Joint Informational Hearing

Senate Health Committee
Senate Subcommittee on Stem Cell Research Oversight
Assembly Health Committee
Assembly Judiciary Committee

Chairs:
Senator Deborah Ortiz
Assemblymembers Wilma Chan and Dave Jones

"Implementation of Proposition 71: Options for Handling Intellectual Property Associated with Stem Cell Research Grants"

Background Paper

Proposition 71, the California Stem Cell Research and Cures Act (Act) approved by voters in November, 2004, provides $3 billion in general obligation bonds to provide funding for stem cell research and research facilities in California. The Act establishes the California Institute for Regenerative Medicine (Institute) to award grants and loans for stem cell research and research facilities.

The Institute is governed by a 29-member Independent Citizen's Oversight Committee (ICOC), comprised of representatives of specified University of California campuses, other public or private California universities, nonprofit academic and medical research institutions, companies with expertise in developing medical therapies, and disease research advocacy groups. The ICOC and several of its working groups have been meeting regularly since December, 2004, and the ICOC awarded a first set of grants in September, 2005. For the most part, the organization has been unable to make grants because lawsuits challenging the validity of Proposition 71 have thus far prevented the state from issuing any bonds.

The Act authorizes the state to sell $3 billion in general obligation bonds, and limits bond sales to no more than $350 million per year, with the intent that the bonds be sold during a ten-year period. The Act provides that for the first five years, repayment of the principal is postponed and interest on the debt is to be repaid using bond proceeds rather than the General Fund revenues. The funds authorized for the Institute are continuously appropriated without regard to fiscal year.

While the Act does not specifically determine ownership rights for the research findings, tools and therapies to be developed with Institute-awarded grants, it does contain

language requiring that the ICOC balance the opportunity of the state to benefit from the patents, royalties, and licenses resulting from the taxpayer funded grants, with the need not to delay essential research.

The official text of the Act specifies that its purpose and intent is, among other things to "[p]rotect and benefit the California budget . . . by funding scientific and medical research that will significantly reduce state health care costs in the future; and by providing an opportunity for the state to benefit from royalties, patents, and licensing fees that result from the research."[1] The Act also specifies fiscal benefits to the state through creation of "projects, jobs and therapies that will generate millions of dollars in new tax revenue in our state."

The Legislative Analyst, in its official ballot information, stated that the state would "receive payments from patents, royalties, and licenses resulting from the research funded by the institute" through ICOC-established standards "requiring that all grants and loans be subject to agreements allowing the state to financially benefit from patents, royalties, and licenses resulting from the research activities funded under the measure."[2] The LAO found that the amount of revenue from this source is unknown, but could be significant and "would depend on the nature of the research funded by the institute and the exact terms of any agreements for sharing of revenues resulting from that research." In addition to these direct economic benefits, the Legislative Analyst also noted the potential for indirect state and local revenue gains and cost savings, including jobs gains, increased tax revenue, and reduced government-funded health care expenditures.

An economic impact analysis commissioned by the proponents of Proposition 71 suggested that the initiative would provide total state revenues and health care cost savings of between $6.4 billion and $12.6 billion, including between $537 million and $1.1 billion in royalty payments, reduced health costs to the state of $3.4-$6.9 billion, and direct and indirect tax revenues generated by increased biotechnology activity in the state and the creation of new jobs in California. The combination of royalties and savings from reduced costs to treat chronic diseases, the study concluded, would more than offset the $6 billion state taxpayers will be obligated to spend to repay the Proposition 71 bonds.[3]

Ballot arguments in favor of Proposition 71 claimed that the initiative would produce substantial direct and indirect economic benefit to the state, reduce health care costs by billions of dollars, and generate thousands of new jobs and millions in new state revenues by making California a leader in stem cell research and giving the state an opportunity to share in royalties from the research.

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[1] Proposition 71, California Stem Cell Research and Cures Initiative, Sec. 3.
[2] Proposition 71 Analysis by the Legislative Analyst.
[3] Analysis Group, "Economic Impact Analysis: Proposition 71, California Stem Cell Research and Cures Initiative", September 13, 2004.

