimating both the projected revenue stream from IP generated by CIRM-funded grants and the timeline to achieve it.

While expectations of a short-term revenue stream and quick availability to the public of new treatments may well be overstated, CIRM-funded research can, nonetheless, be expected to benefit the state in significant ways, particularly in the long term. The greatest potential long-run benefit arising from CIRM's research will be improvements in the quality of life of citizens who now suffer from debilitating degenerative disease and traumatic injuries. CIRM's research grants may also add to the considerable attractiveness of California as a location for biotechnology research firms, but this effect is not likely to be large in the near term. Because a large portion of the research will be basic in nature, particular attention needs to be paid to the treatment and dissemination of research tools and databases. Making research tools developed with CIRM funding largely available to other scientists for use in ongoing research would be consistent with the language of Proposition 71, which specifies that CIRM is expected to assure that "essential medical research is not unreasonably hindered." This is a standard policy for research funded by the National Institutes of Health (NIH) and should be encouraged by CIRM.⁵ We recommend that exclusive licenses to research tools, if used, should retain rights for the grantee and the CIRM research community to continue to use the IP for research purposes. CIRM also should encourage researchers to make databases as widely available as possible, while at the same time recognizing the need to maintain quality data. Scientific and research progress in stem cell research, like other research, 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.

CIRM's mission, as a new state agency, is to make grants and provide loans for stem cell research and training, research facilities, and other vital research opportunities, with an ultimate goal of discovering and developing new ways of treating degenerative diseases. The primary objectives of CIRM IP policies should be to maximize CIRM's 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;
- Encourage practical application of CIRM-funded research results for the development of medical therapies that benefit the public;

³ Laurence Baker and Bruce Deal, *Economic Impact Analysis: Proposition 71, California Stem Cell Research and Cures Initiative*. Analysis Group, Inc. (Sept. 14, 2004) pp. 2-3.

⁴ National Science Board, 2004. *Science and Engineering Indicators*.

⁵ <http://ott.od.nih.gov/pdfs/64FR72090.pdf>.

- Accelerate the transition of discoveries from research to commercially available diagnostics and treatments;
- To the extent possible, balance existing investments with state investments such that each receives appropriate returns;
- Promote collaboration between commercial entities and non-profit research institutions;
- Encourage private investors to invest in further research and development of new technologies resulting from CIRM-funded research;
- Minimize costs of administering policies; and
- Be mindful of the time delay and private investment needed before significant benefits accrue to the state.

Models for IP Policy

Research, especially in universities and non-profit institutions, receives funding from many sources, including federal and state agencies, private industry and non-profit 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.

Bayh-Dole rationalized and simplified the process of moving technologies generated by federally funded research from university laboratories to the private sector.

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

There is a general consensus that Bayh-Dole rationalized and simplified the process of moving technologies generated by federally funded research from university laboratories to the private sector. Bayh-Dole is considered to have contributed positively to the development of some technologies that may not have been made available to the public in its absence.⁶

In many ways, the situation in California today regarding treatment of IP resulting from state-funded research resembles the federal situation in the late 1970s prior to the passage of Bayh-Dole: contracting is possible, but complicated. The absence of clear guidance leads to considerable time and costs associated with negotiating the handling of IP stemming from state funded research.

State level policies in California are not uniform and do not have a common set of clearly stated objectives.

⁶ Jerry G. Thursby and Marie C. Thursby, "University Licensing under Bayh-Dole: What are the Issues and Evidence?" (May 2003) p.9.

As CIRM develops its IP policies, consideration should be given to the likely circumstance where CIRM funds would be deployed alongside federal funds, or potentially leveraged with federal funds in the same research project. To minimize confusion and maximize the return on grant funds, CIRM's policies should be consistent with Bayh-Dole. This is not to say that CIRM's policy needs to 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.⁷

Ownership of Intellectual Property

Ownership of intellectual property resulting from sponsored research is a central issue in establishing an intellectual property policy and allowing ownership to reside with the grantee is the central feature of the Bayh-Dole Act. From this central feature of IP ownership, many other policy considerations followed. In considering the issue of IP ownership for CIRM, it is important to consider: 1) the relative importance of a policy that is consistent with federal (e.g. Bayh-Dole) statute and policy, 2) who is best able to manage the resulting IP, and 3) the existing financial models that are in place to make appropriate investments in protecting very early-stage research results.

