

NEW YORK STATE SCIENCE AND TECHNOLOGY LAW CENTER

NEW YORK STATE INTELLECTUAL PROPERTY POLICY CHOICES
WORKING DRAFT

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This report considers the various provisions that could be included in a New York State intellectual property policy. The first section of the report discusses the institutional context within which a New York State IP policy would be formulated, focusing on the divergent perspectives of industry, universities and NYS government regarding an IP policy. The second section of the report briefly reviews the law relating to federal preemption of state law and how federal preemption might affect a NYS IP policy. The third section of the report reviews the substantive IP policy provisions proposed in three NYS Assembly Bills, and compares these NYS IP policy proposals to the IP policy provisions contained in (i) the Bayh-Dole Act,¹ (ii) the IP policy recommendations of the California Council on Science and Technology Intellectual Property Study Group (the CCST recommendations) for general state-funded IP,² and (iii) the regulations adopted by the California Independent Citizens Oversight Committee (the CICOC regulations) for stem cell research funded by the California Institute for Regenerative Medicine (CIRM).³ The final section of the report considers IP policy provisions that have not been proposed in the three NYS Assembly Bills, but are contained either in the Bayh-Dole Act, the CCST recommendations or the CICOC regulations.

The purpose of this report is not, in any way, to develop or recommend specific provisions of a NYS IP policy. Rather, the purpose is simply to facilitate discussion of a possible NYS IP policy by framing some of the choices that policy makers will confront.

1. Institutional Context for a New York State IP Policy

A New York State IP policy would directly affect the three participants in the NYS research enterprise that are responsible for the creation of intellectual property: industry which

¹ 35 U.S.C §202-212.

² Policy Framework for Intellectual Property Derived from State-Funded Research: Final Report to the California Legislature and the Governor of the State of California, January 2006, *available at* <http://www.ccst.us/publications/2006/2006IP.php>.

³ The California Independent Citizens Oversight Committee Intellectual Property Regulations, effective July 14, 2007, *available at* http://www.cirm.ca.gov/reg/pdf/IP_Regs_100300.pdf.

sponsors university research; universities which perform research; and NYS government which funds university research. Industry, universities and NYS government each have different imperatives and, hence, different perspectives regarding a NYS IP policy.

Industry

Industry is subject to ever increasing domestic and foreign competition which, in turn, requires ever higher rates of return on research investments. These pressures have caused industry to become much more resistant to university claims regarding intellectual property rights, to university procedures for approval of research projects and to university valuations of licensed technology. Industry believes that companies should have greater rights in the intellectual property generated from the research they sponsor; that university bureaucratic procedures diminish the value of research by delaying commercialization of research results; and that universities overestimate the value of licensed technology because they are naïve regarding the commercial risks and follow-on investment required to bring a new product to market.

Against this backdrop, industry's perspective on a possible NYS IP policy is generally negative. From industry's standpoint, a NYS IP policy could exacerbate the existing problems in working with universities. A NYS IP policy could further delay approval of sponsored research projects, and further complicate the allocation of intellectual property rights needed to commercialize research results. In addition, a NYS IP policy could cause universities to overvalue licensed technology to an even greater extent in order to make up for royalty revenue lost in payments to NYS, and to offset the additional transaction costs that might be associated with accounting for state-funded research.

Universities

Universities confront a different set of challenges. University technology transfer offices are under growing internal pressure to be self-funding, if not profit centers. University technology transfer offices are also often under-staffed. Finally, university industry-sponsored research funding is increasingly threatened by the prospect of U.S. companies conducting sponsored research at foreign universities, especially in China and India. Many university technology transfer offices believe they are being given inadequate resources while, at the same time, being held to unrealistic financial expectations; and many university sponsored program offices believe they are being unfairly treated in their dealings with industry.

