CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Agenda Item # 3 Memo
11/18/08 IP Task Force Meeting

MEMORANDUM

TO: Members of the ICOC Intellectual Property Task Force

FROM: C. Scott Tocher

RE: Proposed Revisions to Intellectual Property Regulations

DATE: November 11, 2008

Executive Summary

At the ICOC's September 25, 2008 meeting, the Board gave its approval for a project that (a) consolidates the intellectual property regulations for Non-Profit Grantees and the intellectual property regulations for For-Profit Grantees into a single set of regulations, and (b) clarifies the scope of certain regulations. The ICOC tasked the Intellectual Property Task Force (IPTF) with drafting the revisions to the regulations and initiating the formal adoption process with the Office of Administrative Law. To that end, staff has proposed amendments to the regulations for the IPTF's consideration. This memorandum discusses the major proposed revisions.

Proposition 71 required the ICOC to adopt policies that balance competing benefits to California from patents, royalties and licenses, while assuring that essential research is not unreasonably hindered by intellectual property agreements. To that end, the ICOC adopted regulations implementing two intellectual property policies, one set for Non-Profit grantees and one for For-Profit grantees. These regulations were carefully crafted after dozens of interviews, public meetings of the Intellectual Property Task Force, hundreds of public comments and presentations by experts and stakeholders. The regulations strike the appropriate balance in the areas of revenue sharing, biomedical materials sharing and access provisions, to name a few.

As stem cell research moves toward the clinic and structures for research proposed by grantees become more complicated, the need to clarify existing regulations has become apparent. For instance, collaborations between and among both non- and for-profit sectors suggest that a single set of regulations will be more user-friendly for our grantees and easier for CIRM to administer. The goal of the consolidation project is not to reopen

the issues settled in the policies or to materially reset the balance made therein – rather, the project will harmonize the two into a single set of regulations and better provide greater definition to the scope and application of the policies themselves.

I. Background

The adoption of policies and their transformation into formal regulations is a complicated process governed by the Administrative Procedures Act ("APA"), which is administered by the Office of Administrative Law ("OAL"). Generally speaking, this multi-step process begins with the preparation by the task force of a draft policy, which in turn is approved by the ICOC as an interim policy. From that document, staff translates the elements of the policy into formal regulatory language and submits the regulations ("notices") to the OAL. This commences the one-year period for the agency to fine-tune the regulations through a series of drafts and changes developed in light of public input. When all the comments have been received and there are no further changes to the draft regulations, they are brought before the ICOC for final adoption and then sent to the OAL, which conducts an exhaustive review of the regulations. If approved by the OAL, the regulations are published by the Secretary of State and have the force and effect of law.

In their original process, the IP Task Force and ICOC held at least 15 public meetings devoted to the IP policy development, observed 18 public presentations by experts and stakeholders, surveyed the best practices of more than 20 funding entities, conducted over 100 interviews, refined the regulations over 12 public comment rounds and responded in detail to more than 100 comment letters according the APA.

Pursuant to Proposition 71's mandate to provide for a return to the State of California on its investment of state resources in stem cell research, the ICOC propounded policies and regulations that will ensure a fair return on investment while assuring that research is not unduly hindered.

The application of the existing regulations turns largely on the type of grant recipient – commercial versus noncommercial. The ICOC first approved an intellectual property policy for non-profit and academic research institutions, as those institutions were the first recipients of CIRM grants. That policy, initially adopted in February of 2006, completed the formal regulatory adoption process and went into effect in 2007. The formal adoption of regulations governing for-profit institutions began during the development of the non-profit policy and concluded earlier this year.

CIRM has received feedback from many sources concerning the IP regulations from several perspectives since the regulations were adopted. Prospective grant applicants asked numerous questions and some grantees have sought clarification. In addition, staff conducted two public (and well attended) IP workshops in September of 2008 intended to familiarize the for-profit community with how the regulations work. This feedback, coupled with internal legal analysis, suggests that consolidating and clarifying the

existing IP regulations would eliminate confusion, make the regulations more user-friendly and ease administration.

II. Project Principles

The purpose of the consolidation project is not to reexamine fundamental concepts and issues already considered by the ICOC in promulgating the existing IP regulations. In other words, the intent of the project is not to reconsider fundamental requirements relating to access plans and pricing provisions for uninsured and underinsured Californians. Nor is the project intended to revisit the threshold requirement that grantees are bound by the regulations with receipt of the first CIRM dollar or whether CIRM should require its grantees to share publication-related biomedical materials. Rather, the focus of the project is to identify those regulations that will benefit from further clarification as to their scope and give further meaning to the ICOC's intent in circumstances not explicitly addressed in the existing regulations.