Clearly, consistency with federal statutes and policy suggest that ownership of IP resulting from CIRM-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 conclusion was a central feature of the California Technology Trade and Commerce Agency report of 2003, which recommended that the University of California decentralize its technology transfer programs to the local campus level.⁸ Because IP resulting from basic research is very early stage, the ability to manage this IP is also related to the institutional capacity to invest in filing patent applications before there is any prospect of a return on that investment. Thus, if CIRM or a surrogate agency 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. Research universities and not-for-profit research institutes 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.

Based on compliance with Bayh-Dole, as well as who is best able to manage the resulting IP and having existing financial models to invest in patent filings, we find that there are compelling reasons to recommend that ownership of IP resulting from CIRM-sponsored research reside with the grantee. This will provide a policy framework that will not conflict with federal statutes and policy, but more significantly recognizes the importance of the researchers themselves in helping to manage and advance the IP as well as the existing institutional infrastructure to manage and fund investments in IP protection.

⁷ In the version of ACR 24 amended 7/13/05, other programs such as the William and Melinda Gates Foundation and the AIDS Initiative were cited as additional possible points of comparison for CIRM policy. While these programs employ interesting approaches to handling of IP, there are differences between the functions they perform and the role CIRM will play; in addition, both are too recent to have an established track record. A more complete discussion of these has been included in an addendum at the end of the report.

⁸ 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).

Return on Investment

The Legislature, through ACR 24 (as amended in April 2005),⁹ asked the Study Group to give particular consideration to the generation of “public benefit” via state revenues, favorable pricing, revenue sharing, and reinvestment into research.

All of these issues were debated extensively at the federal level prior to and following the passage of Bayh-Dole in 1980, and continue to be a subject of discussion today by federal agencies such as the National Institutes of Health.

State Revenues and Revenue Sharing

There are several ways for the state to benefit from IP generated by CIRM-funded research. In most ways, this IP will be no different than any other state-funded biomedical IP generated in California. There are, however, some aspects of CIRM-funded IP that merit special consideration, because of the nature of the research and because of current federal policies.

First, in contrast to research in other areas such as information technology, the IP generated by CIRM-funded research will likely involve:

- A longer time to develop into useful products;
- A greater cost to develop than other IP (because of the longer time necessary and highly regulated development environment); and
- A much higher level of public visibility and scrutiny than most research programs.

Second, as is well known, the federal government has restricted federal funding for human embryonic stem cell research to a limited set of stem cell lines extant at the time the relevant federal policy was issued in 2001.¹⁰ In the future, it is possible that current federal restrictions will be changed. To the extent that CIRM funding can be used to leverage federal funds, this should be encouraged, as it will maximize the effectiveness of the state’s investment in stem cell research.

In any scenario, it will take many years for the state to accrue benefits from CIRM-funded research. Moreover, within the state, the high level of expectation about return on its investment is unusual in research. At the federal level, this has not been much of an issue in the 25 years since the passage of Bayh-Dole. Instead, after considerable debate, 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.

Regardless of CIRM’s IP policies, long time periods are required to do research and develop useful and safe biomedical products and therapies and usher them through the regulatory approval process. 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.

In the near term, economic benefits will most likely accrue to the state from its investment in the stem cell initiative through retention and recruitment of high-quality research personnel and enhanced business activity in support of research institutions and programs.

⁹ ACR 24 of the 2005-06 Regular Session, (Mullin), Amended 4/21/05.

¹⁰ Address to the Nation on Stem Cell Research, 2 Pub. Papers 953 (Aug. 9, 2001); see also Press Release, The White House, Fact Sheet: Embryonic Stem Cell Research, <http://www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html>.

Regarding benefits from new discoveries, the primary IP derived from CIRM-funded research in this early period will be either research tools or inventions that have therapeutic promise, but for which much more research funded by venture capital and companies will be required to determine their optimal use and commercial viability.

