CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

MEMORANDUM

TO: MEMBERS OF THE ICOC

FROM: C. SCOTT TOCHER, ELONA BAUM

SUBJECT: **AGENDA ITEM #7**: RECOMMENDATIONS OF INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEE: IOM COMMITTEE RECOMMENDATIONS ON CIRM'S INTELLECTUAL PROPERTY POLICIES.

DATE: MARCH 8, 2013

Executive Summary

At the December 2012 meeting of the ICOC, the Institute of Medicine ("IOM") presented certain findings and recommendations based on its review of CIRM and ICOC operations. While concluding that CIRM's intellectual property ("IP") policies reflect "a reasonable effort to balance conflicting interests of different constituencies that each have a legitimate stake in these policies," the IOM made two recommendations:[1] 1) incorporate future enforcement of IP policies in the sustainability platform; and 2) consider harmonizing the IP policies with federal policy embodied in the Bayh-Dole Act.[2] In January, the Board referred these recommendations to the Intellectual Property and Industry Subcommittee ("Subcommittee") for consideration and recommendation to the Board for further action.

Last month the Subcommittee met to consider the recommendations of the IOM. After reviewing the report and recommendations of staff, the Subcommittee makes the following **Recommendations:** The ICOC should continue to consult with stakeholders and monitor the impact of CIRM's IP policies and await further changes; and resume discussions with other

[1] IOM (Institute of Medicine). 2013. *The California Institute for Regenerative Medicine: Science, governance, and the pursuit of cures*. Washington, DC: The National Academies Press; (prepublication copy) hereinafter referred to as "IOM."

[2] The Bayh-Dole Act was enacted in 1980. The key change made by Bayh-Dole, was in ownership of inventions made with federal funding. Before the Bayh–Dole Act, federal research funding contracts and grants obligated inventors (where ever they worked) to assign inventions they made using federal funding to the federal government. Bayh-Dole permits a university, small business, or non-profit institution to elect to pursue ownership of an invention in preference to the government.

agencies regarding future enforcement of CIRM's IP regulations and report back to the Subcommittee with proposals for moving forward.

I. Development of CIRM IP Regulations

Proposition 71 requires CIRM to balance competing benefits to California from patents, royalties and licenses, while assuring that essential research is not unreasonably hindered by IP agreements. (H&S Code § 125290.30, subd. (h).) This subcommittee has led the development of CIRM's policies over the course of seven years. The concepts first approved in 2006 and which formed the basis of the agency's first IP policy applicable to non-profit and academic institutions (sections 100300 *et seq*.), were further developed and refined with the adoption of the IP policy applicable to for-profits (sections 100400 *et seq*.) in 2008 and the consolidated policy applicable to all grantees in 2009 (sections 100600 *et seq*.). CIRM has amended the specific policies themselves from time to time in response to feedback and experience with the regulations as applied.[3] The IP subcommittee has convened 20 meetings at which public input from all stakeholders has been sought and incorporated into final recommendations to the ICOC. As part of the legally required regulatory adoption process, the agency has gathered and considered additional input and guidance from scores of participants. Indeed, the agency is currently in the midst of a rule-making process to fine-tune the revenue sharing provisions and has obtained input from multiple constituencies on their development. In addition to the legal requirements of Proposition 71, recent legislation in 2010 codified portions of the agency's IP policies relating to revenue sharing and submission of access plans to make commercial products affordable for low income, uninsured Californians.

II. IOM Report and Recommendations:

As stated earlier, the IOM observed that CIRM's IP policies represent a "reasonable effort" to achieve the aims imposed by Proposition 71 and other legislation. In its conclusion, the IOM makes two recommendations.