The university perspective on a potential NYS IP policy, therefore, is also generally negative. University technology transfer offices are concerned that a NYS IP policy could reduce their royalty revenues, making it more difficult to satisfy the financial goals imposed on them. University technology transfer offices are also concerned that a NYS IP policy could entail substantial administrative costs further straining their limited personnel resources. Finally, university sponsored program offices are concerned that a NYS IP policy might further disadvantage them in competition for industry sponsored research funding. The concern here is that other states, and countries, that do not have IP policies might be more attractive destinations for sponsored research investments.

New York State Government

Finally, New York State government has its imperative; accounting to the citizens of NYS for a return on its investment in research. The return on government investment in research can be direct and/or indirect. Direct return on investment occurs when government receives a share of the royalty revenue generated from its research funding. Indirect returns on government investment in research, which economists call social returns, comes in the form of new jobs, economic growth, more highly educated workers, and increased tax revenues. Although it is difficult to measure indirect return on investment in research, a number of studies over the years have reached similar conclusions - social returns on investment in research are somewhere between 30% and 100% and this is considerably higher than the social returns on investment in physical capital and human capital (education). Despite the high level of indirect return on investment in research, state governments are nonetheless under pressure to show more visible, direct returns on research investments. (See discussion of revenue sharing provisions in the CCST recommendations and CICOC regulations below.)

In the debate over a New York State IP policy, it is important to recognize the mutuality of interest between industry, universities and NYS government. If a consensus can be reached between the stakeholders in the NYS research enterprise, research in New York State will be more efficient and effective, and New York State will gain a competitive advantage over other states and countries in attracting research investment. If a consensus cannot be reached, NYS universities could lose financial support for research, NYS industry could lose access to state-of-the-art research expertise and facilities in NYS, and NYS government could lose the citizen

support necessary to continue state-funded research. This could result in lesser scientific progress, reduced industry competitiveness, fewer jobs and slower economic growth.

2. Federal Preemption of State Law

As an initial matter, a New York State IP policy must be consistent with federal law. The U.S. Constitution provides that federal law preempts state law when there is a conflict between the two. The Patent Act does not contain a provision expressly stating that it preempts state law. However, courts have found that federal law impliedly preempts state law in three situations: (i) where Congress has indicated that it intends to occupy the entire field in which the state is attempting legislate; (ii) where the state law directly conflicts with the federal law; and (iii) where enforcement of the state law would frustrate the purpose of the federal law.⁴

In the case of a NYS IP policy, the federal law of concern is the Bayh-Dole Act which is contained within the Patent Act. Congress has not indicated that it intends to occupy the entire field of intellectual property, and numerous cases have found that state intellectual property laws are valid and not impliedly preempted. Therefore, the adoption of a NYS IP policy would not, in itself, be preempted by the Patent Act. Nonetheless, a NYS IP policy must not conflict with the provisions of Bayh-Dole Act nor frustrate the purposes for which the Bayh-Dole Act was passed. For example, a NYS IP policy could not prohibit universities from sharing royalty revenues with inventors because this would conflict with the provision of the Bayh-Dole Act which requires universities to share royalty revenues with inventors. Similarly, a NYS IP policy could not impose limitations on universities in licensing patents to private companies because this would frustrate the purpose of the Bayh-Dole Act which is to promote commercial development of patents resulting from federally-funded research.

On the other hand, although there are no court decisions on point, it would seem that a NYS IP policy could replicate the provisions of the Bayh-Dole Act. For example, a NYS IP policy could provide NYS with the right to recover ownership of patented technologies resulting from state-funded research in the event insufficient efforts were made to commercialize the patented technologies; this NYS right would replicate the federal government's "march-in rights" provided for in the Bayh-Dole Act. Again, although there are no court decisions on point, it would seem that a NYS IP policy could provide rights to NYS beyond the rights provided to the federal government in the Bayh-Dole Act. For example, a requirement that NYS

⁴ For a discussion of patent preemption see Joan E. Schaffner, *Patent Preemption Unlocked*, 1995 WIS. L. REV. 1081.

share in the royalty revenues received from NYS state-funded research would not conflict with the provisions of the Bayh-Dole Act nor, arguably, frustrate the purposes of the Bayh-Dole Act.