Over time, the returns on CIRM investments in research will have to be evaluated by considering the full scope of the benefits that medical research offers to society. Conventional thinking measures traditional quantifiable investments, both direct (dollars spent) and indirect (jobs created, total sales, etc.). More difficult, although still possible to measure, are cost savings from diagnostic and treatment procedures for particular diseases, increases in life expectancy, and improvements in the standard of living.

Royalty Revenues

The expectation exists that CIRM's IP policy needs to direct a revenue stream to the state. It is critical that this expectation not work against CIRM's primary mission, which is to fund research with the goal of discovering and developing new ways of treating degenerative diseases.

The desire for a 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

The expectation that CIRM's IP policy needs to direct a revenue stream to the state should not work against CIRM's primary mission...to discover and develop new ways of treating degenerative diseases.

incentives for the much greater commercial investment that is necessary to develop useful treatments and therapies. A requirement that the state be entitled to a royalty stream from any commercialization of CIRM-funded therapeutics is likely to create disincentives to invest; more importantly, such a requirement may also impact CIRM's ability to use tax-exempt bonds to fund research which will cost the state much more in terms of the cost of bonds than it could ever hope to realize through royalty revenues.

Thus, CIRM's IP policy should focus on providing incentives for commercial investment and development of new technologies within the state of California. That strategy will potentially

The overriding IP consideration for grantees should be to move technology from research to other entities as effectively as possible for the public benefit.

contribute the largest economic impact of the initiative in the near term through job creation.

Even though we do not recommend any form of direct royalty revenue sharing with the state because of the likely impact on tax-exempt bond status, some portion of royalties could be used to support additional research or for other purposes that support CIRM's mission (see below). In considering how royalty revenues could be used,

several details need to be addressed to ensure that the appropriate incentives remain in place to support effective IP management. Some of the issues include:

- Permit grantees to recover all direct expenses incurred in pursuing patent protection and licensing opportunities.

- Begin royalty revenue sharing only when certain landmarks have been passed, e.g. net revenues exceeding \$500,000/year, to avoid the administrative inefficiency of dealing with marginal amounts of money and to help grantees offset the cost of the risks they make in IP 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.

Reinvestment into Research

An option is to direct a share of royalty revenues to fund further stem-cell related research and education, which is consistent with the objectives of CIRM and with the mission of non-profit research institutions. This option also minimizes potential conflicting requirements with Bayh-Dole for non-profits that also have federally funded research in this area. Bayh-Dole requires non-profit grantees to use net licensing revenues for research and education. As with IP ownership, consistency with the requirements of other providers of research funding will allow CIRM grantees to leverage such funds where available and appropriate, and avoids the necessity and expense of complex administration or of isolating CIRM-funded research activity.

Favorable Pricing

There has been much discussion of requiring that CIRM-funded drugs and medical treatments be made available to consumers at “reasonable prices.” While certainly a well-intentioned public policy objective, the pricing of future treatments and therapies is not directly an IP policy issue. The linkage of such an important healthcare financing policy with IP policy, and the subsequent management of IP, may have unfortunate and unintended consequences. Experience at the federal level strongly suggests that it would actually *hinder* the availability of medical advances, rather than make them more widely available.

In 1989, NIH implemented a reasonable pricing policy for its Cooperative Research and Development Agreements (CRADAs). Under this policy, potential collaborators had to agree to “a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public.”¹¹ Ultimately, the policy had a chilling effect on the NIH’s relationship with industry. Many companies considered “reasonable pricing” a means of price control and simply declined

The NIH concluded that ensuring royalties and monitoring returns was a less important issue than expeditious development of new products.

¹¹ Report of the NIH Panels on Cooperative Research and Development Agreements, July 21 and September 8, 1994, p.27.

further interaction with NIH, leading to a zero growth rate of CRADAs. The NIH chartered review panels that concluded that ensuring royalties and monitoring returns was a less important issue than expeditious new product development. Consequently, the policy was revoked in 1995, and CRADA growth rebounded.