Limitations of Bond Financing

In approving Proposition 71, California voters agreed to the issuance of $3 billion in general obligation bonds for stem cell research and research facilities in California. General obligation bonds, used to finance a variety of public projects, are debt instruments issued by the state.

Proposition 71 authorizes the Institute to use both tax-exempt and taxable bonds to fund its operations and its grants for medical and scientific research. As stated above, the Proposition also requires the ICOC to establish standards that require that all grants and loans awards be subject to intellectual property agreements 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.

As discussed below, it is possible that royalty or license agreements that generate revenue for the state could affect the tax status of the bonds. Under the Internal Revenue Code, a bond is considered a taxable private activity bond if it satisfies two tests – the private business use test and the private security or payment test. If more than 10 percent of a bond's proceeds are used for private business purposes, the private business use test is generally satisfied.[4] The private security or payment test is satisfied if payment of the principal or interest of more than 10 percent of the bond is secured or paid, whether directly or indirectly, with private property or funds.[5]

According to a recent Legislative Counsel opinion, the private use test is generally satisfied if more than 10 percent of the bond's proceeds are used to fund nongovernmental entities (for 501 (c)(3) entities, the threshold is somewhat lower). The private security or payment test is generally satisfied if payment of the principal or interest of more than 10 percent of the bond is secured or paid, whether directly or indirectly, with private property or funds (again, for 501 (c)(3) entities the threshold is somewhat lower). A royalty or license agreement that provides an income stream to the state from private business activity that amounts to more than 10 percent of the principal and interest of the bond would satisfy this second test. Thus, it is conceivable that the tax-exempt status of bonds issued for stem cell research could be jeopardized if the sate contemplates or receives royalties or licensing fees pursuant to intellectual property agreements associated with the grants that total more than 10 percent of the bond costs.

The Legislative Counsel opinion indicates that research projects containing intellectual property agreements that call for the state to receive direct royalty payments are more likely to require use of taxable bonds, if the above thresholds are met, than those

[4] Internal Revenue Code Sec. 141(b)(1)
[5] Internal Revenue Code Sec. 141(b)(2)

containing agreements requiring that clinical treatments, products, and services resulting from the research be made available at reduced cost to state health care programs.

However, even assuming the private activity tests are met, there may be ways to structure intellectual property agreements and bond sales to avoid having to use taxable bonds. For example, bonds for stem cell research may be packaged with bonds for other public purposes and have relatively short maturity dates that allow basic research to be funded and paid off before any intellectual property is developed. Alternatively, intellectual property agreements may be structured in a way that requires any revenue generated to be paid not to the state, but to a nonprofit entity. It is likely that further guidance will be sought by the Treasurer's Office and CIRM from the Internal Revenue Service on permissible options for structuring grants and IP provisions that permit use of tax-exempt status of bonds for Proposition 71 grants to the greatest extent.

According to informal estimates from the LAO, if the state were required to use taxable bonds in lieu of tax-exempt bonds for funding stem cell research, it could raise the debt servicing costs to the state by $700 million or more over the life of the program.

The Bayh-Dole Act

Historically, the federal government generally maintained its ownership rights for inventions made with public funds, including research grants to universities. The government usually allowed its inventions to be used freely. During the 1970s, however, many believed that the United States was losing its competitive edge to Germany and Japan, in part due to lack of commercially viably innovation, which, it was argued, was due to ineffective transfer of research from universities to the private sector. Though many federal agencies had long contracted with universities and private businesses to conduct research and development, patent policies were inconsistent and considered ineffective for businesses. As result, it was argued, substantial innovation never made it out of university laboratories to the marketplace. The Bayh-Dole Act, along with the development of the biotechnology industry itself, changed that.