Finally, a NYS IP policy can only apply to patents resulting from NYS-funded research. In research projects funded solely with NYS funds, it will be easy to associate patents with the source of the research funding. However, in instances where a research project is funded by multiple parties and results in multiple patents, the association of patents with different funding sources will require careful segregation of the research funds and careful tracking of the research results. For example, if a research project is funded with NYS funds and federal funds, the NYS funds, and the patents resulting from the use of these funds, would have to be accounted for separately. If the segregated NYS funds can be associated with individual patents, then the NYS IP policy can apply to these patents. However, patents that cannot be associated with a single source of funding pose a greater problem. A NYS IP policy could attempt to apportion the application of the policy according to the percentage of NYS funding used in the research resulting in the patent; this would be a difficult accounting task. Or a NYS IP policy could attempt to apply the policy to the entire patent regardless of the percentage of NYS funding used in the research resulting in the patent; this could possibly create federal preemption problems based either on a conflict with, or the frustration of the goals of, the Bayh-Dole Act.

3. Proposed Substantive Provisions of NYS IP Policy

This section will review the IP policy provisions proposed in three NYS Assembly bills, and compare these NYS IP policy provisions with the IP policy provisions contained in the Bayh-Dole Act, the CCST recommendations and the CICOC regulations.

IP Policy Provisions Proposed in NYS Assembly Bills

Three bills have been introduced in the NYS Assembly relating to state IP policy: NYS Assembly Bill 3017 introduced on January 22, 2007;⁵ NYS Assembly Bill 8676 introduced on May 23, 2007;⁶ and NYS Assembly Bill 8787 introduced on May 30, 2007.⁷ These bills will be discussed below.

⁵ Available at <http://assembly.state.ny.us/leg/?bn=A03017&sh=t>.

⁶ Available at <http://assembly.state.ny.us/leg/?bn=A08676&sh=t>.

⁷ Available at <http://assembly.state.ny.us/leg/?bn=A08787&sh=t>.

1. *NYS Assembly Bill 3017* proposes the creation of an Intellectual Property Asset Management Advisory Council within the New York State Foundation for Science, Technology and Innovation that would make recommendations to the Foundation Board on the following questions:

- Whether all, none, or some of the rights arising out of state-owned IP should be dedicated to the public domain;
- How the state should maximize protection of IP that it owns;
- How state employees and officials should be made aware of requirements regarding state-owned IP;
- Whether a uniform system of invention disclosure should be developed for state-funded research;
- What actions are being undertaken by state agencies to manage state-owned IP; and
- How ownership rights should be determined when IP is created by state employees in the course of their state employment.

NYS Assembly Bill 3017 also proposes that the Foundation Board then submit a report to the Governor, the Speaker of the Assembly and the Temporary President of the Senate that provides guidance on the following questions:

- How to promote utilization of IP arising from state-supported contracts, grants and agreements;
- How to encourage maximum participation of small-business firms in licensing state-owned IP;
- How to promote collaboration between commercial firms and state entities in commercializing state-owned IP; and
- How to ensure that the state has minimal rights in state-supported IP to meet the needs of the state and protect against nonuse, or unreasonable use, of state IP.

The proposed creation of a NYS Intellectual Property Asset Management Advisory Council to make recommendations on the management of IP developed with state funding is similar to the approach adopted by California. The California Legislature passed a resolution

requesting the CCST (a standing non-profit organization) to “create a special study group to develop recommendations to the Governor and the Legislature on how the state should treat intellectual property created under state contracts, grants and agreements...”

The CCST proposed four general principles to guide the state’s IP policy: (i) the state IP policy should be consistent with the Bayh-Dole Act, especially the provision for ownership of IP by grantees and the requirement that the balance of royalties above expenses be used to support research and education activities; (ii) the state policy should create incentives for commerce in California from state-funded research to the greatest extent possible; (iii) the state policy should encourage wide diffusion of knowledge and provide guidance on the kinds of data to be placed in the public domain; and (iv) the state policy should require diligent commercialization of IP-protected technology into products that benefit the public.