CIRM and ICOC counsel, assisted by outside counsel and the feedback provided during two public IP workshops, have drafted proposed amendments to do essentially four things: 1) consolidate and harmonize the two policies to eliminate the potential for unintended differences in application; 2) clarify the reach of the IP regulations to better illuminate what happens when non-grantee/licensees use CIRM-funded intellectual property; 3) clarify how the regulations will operate in collaborative research environments consisting of multiple for- and non-profit organizations; and 4) improve existing language or concepts to address inadvertent blind spots in the existing language.

III. Proposed Amendments

This section discusses key aspects of the proposed amendments to the Regulations. It also identifies decision points for the task force.

A. Consolidation:

Perhaps the most fundamental aspect of the proposed amendments is to consolidate different sets of IP regulations into one comprehensive scheme. Because the two sets of regulations address essentially the same concepts and because the For-Profit regulations were finalized more recently, staff used the For-Profit regulations as the starting point for merging the regulations. Because the two policies key off differing definitions of the term "Grantee," that term is amended to encompass both Non-Profit and For-Profit organizations (see section 100401, subdivision (l).) In doing so, a single set of regulations now apply to all CIRM grantees.

B. Scope Clarifications:

1. "In whole or in part."

One of the cornerstones of CIRM's IP regulations is the access requirements embodied in section 100407. Existing rules require a Grantee or its Exclusive Licensee to submit a plan for access to uninsured Californians for Drugs sold in California, participate in the state's prescription drug discount program[1] and provide discounts to entities purchasing drugs with public funds. While Section 100407 refers only to a "Grantee" or an "Exclusive Licensee," existing language also refers to Drugs, "the development of which was in whole or in part the result of CIRM-funded Research." (Section 100407, subdivision (a).) The notion behind "in whole or in part" is the concept that the access requirements apply with the first dollar of CIRM funding, regardless of whether other non-CIRM funds contributed to Drug development.

Questions have arisen, however, as to whether, through the phrase "in whole or in part," the regulations apply to non-CIRM funded third parties that are neither Exclusive Licensees nor Grantees. For example, do the regulations attach if CIRM research displayed at a poster session or published in a journal causes a third party scientist to conceive of a new invention

To clarify the scope of the regulations, several key terms were developed or amended, found in Section 100401. Together, these amendments keep the scope of the access plans, for instance, to inventions that arise during CIRM-funded work that is paid for in part with CIRM funds. This reaches collaborators on a CIRM grant who are working together and jointly invent something, but does not reach collaborators who receive no CIRM funding and who do not share co-inventorship with a Grantee. Also, the amendments do not impose the regulations' reach to a collaborator who brings its own inventions to the table or invents outside the CIRM project. Nor do the regulations impose obligations on the third party who sees CIRM funded research at a poster session or in a publication and uses it to lead to a new invention or discovery.
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a. Subdivision (b) – "CIRM-Funded Invention." This term replaces "CIRM-Funded Patented Invention," which currently is the trigger for licensing revenues and certain blockbuster payments. The new term addresses inventions, regardless of whether they have been patented, and tracks Bayh-Dole language to define an "invention." This will close a potential loophole that would otherwise unnecessarily narrow the activities subject to reporting and revenue sharing. Also, the term clarifies the "in whole or in part" scope by adding a temporal limitation (during grant performance) and also limits entities subject to the regulation (Grantees and Collaborators who receive CIRM funds).

[1] The proposed amendments do not change requirements concerning compliance with the California Discount Prescription Drug Program ("Cal Rx"). Staff anticipates that future clarification and possible amendments of this pricing requirement will be undertaken. At this juncture, before any CIRM funded invention even enters clinical trials and commercialization likely years away, it would be premature to substantively and practically address amendments to the commercial pricing requirement.

b. Subdivision (c) – "CIRM-Funded Research." This term includes research conducted by both Grantees AND collaborators on a "Currently Active Grant." By including "Collaborators" on a "Currently Active Grant" (defined terms), the proposed regulations ensure that all of the funded participants on a grant abide by the same rules. But, the proposed amendment also clarifies that, for example, third parties who review publicly available research results are not themselves covered by the CIRM regulations. Together, these amendments are designed to clarify "in whole or in part" by adding a temporal limitation (during grant performance) and also limits entities subject to the regulation (Grantees and Collaborators).