A. Recommendation 5-1: Because CIRM is a new institution without a track record to reassure stakeholders, and because its finite funding timeline means as yet unknown agencies will be enforcing these policies years down the road, CIRM should "propose regulations that specify who will have the power and authority to assert and enforce in the future rights retained by the state" in CIRM IP, specifically referring to march-in rights, access plans and revenue sharing.[4]

B. Recommendation 5-2: Second, as other sources of funding become more prevalent, the agency should "reconsider whether its goal of developing cures would be better served by harmonizing CIRM's IP policies wherever possible with the more familiar policies of the Bayh-Dole Act."[5]

[3] For instance, the 100300-, 100400- and 100600-series regulations have been amended to refine revenue sharing provisions, biomedical materials sharing requirements, publication-related requirements, and the development of access plans.

[4] IOM, at p. 5-14.

[5] IOM, at p. 5-14.

In arriving at these conclusions, the report begins with an acknowledgement that CIRM's "intellectual property regulations follow the broad contours of the Bayh-Dole regime by allowing grantees to retain ownership of inventions and by giving them considerable discretion by giving them considerable discretion in deciding when to pursue, retain, transfer, and license their rights."[6] The report further acknowledges that "CIRM also follows the Bayh-Dole approach in obligating grantees to make reasonable efforts to achieve practical application of their inventions through either commercialization or licensing, and in fortifying this obligation by retaining march-in rights that allow CIRM to grant licenses if necessary."[7] While there are a number of similarities between CIRM's intellectual property regulations, the IOM notes that CIRM's regulations depart from Bayh-Dole. The IOM focused its discussion on CIRM's regulations in the following areas revenue sharing, access plans, march-in, and publication-related biomedical materials sharing.[8]

A. Revenue Sharing:

One of the most significant differences between federal policy and CIRM's policy is in the area of revenue sharing – Bayh-Dole does not require revenue sharing with the government sponsor while CIRM provides for revenue sharing with the state under certain circumstances. While the IOM notes that federal policy has rejected such revenue sharing, the IOM observed that industry and academic criticisms of CIRM's revenue sharing policies has been "muted" and that "although it may be premature to assess whether the revenue-sharing provisions will ultimately dampen incentives for commercialization of CIRM-funded inventions, at this point they do not appear to rank high among the concerns of potential grantees and licensees."[9]

B. Access Plans:

The IOM next discussed CIRM's access plans provisions. Under certain circumstances California law[10] requires an entity commercializing a drug in California that arose from CIRM-funded research to provide a plan to afford access to Californians who have "no other means to purchase the Drug." The access plan provision requires that the plan be consistent with industry standards at the time of commercialization and has evolved to provide a mechanism for waiver

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[6] IOM, at p. 5-2.
[7] *Id*.

[8] Title 17, Cal. Code of Regs §§ 100608, 100607, 100610 and 100604, respectively.

[9] IOM, at p. 5-7. The IOM also observed that California is not alone in requiring revenue sharing with the state, citing programs in Connecticut and Texas that also require grantees to pay to the state a certain percentage of revenues derived from the funded activities.

[10] Health & Safety Code § 125290.80. This statute was enacted in 2010 (SB 1064, Alquist), which slightly modified CIRM's existing access plan policy embodied in section 100607, which has since been amended to conform with this statute.

of the plan by the ICOC. In addition, this provision requires that the drug be provided under the state's discount prescription drug program. The IOM noted that the closest parallel in federal law was an NIH policy in the 1990s that applied a "reasonable pricing clause" to partners, but which was abandoned in the face of industry opposition.[11] The IOM stated, however, that CIRM's access plan provision is "much less far-reaching" than the NIH, noting that it only applies to a select group of Californians and need simply be consistent with industry standards often found in current company practice. Nevertheless, the IOM cautions that uncertainty about how the system will operate going forward and whether another agency with a different agenda would enforce this provision "could make industry cautious" about partnering with CIRM researchers (although no definitive finding was made to this effect).[12]

C. March-In Rights:

The IOM turned next to CIRM's march-in rights, which parallel in part the federal equivalent. The IOM report states that march-in rights may make it difficult to license technologies due to industry fear that CIRM might be more likely than the federal government to exercise its rights, reciting feedback CIRM received during development of its original policies. As with access plans, while CIRM may, over time (as with the federal government) relieve industry anxiety by exercising its rights as sparingly as the federal government, there nevertheless remains the risk that after CIRM ceases to exist the march-in rights will be exercised by a different agency responding to different pressures. Although not discussed in the IOM report, it is important to note that unlike Bayh-Dole, CIRM's regulation providing for march-in rights includes an escalation approach with meet and confer obligations between CIRM and the grantee before CIRM's march in rights may proceed.[13]

[11] IOM, at pp. 5 -8-9.
[12] IOM, at pp. 5 -9-10.