Some of the questions raised in Assembly Bill 3017 are addressed in the Bayh-Dole Act, the CCST recommendations and the CICOC regulations.

Uniform System of Invention Disclosure

Although the Bayh-Dole Act does not provide for a uniform system of invention disclosure, it does require grantee organizations to disclose inventions to the federal funding agency within a reasonable time after the invention has been disclosed by the inventor. The CCST recommendations also do not provide for a uniform system of invention disclosure. However, the CCST does recommend the creation of a single office within each state-funding agency that would track IP generated by state employees, track IP that results from state-funded research, monitor the use of state-funded IP, and collect and manage any revenues the state may receive from state-funded IP. The CICOC regulations do provide specific invention reporting requirements. Grantee organizations are required to have written agreements with researchers requiring prompt disclosure of inventions made with CIRM-funded research, and to disclose these inventions to the CIRM within 60 days of the researchers’ disclosures.

Promoting Utilization of IP Resulting from State-funded Research

The Bayh-Dole Act, the CCST recommendations and the CICOC regulations directly address the utilization of government-funded IP. The Bayh-Dole Act seeks to promote utilization of federally-funded inventions by providing the funding agency with the right to require additional licenses, or to retake title, when the efforts to utilize inventions are insufficient. (See discussion of “march in” rights below.) The CCST recommendations would

require grantee organizations to include a “diligent efforts” clause in license agreements and provide the state with the right to retake title to inventions when effective steps are not being taken to achieve practical application of the invention within a reasonable time. The CICOC regulations require grantee organizations to include commercial development plans, milestones and benchmarks in exclusive licenses. If the plans are not implemented, or the milestones and benchmarks are not achieved, the CICOC regulations give the grantee organization the right to modify, or terminate, the license.

Encouraging Maximum Participation of Small Business Firms

The Bayh-Dole Act expressly requires that a preference be given to small business firms in licensing federally-funded inventions, unless it proves infeasible after reasonable inquiry. The CCST recommendations and the CICOC regulations do not contain any preferences for small business in licensing state-funded inventions.

Promoting Collaboration Between Commercial Firms and State Entities

The Bayh-Dole Act seeks to promote collaboration between commercial firms and grantee organizations that receive federal research funding by allowing grantee organizations to elect to take title to federally-funded inventions. This gives grantee organizations a strong incentive to collaborate with commercial firms through licensing and sponsored research projects. The CCST recommendations specifically list promoting collaboration between commercial entities and non-profit research institutions as one of the objectives for a state IP policy. The CICOC regulations do not directly address collaboration between commercial firms and grantee organizations. However, such collaboration is implicit in provisions governing the licensing of CIRM-funded inventions.

Ensuring State Has Minimal Rights to Meet State Needs and Protect Against Non-use

Government rights to meet government needs and protect against non-use of government-funded IP are addressed in the Bayh Dole Act, the CCST recommendations and the CICOC regulations in their respective provisions for “march in” rights. (See discussion below.)

2. *NYS Assembly Bill 8676* proposes the creation of a public, interactive database of all IP developed by state employees or through state-funded research. In addition, *Bill 8676* would require periodic reporting by colleges and universities on the number of

patents obtained as a result of state-funded research, and the income received from licensing or sale of state-funded IP.

The Bayh-Dole Act provides that federal agencies have the right to require grantees, licensees and assignees to make periodic reports on efforts to utilize patented inventions resulting from federally-funded research. The Bayh-Dole Act, however, does not contain any provision for the creation of a public, interactive database for all federally-funded IP. The CCST considered oversight provisions for California state-generated and state-funded IP. The CCST recommendations, which implicitly require periodic reporting by grantees, include tracking IP generated by state employees and state-funded research, monitoring the way in which state-funded IP is used, collecting and managing royalty revenues which the state might receive, and, possibly, overseeing march-in rights in cases where a licensee does not take effective steps to achieve practical application of an invention within a reasonable period of time. The CCST recommendations do not expressly provide for the creation of a public database for state-funded IP.