The issue of affordable pricing of treatments and therapies that may emerge from CIRM-funded research, however, must be addressed. In all likelihood, new treatments and therapies will not emerge for several years, so there is sufficient time to seek the advice and counsel of a wide range of experts and deliberate carefully. To that end, we recommend that a more detailed examination begin in the near future that engages the full range of non-IP technical expertise required to lay out the key issues involved in reasonable or favorable pricing. Among the kinds of expertise needed are healthcare financing, health insurance, and business development. Members of ICOC and Legislature also should be part of that deliberative process as it proceeds, and before policy decisions are made.

Recommendations

Our recommendations are consistent with general principles we are likely to recommend for state-funded research in the Study Group's final report to be completed later this year. These general principles assert that the IP policy:

- Is to be consistent with the 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, who is required to diligently develop IP for the public. In addition, the balance of any net royalties must be used to support research and education activities.
- Creates incentives for commerce in California from state-funded research to the greatest extent possible.
- Encourages timely publication of results to diffuse knowledge widely, and provide 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 development of IP into products that benefit the public.

With these general principles in mind, we recommend that CIRM consider policies that accomplish the following:

- Permit grantees to own IP rights from CIRM-funded research.
- Require grantees (institutions, individuals, or both) to provide a plan describing how IP will be managed for the advancement of science and California public benefit.
- Grant basic research funds without requiring grantees to 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.
- Generally make CIRM-developed research tools widely available to other researchers.
- Require diligent efforts to develop CIRM-funded IP into therapeutics and diagnostics that can benefit the public.
- Retain within CIRM Bayh-Dole-like rights to step in if the owner of IP is not undertaking appropriate steps to transfer technology to benefit the public.

- 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.
- Reserve the right to use IP by or on behalf of CIRM.
- Establish and maintain a CIRM database to track all IP generated through CIRM funding.

Finally, in the time available to prepare this interim report, we were only able to begin to explore options for returns on investment. In light of the tremendous level of public expectations about benefits to California, we also recommend that CIRM, to the extent possible, fund further research on models to optimize returns to the state. In addition, we recommend that a more detailed examination begin in the near future that engages the full range of non-IP technical expertise required to identify and deliberate over key issues involved in reasonable or favorable pricing of treatments and therapies derived from CIRM-funded research.

Conclusions

With the creation of CIRM and the commitment to invest \$3 billion in stem cell research, California is setting a precedent that is being closely watched by the nation and the world. The size and visibility of the public investment approved by voters through Proposition 71, and operationalized by CIRM, is creating high expectations for measurable impacts over the next decade. As it establishes policies for IP, CIRM will be defining a fundamental framework to be used by the research institutions and businesses that will translate creative ideas into tangible products. The careful management of the IP derived from CIRM-funded research will be critical in determining how well the intellectual outputs of this public investment are translated into useful products, therapies and treatments. We believe this interim report addresses the key issues that CIRM needs to consider as it undertakes this important task.

APPENDICES



The first four appendices are 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.

Appendix A explains the different types of intellectual property in greater detail, explaining what each entails, how they apply to biotechnology research, 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, and how the Bayh-Dole Act might apply to research institutions which may receive CIRM funding.

Appendix C is an example of how research led to the development of an effective therapy for childhood leukemia. It provides a valuable timeline for the process and illustrates the different stages of the research and development process along the way. This document is part of the “Beyond Discovery” educational series and is reproduced courtesy of the National Academy of Sciences.

Appendix D provides key excerpts from guidelines for disseminating research resources arising out of NIH-funded research. CIRM will be performing a function similar to the NIH in funding research, although on a much smaller scale. The NIH policy is an instructive example on how an institution such as CIRM might implement a set of policies on dissemination research resources.

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The California Council on Science and Technology has the highest principles in providing independent, objective and respected work. The Council is in itself a review process in that all work that bears the Council's name is reviewed by Council members, Fellows, and outside experts. The Council seeks guidance and approval of outside experts for peer review. This results in a protocol that ensures the issue is well addressed, the response is targeted, and the results 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, including experts from academia, high-tech industry (both biotechnology and other), government agencies, the national laboratories, venture capital corporations, and private foundations.