[13] Section 100610 provides, in pertinent part:
"(e) CIRM will not exercise its march-in rights if the Grantee, Collaborator or an Exclusive Licensee promptly takes action to cure the deficiency and such deficiency is cured sooner than one year from the date of the March-In Notice (or longer period by mutual agreement). With respect to a deficiency described in subdivision (b)(3) of this regulation, however, CIRM may exercise such right at any time in the event of a public health or safety emergency declared by the Governor and where CIRM finds that exercise of march-in rights is likely to alleviate the circumstances or conditions that give rise to the emergency declaration.
"(f) Within thirty (30) days of the date CIRM issues a March-In Notice, the subject Grantee may appeal CIRM's decision to the ICOC by notifying the President of CIRM in writing of its intent to appeal CIRM's decision. Within sixty (60) days of the March –In Notice date, the subject Grantee must submit a written statement of the reasons for the appeal and any supporting materials it wishes to have considered by the ICOC. Absent extraordinary circumstances, the ICOC shall render a final determination on the appeal within one hundred twenty (120) days of the March-In Notice. In cases where an appeal is filed, CIRM shall not effect a march-in unless and until the ICOC renders a final determination on the appeal. The ICOC may reverse the decision of the CIRM to exercise march-in rights under this regulation for any reason.
"(g) Unless provided otherwise by CIRM, any applicant to receive a License or Assignment pursuant to this regulation will be bound by this Chapter as if it were an original Grantee recipient of the funding that resulted in the applicable CIRM-Funded Invention or CIRM-Funded Technology."

D. Biomedical Materials Sharing:

Last, the IOM focused on the unique requirement of sharing of publication-related biomedical materials.[14] Grantees must share such materials within 60 days of receiving a request for research purposes in California. The requirement provides various exceptions to the requirement in the event, for instance, the sharing because unduly burdensome or the materials are made broadly commercially available. The report goes on to cite other similar sharing requirements in other jurisdictions, such as Connecticut, Texas, Maryland and New York. While no direct corollary in federal law, the report cites the NIH requirement that requires applicants seeking more than $500,000 to address plans for dissemination of research results, and encourages universities to retain the right to share research tools for noncommercial purposes.

IV. IPIS Subcommittee Recommendations.

A. Recommendation 5-1:

CIRM staff has engaged in preliminary discussions several years ago with other agencies regarding future enforcement of CIRM's regulations and agreements. The subcommittee proposes to restart those discussions and return to the Subcommittee with a formal proposal to address future enforcement of CIRM's IP regulations.

B. Recommendation 5-2:

As stated by the IOM, the areas where CIRM's intellectual property regulations differ from Bayh-Dole are in areas that "are sanctioned and required by the text of Proposition 71 and subsequent legislation [codifying CIRM's regulations for revenue sharing and access plans]."[15] In addition, CIRM has in the past invited feedback on its policies from various stakeholders and received valuable input on a regular basis, and this has periodically resulted in recalibration of existing policies which is evidenced by pending amendments. In light of the IOM's own recognition that it may be premature to assess whether CIRM's regulations will act as a deterrence to future investment, the fact that a number of CIRM's regulations have been codified in statutes and CIRM's positive progress in its industry engagement efforts to date, although quite early, the Subcommittee proposes to continue to monitor this area and not to pursue any changes at this time.

[14] *Id*., at pp. 5 -11-12.
[15] IOM, at p. 5-2.