The CICOC regulations require that grantee organizations must report annually to the CIRM on the filing of patent applications and the execution of license agreements. In addition, grantee organizations must submit annually an Invention Utilization Report that lists all CIRM-funded inventions, the status of the inventions' development, the date of first commercial sale or use, and the receipt of all licensing fees and royalties received. The CICOC regulations also do not provide for the creation of a public database.

3. *NYS Assembly Bill 8787* proposes a set of principles for the management of intellectual property resulting from research conducted in state facilities, by state employees, or with state funds. *NYS Assembly Bill 8787* would require the intellectual property policies of all state agencies to conform to the following principles:

- The state must retain a non-exclusive, royalty-free license to use the intellectual property for non-commercial purposes;
- The state must be able to take title to inventions when a state agency does not pursue commercialization of patent rights within a reasonable period of time;
- Good faith efforts, such as active technology transfer offices, and outreach to business associations and venture capital and angel networks, must be made to

commercialize the technology in New York State, unless the intellectual property is dedicated to the public domain;

- The state must receive a return on its investment in research when the resulting intellectual property is sold or licensed to private businesses, and a sufficient revenue stream is generated;
- The state's return on its investment in research must be higher when the resulting intellectual property is sold or licensed to non-resident private businesses than when it is sold or licensed to resident private businesses; and
- State agencies must share proceeds from the sale or license of an invention with the inventor.

Some of the policies enumerated in *Assembly Bill 8787* are similar to IP policy provisions contained in the Bayh-Dole Act, proposed in the CCST recommendations and enacted in the CICOC regulations. Other policies enumerated in *Assembly Bill 8787* are not included in the Bayh-Dole Act, the CCST recommendations or the CICOC regulations.

Reservation of Non-Exclusive, Royalty-Free License

The Bayh-Dole Act provides that federal agencies have a non-exclusive, non-transferable, irrevocable, paid-up license to practice federally funded inventions on behalf of the United States anywhere in the world. The Bayh-Dole Act federal license is not limited to non-commercial use as is the license proposed in *NYS Assembly Bill 8787*; the Bayh-Dole Act license can be used for any purposes “for or on behalf of the United States.” The CCST also recommends that the California IP policy reserve a license to use IP by or on behalf of the state for research or non-commercial purposes. This license would include the right to sublicense other researchers to use this IP for state-funded research activities. Likewise, the CICOC regulations require that grantee organizations retain the right to practice CIRM-funded patented inventions for non-commercial purposes. The CICOC regulations also require grantee organizations to make CIRM-funded inventions readily accessible, directly or through licensees, to other grantee organizations for non-commercial purposes.

Retaking Title to Inventions (March-In Rights)

The Bayh-Dole Act provides that federal agencies shall have the right to require grantees of federal research funds that elect to take title to patented inventions to grant additional licenses to third parties, or to the federal funding agency, when the federal funding agency determines: (i)

the grantee or licensee has not taken effective steps to achieve practical application of the invention within a reasonable period of time; (ii) the action is necessary to alleviate health and safety needs not being satisfied by the grantee or licensee; (iii) the action is necessary to meet requirements for public use specified in federal regulations; or (iv) the action is necessary because a licensee has not agreed to manufacture the invention substantially within the United States, or has breached such an agreement.

The CCST has recommended that California retain Bayh-Dole-like “march-in rights” if the owner of the IP is not undertaking appropriate steps to transfer the technology to benefit the public. The proposed CCST “march-in” rights include the ability to require a grantee to grant a license to a responsible applicant on reasonable terms. The CCST cautions that ‘march-in’ rights were strongly resisted by industry during the passage of the Bayh-Dole Act because of the uncertainty they create in licensing federally-funded inventions. However, the CCST notes that industry’s concern over “march-in” rights have been largely mitigated by the fact that no federal government agency has ever exercised its “march-in” rights.