We wish to extend our sincere appreciation to the external reviewers listed below, whose 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. 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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ADDENDUM



By Alan B. Bennett and Stephen D. Rockwood

Co-Chairs, IP Study Group

Overview of the History of ACR 24

When CCST's Study Group undertook this project earlier this year in response to ACR 252 (chaptered), it set out to provide a framework for intellectual property policy for CIRM and the state. ACR 24 (pending) was subsequently authored to request CCST consider the disposition of IP derived under Proposition 71 and produce recommendations for the state to consider. The Study Group worked to respond to Assembly draft of ACR 24. It understood at the time that ACR 24 had not yet been passed and that it could potentially be subject to change. In keeping with its original 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, we do not believe that they will affect the Study Group's conclusions and recommendations for intellectual property policy as set forth in the interim report.

This addendum contains our reply to the amendments. Some, as indicated below, will be explored more fully by the Study Group and will be incorporated in its final report that will be completed later this year. Others are beyond the scope of this group's expertise and experience and will need to be studied more thoroughly elsewhere.

Amendments to ACR 24 as of July 13, 2005

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.

This interim report provides an overview of California's potential return(s) on investment from IP generated by CIRM-funded research in Section 5. Our 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. 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 investigation.

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 has consulted with Orrick, Herrington & Sutcliffe, LLP, the bond counsel retained the State Treasurer's Office, in order to assess the scope of the issues involved in the use of tax-exempt versus taxable bonds. Although the ultimate disposition on several issues related to the use of tax-exempt bonds will be dependent upon decisions yet to be rendered by the Internal Revenue Service, the direct return of intellectual property or its licensing revenue to the state appears to be in conflict with using tax-exempt bonds to fund Proposition 71 research. In this regard, the report's recommendations would appear to be consistent with the use of tax-exempt bonds. Full consideration of this issue, and the consideration of other potential mechanisms to utilize a portion of licensing revenue to meet state needs is beyond the scope of this Study Group's charge and will need to be studied further by the Treasurer's Office and the State Attorney General's Office in consultation with the IRS.

Resolved, That the Legislature requests that the [California] Council on Science and Technology establish a review group that shall include representatives of bond counsel firms, the Legislative Analyst, the Treasurer's Office, 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 interim report has been reviewed by external reviewers (Appendix H) and the CCST Board and Council (Appendix I) in accordance with CCST's peer review procedures. The current report reflects the input and expertise of both the Study Group members and those who reviewed the report. Upon its release, we anticipate that the interim report will attract commentary from the groups and organizations listed above as well as others. It is our hope that the document serves as a constructive starting point for additional discussion and we look forward to whatever commentary and analysis may be offered by these other groups.

Resolved, That the Legislature requests that the [California] Council and 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 is being released prior to November 1 because the Study Group has completed its initial analysis, and we believe it will be of use to the state and to CIRM as it begins the process of developing IP policies. The final report with recommendations for the state of California, as requested by ACR 252, will be released at the end of 2005 as originally scheduled.

Consideration of Additional Models for Managing IP

It has been noted that, in addition to the National Institutes of Health (NIH), there are other organizations that may be compared with CIRM for the purposes of proposing IP policies. While it is the Study Group's belief that the NIH is the most appropriate institution to use as a reference point in examining possible policies for CIRM, two programs mentioned in the amended ACR 24 merit consideration. The International AIDS Vaccine Initiative (IAVI) and the Grand Challenges in Global Health Initiative 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.” These non-governmental organizations are substantially different from CIRM, as a state agency, in many respects, but offer some interesting points of comparison with regards to their IP policies.

The International AIDS Vaccine Initiative (IAVI) is a not-for-profit organization in operation in 23 countries. Since its inception in 1996, IAVI has invested more than \$100 Million in AIDS vaccine development. 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 development of new product development candidates and 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.

IAVI’s vaccine research program supports projects that bridge the gap between fundamental research and product development efforts, with a focus on applied research and vaccine design. IAVI seeks to harness the global talent and infrastructure necessary to work on complex applied research problems. Among the goals of IAVI is to support new kinds of consortia that would not otherwise occur by identifying key problems to be solved, and then identifying collaborators in wide ranging institutions 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. Several other models are also underway or in development, and the technical problems being worked on are exceedingly complex.