c. Subdivision (d) – "CIRM-Funded Technology." This proposed definition makes clear that know how and data which are conceived and/or first reduced to practice during grant performance is subject to the IP regulations thus eliminating a potential loophole and ambiguity with the former definition of CIRM funded Patented Invention.

d. Subdivision (e) – "Collaborator." As indicated above, defining the term "Collaborator" to reach persons or entities other than a grantee, such as Principal Investigators, researchers and Key Personnel, ensures that all who receive CIRM funds on a Grant are under the same umbrella of rights and responsibilities. But, the definition also clarifies that third parties and mere service or material providers are not swept into the CIRM IP obligations.

2. Collaborative research.

As stem cell research gets closer to clinical trials, teams of scientists with different fields of expertise will be required. To that end, CIRM likely will fund research that is carried out by multiple organizations or individuals within a single grant – and in some cases involving both for- and non-profit organizations. While consolidating the policies is an important first step in providing clearer responsibilities in collaborative research, it is also necessary to clarify that the regulations apply not only to the named "Grantee" that is identified in the Notice of Grant Award but also to collaborating individuals and institutions participating in the grant research. For instance, a grant for research that will be conducted by Institutions A, B and C will only identify one institution as the "Grantee." The regulations must ensure, however, that B and C also are subject to the same rules as A that require, for example, access plans and biomedical materials sharing.

Therefore, Sections 100402 (subdivision (a)) (Invention Licensing and Reporting) and section 100407 (Access Requirements) are clarified to include a "Collaborator" within their scope. That term is then in turn defined in the "Definitions" of Section 100401, subdivision (e). As a result of these amendments, including the consolidation identified above, collaborative research among and across different types of organizations

and individuals will operate under the same umbrella of rights and responsibilities. These amendments will ensure not only that obligations are not evaded by shifting IP ownership to non-Grantee Collaborators, but also ensures that all collaborators are treated identically.

C. Definitional Tightening:

A review of the IP regulations as a whole reveals opportunities to tighten certain definitions such that CIRM's intent is better described and uncertainty of how the regulations apply in a given context is resolved.

1. "Exclusive License." CIRM's access requirements (Section 100407) apply not only to Grantees but also to Exclusive Licensees of CIRM Grantees. The term (see 100407, subdivision (i)) is amended to capture other forms of transfers of exclusivity, such as by assignment. This ensures that revenue due the State is not lost merely by avoided transfers of technology by means other than an Exclusive License (such as by a sale of the IP).

2. "CIRM-Funded Invention." CIRM's existing revenue sharing requirements (Section 100408) apply to a share of revenues a Grantee receives when it licenses a US-Patented invention that was funded in part by CIRM. Limiting the revenue sharing trigger only to revenues from US patents (thus excluding foreign patents and non-patented inventions) unnecessarily and unintentionally restricts the revenue sharing base of revenues that a Grantee may receive. Therefore, the regulations are amended to refer to a "CIRM-Funded Invention" and "CIRM-Funded Technology. (See Sections 100407, subdivisions (b) and (d), and 100408. See also Section 100406 (applying to licensing of CIRM-funded discoveries.) With these two new terms, the regulations now ensure that CIRM will be notified of the transfer of CIRM-funded IP, regardless of whether it is patented, and ensure that the State receives its fair share of revenues. These amendments clarify the obligations of our Grantees and ensure that the principles of the CIRM's IP policies are not easily side-stepped merely by avoiding US patent status. The proposed amendments also clarifies that foreign patents and applications and revenues derived therefrom fall within the scope of the regulations.

D. Grantee Ownership of IP – Reinforced:

While a longstanding principle of CIRM's IP policies, section 100405 is amended to state directly what previously has only been implied: that CIRM retains no ownership interest in CIRM-Funded Research or CIRM-Funded Technology (though CIRM does retain narrow March-In rights (100410) consistent with Bayh-Dole.) This amendment reinforces the power Grantees have to determine the most effective ways of advancing stem cell technology toward practical application. Similarly, the proposed amendment clarifies that Grantees control patent prosecution and enforcement.