The CICOC regulations also provide for “march-in” rights. These “march in” rights give the CIRM the right to require grantee organizations, or exclusive licensees of CIRM-funded inventions, to grant additional licenses to responsible applicants on reasonable terms when such action is required: (i) because the grantee organization or licensee has not made responsible efforts in a reasonable time to achieve practical application of the CIRM-funded invention; (ii) because the licensee has failed to adhere to the agreed-upon plan for patient access to the CIRM-funded invention (see below); (iii) to meet requirements for public use not being satisfied by the grantee organization or its licensees; or (iv) to alleviate unmet public health and safety needs which constitute a public health emergency. The CICOC regulations provide that the CIRM will give notice to a grantee organization or licensee prior to exercising its “march in” rights, and will not exercise “march in” rights if the grantee organization or licensee takes diligent action to cure the deficiency within one year from the receipt of notice.

Good Faith Efforts to Commercialize Technology in New York State

The Bayh-Dole Act provides that in licensing a federally-funded invention preference should be given to United States industry. This preference is implemented by requiring a licensee of a federally-funded invention to agree to manufacture substantially all products embodying the invention in the United States. However, this requirement may be waived by a

federal agency upon a showing that reasonable efforts have been made to comply with this preference, but these efforts have been unsuccessful; or that manufacturing in the United States is not commercially feasible.

As noted above, one of the four guiding IP principles proposed by the CCST is that California's IP policy should create incentives for commerce in California from state-funded research to the greatest extent possible. However, the CCST rejected a requirement that every state-funded invention be licensed and developed in California because such a requirement would put California at a competitive and economic disadvantage. The compromise provision recommended by the CCST is that grant applications for state research funding ask potential grantees to explain how the research is expected to benefit California and how the IP management strategies will attempt to direct commercialization opportunities to California. Evaluation of this information is left to the discretion of the grant funding agency.

The CICOC regulations address commercialization efforts and benefits to California citizens, but do not contain any provisions requiring commercialization within California. In terms of commercialization efforts, the CICOC regulations require grantee organizations to document licensees' development and commercialization capabilities, their plans to bring an invention to practical application, and the milestones and benchmarks by which these plans can be assessed and monitored. In terms of benefits to California citizens, the CICOC regulations make exclusive licenses conditional upon providing access to drugs and diagnostics to uninsured California residents, and agreeing to price caps on drugs and diagnostics sold to California residents eligible under California's healthcare program. (See below.)

Return to NYS When Sufficient Revenue Stream is Generated

In the debates over the Bayh-Dole Act, Congress considered, but rejected, any financial return to the federal government from federally-funded research. Rather, grantees were allowed to retain all revenue from federally-funded inventions subject only to the requirements that a portion of these revenues be shared with the inventors and that revenues in excess of expenses be reinvested in research and education.

However, both the CCST recommendations and CICOC regulations include provisions regarding revenue sharing with California. The CCST rejects a dollar-for-dollar revenue sharing provision because it would discourage commercial development of new products for the public good, yield a miniscule amount of revenue compared to the state's research budget, risk

alienating commercial partners and entail transaction costs greater than the revenue collected. The CCST does recommend that in exceptional cases where licensing revenue is large there should be a revenue sharing agreement between the grantee organization and the state funding agency with an agreed percentage of the revenues going to the state funding agency to support further research. The CCST gives as an example of “large licensing revenue” aggregate net revenues to the grantee-licensor greater than \$500K.

The revenue sharing provisions contained in the CICOC regulations are more detailed. The CICOC regulations allow the grantee organization to retain a threshold amount of aggregate licensing revenue of \$500K, after payments to inventors. Twenty-five percent of the licensing revenue above this threshold amount must be paid to the State of California for deposit in the state’s general fund. In cases where a patented invention results from both CIRM funding and other funding, the CICOC regulations provide that the return to California shall be proportionate to the amount of CIRM funding for the licensed invention.

Higher Return to NYS When IP Licensed to Non-Resident Business

Neither the Bayh-Dole Act, the CCST recommendations or the CICOC regulations provide for different governmental rights or returns depending upon where the licensed technology is manufactured or upon the domicile of the licensee.