In 1980, the Bayh-Dole Act (BDA)[6] created a uniform patent policy for federally funded research. The promulgation of this law expanded the government's role in promoting technological innovation by providing inventors with a monetary incentive to move their ideas from the laboratories into the stream of commerce. The BDA generally allows non-profit organizations, including universities, and small businesses, to acquire ownership of inventions they make under federally funded research, except in exceptional circumstances. In return, these institutions are expected to file for patent protection and to ensure commercialization upon licensing. Under BDA, all inventions conceived or first reduced to practice in the performance of a federally funded project, whether funded in full or in part by federal funds, must adherence to the following requirements:

[6] P.L. 96-517, Patent and Trademark Act Amendments of 1980 as amended by P.L. 98-620 (1984), codified in 35 U.S.C. Sec 200 *et seq.*

- Each new invention must be disclosed to the federal funding agency within two months of disclosure to the grantee's patent personnel;
- The federal grantee must elect to retain title in writing within two years or less, as specified;
- The grantee must file a patent application within one year of title election or less, as specified;
- The grantee must grant the federal government a non-exclusive, irrevocable, paid-up license to practice the invention throughout the world;
- If the grantee elects to exclusively license to a company for sales in the United States, the company must have substantial manufacturing capabilities to produce in the United States, except as specified;
- In awarding licenses, the grantee must give preference to small businesses that have the resources and capability for bringing the invention to practical application;
- The grantee must share with the inventor any income collected on the invention and use any additional income, after expenses, to support further scientific research or education;
- The grantee can be required to periodically report on utilization of the invention by the grantee and its licensees;
- The federal government retains the right to vest title to the invention to the contracting federal agency or to grant a license to a third party, called the "march-in" rights.

The "march-in" rights retained by the government allow the funding federal agency to vest title to an invention in itself or to grant a license to a third party, whether exclusively or nonexclusively, under several circumstances. These circumstances include if the invention is not brought to practical use within a reasonable time, if intervention is necessary to alleviate health or safety needs, or if public use of the invention is jeopardized.

Since the inception of the BDA, only a handful of petitions have been filed asking the federal government to exercise its march-in rights, and all have all been denied. These include two 2004 petitions filed by a consumer advocacy organization asking the federal government to compel reasonable drug prices for two drugs developed with federal funding.[7] The first petition involved the HIV drug Norvir, whose price, petitioners alleged, was increased by its developer Abbott Laboratories to 400 percent more than its original price in order to maintain profits when medical advances reduced the drug's required dosage. The petition sought a compulsory licensing to a third party in order to make the drug more affordable and, within the provisions of BDA, to make the drug "available to the public under reasonable terms." The second petition involved glaucoma

[7] Chemical and Engineering News, Vol. 82, No. 38, pp. 34-35 (Sept. 2004). Available at http://pubs.acs.org/isubscribe/journals/cen/82/i38/html/8238gov1.html.

drug Xalatan, which was developed by Pfizer based on federally funded research done at Columbia University. Petitioners alleged that Xalatan was sold at two to five times more in the United States than in other markets, in violation of the spirit of the Bayh-Dole "reasonable terms" provision, the petition claimed.[8] These petitions were both denied by the National Institute of Health.

In addition to its march-in rights, the federal government may retain title to a federally funded invention if the awarding agency determines that to do so would better promote the policy and objectives of BDA.[9] This provision, known as the "exceptional circumstances" provision because it may only be used in those instances, allows a grantee to challenge the determination of exceptional circumstances and also requires a series of procedural steps that, according to commentators, have lead to its extremely rare invoking.[10]

In 1989 in response to rising drug prices, the National Institute of Health instituted a policy to require a reasonable relationship between (1) the pricing of licensed inventions developed with National Institute of Health funding, (2) the public investment in the invention, and (3) the public's health and safety needs. This policy, known as the "reasonable pricing clause," was required in exclusive licensing agreements and Collaborative Research and Development Agreements. The reasonable pricing policy was revoked in 1995 as the result of intense opposition from industry.

It is important to note that the BDA does not apply to Proposition 71 grantees unless their inventions are also funded in part by federal grants. Legal analysis has not been completed to determine to what extent the state is bound to adhere to the BDA or is preempted by the BDA in the application of intellectual property policy to jointly funded projects. In addition, given that Proposition 71 funds are expected to be used for research that does not qualify for federal funding or that utilizes federally approved stem cell lines, the issue of how the BDA applies to Proposition 71 may not apply in many cases.