E. Other Amendments:

1. Section 100400 – Scope:

This section contains technical amendments to consolidate the policies. In addition, the proposed changes eliminate the requirement that CIRM give formal notice of changes to the regulations and instead shifts the responsibility legal compliance on the Grantee. All amendments to CIRM's IP regulations will be noticed and posted in accordance with state law. The CIRM website will also reflect all effective IP regulations and any upcoming amendments that may be proposed. The Notices of Grant Award will refer prospective Grantees to these readily available sources.

Decision: Should the regulation eliminate the requirement that CIRM affirmatively notify all grantees of changes to regulations?

2. Section 100401 – Definitions:

The primary amendments to the definitions are highlighted above in the context of amendments to clarify the scope of the regulations. In addition to those amendments, staff proposed a few additional clarifications including adding "affiliates" within the definition of Grantee thus eliminating a potential loophole which could have unintentionally limited CIRM's ability to recover revenues.

Decision: Subdivisions (b) ("CIRM-Funded Invention"), (d) ("CIRM-Funded Technology") and (m) ("Invention") are new terms that serve to clarify, among other things, which licensing revenues are subject to the sharing requirements and what activities need to be reported to CIRM. The terms include optional bracketed language: "and/or" that calls for use of either word. The use of "or" is broader since it means that an invention need only be conceived or reduced to practice (not both) under the project in order to fall within the regulations. Staff recommends selecting "or," which is consistent with identical principles in Bayh-Dole.

2. Section 100402 -Invention and Licensing Reporting Requirements:

Presently, Grantees must submit annual reports to CIRM regarding licensing activities during and for 15 years after the Project Period of the Grant. The proposed amendments primarily incorporate the new information that would be required in light of new terms such as "CIRM-Funded Invention" and "CIRM-Funded Technology," described above. The reporting is likewise amended to include reports of patenting and licensing activities in other countries to harmonize with the revenue sharing clarifications.

3. Section 100403 - Publication Requirements:

Technical amendments to harmonize with the clarifications made in other sections regarding Invention Utilization reports and other definitions described above.

4. Section 100404 – Publication-Related Biomedical Materials Requirements:

Minor technical amendments.

5. Section 100405 – Patents:

As discussed above, IP ownership with the Grantee is emphasized and described in greater detail. Proposed subdivisions (a) and (b) clarify the ICOC's prior intent that a Grantee retains all rights of ownership in CIRM-funded discoveries and has the right to pursue exploitation of those discoveries as it deems necessary (subject to standard March-In protections maintained by CIRM). Proposed subdivision (d) incorporates from the Non-Profit policy an assurance that the regulations do not prohibit the Grantee from recovering costs of patent prosecution through license fees or other methods.

6. Section 100406 – Licensing and Assignment of CIRM-Funded Discoveries:

Harmonizing changes to reflect shift from "CIRM-Funded Patented Inventions" to "CIRM-Funded Inventions" and "CIRM-Funded Technology."

Decision: The regulation carries over the obligation of Non-Profit grantees to make its discoveries available to other Non-Profit grantees for non-commercial research purposes. The Non-Profit Grantee also is required to retain the right to practice the use of its CIRM-Funded Inventions for non-commercial purposes even in the event the Grantee licenses the Invention to a third party. The Task Force should consider whether to maintain that distinction from For-Profit organizations, to which these provisions do not apply.

7. Section 100407 – Access Requirements for Products Developed by Grantees:

These amendments are technical only to include references to "Collaborator." The other changes reflect amendments already adopted by the ICOC but awaiting Office of Administrative Law approval.

8. Section 100408 – Revenue Sharing:

These amendments are technical to incorporate the references to the new terms defined above and changes already adopted by the ICOC but awaiting OAL approval.

Decision: Subdivision (b)(1) describes a range of 2%-5% rate of return of the first payback of three times the grant amount. The actual rate of payback in a Grant that is awarded by the ICOC would be the subject of negotiation between the CIRM and the Grantee. The Task Force may wish to consider fixing the percentage in the regulation and thus eliminate the need for negotiation on that point.

9. Section 100410 – March-In Rights.

This section contains mostly technical amendments incorporating the changed terms defined above.

Decision: In addition, the draft proposes elimination of the reference in subdivision (b)(3) to March-In in the event the Grantee or Exclusive Licensee fails to "satisfy requirements for public use." The provision, derived from an identical provision in Bayh-Dole, is unnecessary in light of the remaining provisions in the regulation and has created confusion over the circumstances in which it might be invoked.

Recommendation: Staff recommends the Task Force approve the draft changes and direct staff to initiate the public comment process pursuant to the Administrative Procedure Act.