State Agencies Sharing Proceeds from Sale or License with Inventors

Neither the Bayh-Dole Act, the CCST recommendations or the CICOC regulations require *agencies* to share sales or licensing revenue with inventors. However, all three require *grantees* of government-funded research to share sales or licensing revenue with inventors.

4. IP Policy Provisions Not Proposed in NYS

This section will review IP policy provisions contained either in the Bayh-Dole Act, the CCST recommendations and the CICOC IP regulations that have not been proposed for adoption in NYS.

Reinvestment of Licensing Revenues in Research and Education

The Bayh-Dole Act, the CCST recommendations and the CICOC regulations require grantee organizations to reinvest licensing revenues in research and education. The Bayh-Dole Act provides that the balance of any royalties or income earned by the grantee organization from a federally-funded invention, after expenses and inventor payments, must be used for support of

scientific research and education. As noted above, one of the IP policy principles suggested by the CCST is that California IP policy be consistent with the Bayh-Dole Act, and specifically with the requirement that the balance of royalty revenues above expenses be used to support scientific research and education. Finally, the CICOC regulations require grantee organizations to apply their share of revenues earned from CIRM-funded inventions to support scientific research and education.

A provision requiring grantee organizations to reinvestment licensing revenue above expenses in scientific research and education has not been proposed for NYS.

Access to Research Tools

The Bayh-Dole Act does not contain any provision for access to research tools. However, both the CCST recommendations and the CICOC regulations directly address the question of access to research tools. The CCST recommendations provide that the state IP policy should pay particular attention to the treatment and dissemination of research tools, such as cell lines, monoclonal antibodies, reagents, software programs and databases, because access to research tools is critical to scientific and technical progress. The CCST suggests a number of alternatives to achieve broad access to research tools: grantee organizations may choose not to file patents on research tools; if grantee organizations file patents on research tools, they can grant royalty-bearing, non-exclusive licenses to the research tools; or grantee organizations can grant exclusive licenses only for further development of research tools with provisions for broad availability once development is complete.

The CICOC regulations require grantee organizations to share CIRM-funded biomedical materials, such as synthetic compounds, organisms, cell lines, viruses, cell products and cloned DNA, for research purposes in California without cost, or at the actual cost of providing the biomedical materials without charges for overhead, research, discovery or other indirect costs. The CICOC regulations provide exceptions to the biomedical materials sharing requirement when sharing is precluded by law, or refusal to share is approved by the CIRM.

A provision requiring access to research tools has not been proposed for NYS>

Publication Requirement

The Bayh-Dole Act does not contain any provision regarding publication of research results. However, both the CCST recommendations and the CICOC IP regulations address the question of publication. The CCST recommendations suggest that a principle objective of a

California IP policy should be the open dissemination of research results because this is essential for the advancement of science and the development of practical applications. The CICOC regulations are more specific. The CICOC regulations require the principle investigator of a CIRM-funded research project to submit a 500 word abstract of a published article within 60 days of the publication date. The abstract must be written for the general public and highlight the research findings. Copies of the abstract must included with the mandatory annual progress report submitted to the CIRM, and CIRM grantees must acknowledge CIRM support in publications, announcements, presentations and press releases regarding research findings.

Downstream Access and Pricing Requirements

Other than the provision for “march in” rights, the Bayh-Dole Act does not impose any restrictions on the downstream use of federally-funded inventions. However, the CCST recommendations discuss two privately funded research programs that require funding recipients seeking to commercialize research to ensure that therapies and products are accessible and affordable to designated low-income populations. Although the CCST recommendations comment favorably on these privately funded research programs as alternative models for managing IP, the CCST does not recommend the adoption of such a requirement in California. The CICO regulations, on the other hand, specifically impose downstream access and pricing requirements. The CICOC regulations require exclusive licensees of grantee organizations to have a plan in place to provide access to therapies and diagnostics for uninsured California residents. In addition, exclusive licensees of grantee organizations must agree to provide drugs at prices negotiated pursuant to the California Discount Prescription Drug Program to California residents eligible under that program.