The Grand Challenges in Global Health Initiative is a \$482 M 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 M in funding from the Gates Foundation includes \$200 M managed by the Foundation for the National Institutes of Health.

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. 43 grants, for a total of \$436.6 M, were announced in late June. These grants involved scientists in 33 countries.

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.

Management of IP by these initiatives

The IP derived from IAVI funding is owned and managed by the inventors. The individually negotiated IP 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 that will bridge the gap between the basic research and the proofs of concept that overcome the large

technical challenges the currently exist. The IP associated with the proofs of concept will then be licensed by industry, which will play its traditional role in advanced product development and commercialization of the vaccines. In poor countries, those vaccines would be delivered at reasonable prices. The initiative does not establish restrictions in other markets or for use of the IP for other applications.

The Grand Challenge initiative 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 that describes their thought processes about developing a useable product, producing a product maturation plan, criteria for selecting research and commercial partners, and other issues.

The global access strategy 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. 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 through which many lessons will be learned and best practices will emerge.

In many ways, these initiatives are quite innovative. However, the new aspects of both initiatives focus primarily on how IP is licensed and used after it is generated. Ownership will reside with the grantee. The general principles for IP ownership for these initiatives are consistent with the general principles put forward in this report, that IP policy:

- Is to be consistent with Bayh-Dole, where ownership of IP resides with the grantee
- Create incentives for commerce to the greatest extent possible
- Encourage timely publication of results to diffuse knowledge widely, and
- Requires diligent development of IP into products that benefit the public.

The newness of these initiatives does not enable us to point to successful models. It is too soon, therefore, to recommend to the state and to CIRM wholesale adoption of the processes used in either of these initiatives. The efforts of IAVI and the Grand Challenges, however, have succeeded in catalyzing principal investigators, business managers, and technology transfer executives and managers to begin thinking in new ways about licensing strategies to ensure low-cost treatments to people in the poorest countries in the world. To the extent that these new explorations may help CIRM think about ways that licensing agreements based on IP derived from CIRM-funded grants – which in and of itself is still several years away -- can be structured in ways that benefit a particular class of California citizens (low-income individuals), then we encourage ongoing discussions between CIRM and the leaders of these initiatives.

It seems most important in the near term that the general principles offered in this interim report guide CIRM’s initial policy making related to ownership of IP and its diligent development into products that benefit the public. During the next decade, we expect that many lessons will be learned from IAVI and the Global Health Challenge, and perhaps other public-private partnerships, and that best practices will emerge. It is still apparent to us, however, that CIRM, by design and given the basic and early applied nature of the stem cell research to be conducted, especially in the next several years, is much more similar in its goals to the NIH than a private

or public charity. Therefore, consistency with the objectives Bayh-Dole would provide the best incentives to the community of researchers and commercial entities that ultimately will harness the creative spirit required to develop breakthroughs and applications to new treatments and therapies.

For additional information on these two initiatives, see:

The International AIDS Vaccine Initiative -- <http://www.iavi.org>

The Grand Challenges in Global Health Initiative – www.gatesfoundation.org and www.fnih.org

Conclusion

The Study Group was convened to examine the specific question on how to establish an intellectual property framework for the state of California. There is no precedent for the creation of such a statewide policy framework, just as there is no precedent for a state-supported basic research institution on the scale of CIRM. It is perhaps inevitable that the creation of completely new institutions and policies will invite speculation. As noted both in ACR 24 and elsewhere, there is a wide range of other issues that need to be addressed in the creation and administration of CIRM and state funded IP in general. The Study Group has done its best to answer the mandate set forth in the original scope of the project, which focuses on a framework for IP policy. It is our hope that other committees and organizations can give the additional issues cited in the amended ACR 24 the full analysis and attention that they deserve.

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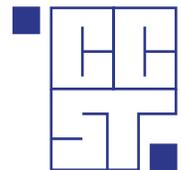
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