Impact of the Bayh-Dole Act

The Bayh-Dole Act has resulted in significant changes in patenting and the commercialization process of federally funded research. Proponents of BDA argue that it has been responsible for significant increases in patenting, commercialization of research tools into market products and income for universities. The Association of University Technology Managers reports that, in 2003, 3,933 U.S. patents were issued and 472 new commercial products were introduced to the marketplace under license agreements with commercial partners, a huge increase over pre-BDA statistics. For that same year, universities reported license income of $1.3 billion and royalties on product sales of $1.1

[8] *Id.*
[9] 35 U.S.C. Sec 202(a); 37 CFR 401.3, 401.4.
[10] Rai, Arti, and Rebecca Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine,* American Scientist, Vol. 91, p. 54 (Jan.-Feb. 2003).

billion.[11] In addition to the explosive growth of patents, proponents of BDA argue that it has created a consistent set of rules familiar to the public-private partners that have dramatically improved university-private industry relationships.

However, critics have reported significant unintended consequences of BDA. A key concern among critics is that the BDA has hindered dissemination of and access to basic research findings. They argue that the BDA has made research more difficult and more costly by keeping basic research out of the public domain.[12] Upstream patenting can limit downstream innovation through, among other things, "patent thickets." Patent thickets can arise when too many owners hold intellectual property rights in previous discoveries that constitute obstacles to future research and downstream inventions.[13]

Another concern is that the focus of research in United States universities has shifted away from fundamental research in order to focus on research targeted to commercial applications. The BDA, critics argue, may have created incentives that undermine the representation of the public interest in the calculus of determining which technologies should be patented and how they should be licensed.[14] They contend that as a result, investment in health-related research and development gravitates toward illness or symptoms that offer the greatest potential returns on investment, regardless of actual needs. Others argue that the commingling of the academic and commercial sectors in part facilitated by the BDA has created a bias in scientific findings and undermined public trust in medical research. BDA "has resulted in egregious conflicts of interest, especially in the biomedical sciences, and has contributed to the near-extinction of the norm of disinterestedness."[15]

Finally, critics of BDA have questioned the wisdom of having United States taxpayers pay for products twice, first through federally funded grants to their inventors and then for the products themselves, particularly when they argue that the BDA has had no impact on affordability or accessibility of inventions paid for by taxpayer's dollars.[16]

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[11] AUTM, Licensing Survey: FY 2003. Available at http://www.autm.net/surveys/dsp.surveyDetail.cfm?pid=16.

[12] Heller, Michael and Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research,* Science Vol. 280, Issue 5364, pp. 698-701 (May 1998); Kesselheim, Aaron and Jerry Avorn, *University-Based Science and Biotechnology Products: Defining the Boundaries of Intellectual Property*, Journal of the American Medical Association, Vol. 293, No. 7, pp. 850-54 (Feb. 2005).

[13] Heller and Eisenberg (1998).

[14] Rai and Eisenberg (2003).

[15] Tansey, Bernadette, *The building of biotech 25 years later, 1980 Bayh-Dole act honored as foundation of an industry*, San Francisco Chronicle (June 21, 2005) (quoting Tufts University Professor Sheldon Krimsky).

[16] Arno, Peter and Michael Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research,* Tulane Law Review, Vol. 75, pp. 631-93 (2001).

Legislation Related to Proposition 71 Intellectual Property Policy

In order to provide guidance to the Legislature and to the ICOC in developing intellectual property policies that appropriately balance the return to the state with the need to develop and transfer technology to the market place as expeditiously as possible, the Legislature passed ACR 24 (Mullin) (Resolution Chapter 111 of 2004) directing the California Council on Science and Technology (CCST) to develop criteria to "determine how the state can achieve maximum public benefit under Proposition 71."[17] The resolution specifically directed the CCST to study how the commercialization of technology developed with the investment of taxpayer dollars in the form of contracts, grants, and agreements could generate some public benefit, including, but not limited to, state revenues, favorable pricing, revenue sharing, and reinvestment into research.

As amended August 16 in the Senate Health Committee, the resolution 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.

The amendments further request that CCST 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.

In August, 2005, CCST released a set of "interim" recommendations that the state adopt policies that are consistent with the BDA. The report authors' argue that this is desirable to avoid confusion and potential conflict, and to leverage federal funds to the extent they may be available. The report also recommends that research results should be timely and widely published and that California Institute for Regenerative Medicine provide guidance on when data should be placed in the public domain or made available for use through open source or other broad licensing arrangements. The report suggests, among other things, the following principles for Institute to consider when developing its intellectual property policy:

- Permitting grantees to own intellectual property rights, similar to BDA;
- Granting research funds without committing a revenue stream to the state;
- Generally, making research tools developed under Proposition 71 grants available to other researchers;

[17] ACR 24 (Mullin), Resolution Chapter 113, 2005.

- Retaining march-in rights, similar to BDA;
- Leaving license particulars to grantees who are in the best position to judge how best to ensure that discoveries are made widely available through commercialization or otherwise;
- Reserving a non-exclusive, royalty-free license for Institute, including the right for other Institute grantees to use the inventions in their Proposition 71-funded research; and
- Establishing an Institute database to track all intellectual property generated through Proposition 71 funding.

In developing these recommendations, the CCST does not appear to have given significant consideration to any of the unintended consequences of the BDA discussed in the previous section.

With respect to the August 16 amendments, the report contains an addendum in which CCST concludes that several organizations are pursuing innovative strategies to address issues of accessibility and affordability of therapies, but that it is too early to evaluate their success.

In response to concerns that the intellectual property provisions of Proposition 71 do not go far enough to ensure that the state gets a return on its investment in stem cell research and that the provisions may also conflict with the goal of using tax-exempt bonds to finance the research, Senators Ortiz and Runner included language in SCA 13 in the current session requiring the ICOC to seek to ensure through its intellectual property agreements that treatments, therapies, and services resulting from the research are accessible and affordable to low-income residents, including those eligible for state and county-funded programs. The bill is currently on the Senate floor.

Policy Options Facing State

In reviewing the language of Proposition 71, literature on the experience with the implementation of the Bayh – Dole Act (BDA), and recent trends in fields of technology transfer and intellectual property policy, it is clear that several major policy challenges will confront the state as it considers implementation of the intellectual property provisions of Proposition 71. The first is determining how to structure an IP policy that ensures access to basic research findings and tools. As many have noted, the ultimate development of therapies based on stem cell research is likely to require incremental improvements and discoveries in basic stem cell science, in addition to a need for close collaboration and sharing of information between researchers. A policy that favors open dissemination of basic research findings is likely to produce clinical applications the most quickly and efficiently.

A second key issue is how and in what form the state should seek to benefit from the patents and licenses associated with inventions developed with state funds. A reasonable

reading of Proposition 71's IP provisions would indicate that the state is required under the proposition to seek an economic return associated with the grants it makes, where it is feasible to do so without impeding dissemination of research findings or violating the balancing test outlined in the initiative. Related issues are whether the state has an opportunity through its policy to address issues involving the accessibility and affordability of therapies that are developed with the assistance of state funds.

A final issue is how to seek an economic return in a manner that maximizes, to the extent possible, the state's ability to use tax-exempt bonds to fund the research.

The remainder of this section discusses options for ensuring dissemination of basic research findings and options for obtaining direct economic returns to the state from the research.

Options for Ensuring Dissemination of Basic Research Findings

Require sharing of basic research findings and tools. The state could require grantees to make basic research findings and tools that they develop openly available to other researchers via simple material transfer agreements (MTAs), while still allowing grantees to patent and license the inventions they develop. The CCST report appears to favor this approach by recommending that applicants be required to provide a plan describing how they will manage IP to ensure that research tools will be made broadly available for further advancement of science.

As some experts have noted, however, even though they are simple 1 to 2 page documents, MTAs can impose impediments to dissemination of research findings if they are not developed and applied consistently from institution to institution, and through the imposition of "reach through" provisions by the provider of the MTA. The latter provisions seek to give the owner of the invention an ownership interest in any new inventions developed by the recipient, require royalty payments to the provider of the MTA, or give the provider joint or exclusive rights to any new intellectual property developed by the recipient. This option also entails costs to owners of intellectual property to protect their interests if a transferee subsequently seeks to license or use the invention for commercial purposes.

Require open source or nonexclusive licensing. The state could requires grantees to license any inventions they develop to any interested party (open source licensing) or at least preclude them from entering into exclusive licensing arrangements in which one party obtains an exclusive license to use the technology (nonexclusive licensing). The advantage of these approaches is that they would ensure greater dissemination of research findings; the disadvantage of both is that there may be situations in which an exclusive license is needed to give a commercial entity the incentive to develop a product or therapy using the invention.

Alternatively, and similar to the recommendations some experts have made for the BDA, the state could allow grantees to enter into exclusive licensing arrangements at their discretion, but retain the authority to declare certain areas of research off-limits for exclusive licensing if the CIRM judges that scientific advancement would be better served by maintaining open access to the research findings and tools. The impetus for this suggestion are the findings of a number of researchers that the presumption in the Bayh – Dole Act that grantees must seek to patent inventions except in "exceptional circumstances" has led to too much patenting and exclusive licensing of basic research findings, and that the procedural requirements on federal agencies for invoking the "special circumstances" provisions are too burdensome.

Nonexclusive licensing or open source licensing would also entail costs of enforcing licensing terms to ensure that licensees do not license or commercialize the underlying inventions.

Adopt viable march-in provisons. Similar to the language of the BDA, the state could retain the right to step in or require a grantee to grant a license to a responsible applicant on reasonable terms if effective steps are not being taken to achieve practical application of a CIRM-funded invention (referred to as "march – in" rights). The CIRM could also retain a non-exclusive, royalty-free license to all CIRM-funded inventions, including the right to allow other CIRM grantees to use such inventions in their CIRM-funded research. These were recommended by the CCST report.

However, a number of experts have questioned the viability of the march-in authority under the BDA. As noted above, the BDA currently requires exercise of march-in rights by sponsoring agencies to be held in abeyance pending exhaustion of all court appeals by the grantee, which many experts believe hinders the exercise of the authority and also hampers the government's ability to ensure that practical application of inventions is achieved within a reasonable time and to meet health and safety needs. These experts have advocated streamlining the process for invoking march-in provisions, a policy which the state could emulate if it decided to adopt this option for ensuring dissemination of research findings.

Patent pooling. Several patenting and licensing experts have recommended patent pools as a mechanism for more effectively managing intellectual property for areas of research such as biomedical research, in which incremental improvements and collaboration between research institutions is needed to advance the technology. Under this approach, the state would require its grant recipients to agree to donate the rights to any inventions or research tools to a patent pool which would be administered by the state or a nonprofit organization. Any researcher could use the inventions or tools in the pool for further research; as a condition of doing so, they would have to agree to contribute the rights to any inventions or improvements that they develop back to the pool. The pool would collectively negotiate licensing arrangements with commercial entities on behalf of the participants in the pool.

A number of such pools currently operate in other fields of scientific research, including Center for Application of Molecular Biology to International Agriculture (CAMBIA).

Advocates of patent pools point out that pooling would have a number of advantages over patenting and licensing of inventions by individual research institutions, including that it would allow researchers' easier access to patented ideas and technologies and lower transaction costs associated with accessing them. In addition, the pool would have greater leverage in negotiating licenses with commercial entities than individual pool participants would have on their own. Theoretically, this could enable the state, as a participant in the pool, to obtain greater economic benefits in return for its contributions, which could take the form of greater royalties, pricing concessions for targeted programs and populations, and more favorable limits on the duration of exclusive licenses to use technology owned by the pool. Some experts have further recommended that patent pools have the ability to auction off the rights to their inventions as a means of promoting competition between biotechnology companies and of generating greater economic returns to pool participants. Some experts have also suggested that the state could perhaps use the leverage of such a pool to negotiate more favorable terms for access to critical technologies and tools owned by other entities, such as Geron and the Wisconsin Alumni Research Fund (WARF).

A key difficulty associated with administration of patent pools is the difficulty of determining how to apportion economic benefits derived from technology or inventions owned by the pool among its participants.

The CCST did not make findings or recommendations on this option, but instead recommended that CIRM maintain a database to track all IP generated through CIRM funding as a means of facilitating researchers' access to IP relevant to their research.

Options for Achieving Economic Benefits from the State's Investment in Research

Assuming Proposition 71 requires or intends for the state to obtain direct economic benefits from the research where it is feasible to do so without impeding dissemination of research, the state has a number of options for doing so.

***Direct a share of royalties to the state*.** The state could require, as a condition of its grants, a share of the net royalties resulting from commercialization of any findings or inventions developed with grant funds. A major drawback of this approach is that it could likely require greater use of taxable bonds for financing the research. As the CCST report notes, the additional costs to the state of using taxable bonds may outweigh the value of economic benefits the state is able to negotiate from its funded research. In part because of this, the CCST report rejects this approach in favor of the Bayh Dole Act model, in which grant recipients are allowed to keep royalties and licensing fees on inventions they develop as long as they use those revenues to fund their education and

research programs. However, it is not clear that CCST's recommended approach complies with the language and intent of Proposition 71.

Reasonable pricing requirement. The state could adopt a policy similar to that adopted by the NIH in 1989 requiring that there be 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. As mentioned above, NIH applied this policy to licenses to inventions developed under its Cooperative Research and Development Agreement (CRADA) program but discarded it in 1995 on the grounds that it was impeding commercialization of research findings.

The CCST report also rejected adoption of a reasonable pricing policy and instead recommended that a more detailed examination begin of the range of technical expertise required to identify and deliberate over the issues involved in reasonable pricing or favorable pricing of treatments and therapies that emerge from CIRM-funded research.

Socially responsible licensing. The state could require its grantees to require any entities to which they license any Proposition 71 – funded inventions to demonstrate how their use of the technology will benefit underserved populations or regions of the state. A number of university-based technology transfer managers throughout the U.S. have been advocating that universities and other research funding entities look for ways to direct the benefits of their inventions and technologies to underserved countries and populations, for example by foregoing royalties on sales of products and treatments to underserved populations and seeking commitments from licenses to produce products and treatments or otherwise make investments in underserved communities.

Tiered pricing arrangements. The state could attach conditions to its grants requiring that any entity that acquires the rights to any inventions or tools developed with the grant funds must agree to make any resulting therapies or treatments accessible and affordable to low-income populations or programs that serve them. This approach is used by a number of grant making organizations, including the Gates Foundation, the International AIDS Vaccine Initiative (IAVI), and the Foundation for the National Institutes of Health.

In 2003, the Gates Foundation established a Grand Challenges in Global Health initiative, designed to foster breakthroughs against diseases that plague residents of the world's poorest countries. The $450 million in funding for the initiative includes $200 million which is managed by the Foundation for the National Institutes for Health. A package of 43 initial grants totaling $437 million was announced in June, 2005. Under the initiative, Gates requires its grantees to outline a global access strategy indicating how they will use any inventions they develop with the funding to facilitate the availability and affordability of therapies to people in the developing world.

IAVI generally retains the rights to inventions developed with its funding and collaborates with commercial partners for development of vaccines and treatments using

the inventions. In its partnerships, IAVI seeks commitments that resulting vaccines and treatments will be made available in developing countries at reasonable prices and in sufficient quantities, and has successfully negotiated a number of agreements containing those conditions. In effect, the commercial entity agrees to discount the price of the product in certain markets while retaining the right to price it freely in others.

A number of biomedical patenting and licensing experts maintain that tiered pricing arrangements are feasible and acceptable to biotechnology and pharmaceutical companies if the scope of pricing concession is well-defined. An example might be an agreement on the part of a biotechnology or pharmaceutical company to sell any resulting products or treatments to public health care programs at the best price they sell it to any purchaser.

The CCST report notes that IAVI and the Grand Challenges program have pushed researchers, business managers, and IP professionals to think in new ways about how to manage IP on biomedical inventions in ways that benefit underserved populations, but concludes that both efforts are too new to provide reliable models for Proposition 71.