



MEMORANDUM

TO: Members of the ICOC

FROM: C. Scott Tocher, Counsel to the Chair

RE: **Agenda Item 11:** Consideration of amendments to CIRM’s Intellectual Property regulations

DATE: March 19, 2013

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Executive Summary

Last September the ICOC initiated a rulemaking process to amend CIRM’s Intellectual Property (“IP”) regulations (sections 100600 – 100602, and 100608). The amendments were recommended to the ICOC by the Intellectual Property and Industry Subcommittee, and primarily address the process of licensing reporting by Grantees and a recalibration of the formulae for revenue sharing. Based on feedback obtained from the public during the amendment process, CIRM refined the amendments further, consistent with the intent of the ICOC. Staff proposes no further amendments and now seeks final approval from the ICOC for the amendments and to present them to the Office of Administrative Law (“OAL”) for its approval (Exhibit B). The proposed changes, including the minor changes¹ from the language approved by the ICOC in September to initiate the process, are described below and in the companion memorandum (Exhibit A) by Elona Baum, General Counsel.²

I. Regulatory Amendments

A. Section 100600 – Scope of IP Regulations^{*3}

¹ Language modified from that reviewed and approved by the Board in September is highlighted in the attached regulations with yellow highlighted text.

² The memorandum attached, dated May 31, 2012, and updated June 19, 2012, discusses the amendments made to sections 100601 (“Definitions”) and 100608 (“Revenue Sharing”). Because staff proposes no further changes to what the ICOC and IP subcommittee considered and approved previously, the memorandum explaining those sections is resubmitted.

³ Staff proposes no further changes to what the ICOC and IP subcommittee considered and approved previously.

When CIRM's IP regulations are amended, the amendments apply to all Grants awarded after the effective date of the new regulations. The question arises, however, about how such amendments will affect existing active grants. Currently, amendments will apply retroactively to existing grants at the start date of the Grant's next budget period, with an important exception. Amendments to licensing, access and revenue sharing requirements (sections 100606, 100607 and 100608, respectively) do not apply to active Grants. This exception is based on the notion that amendments that directly alter financial implications of the regulations should only apply on a going forward basis.

In the context of the Loan Administration Policy, staff has discovered instances where a loan recipient might be receptive to amendments to key provisions of the Policy. Accordingly, the Policy now allows amendments to key provisions to be applied retroactively to existing loans upon mutual agreement of CIRM and the loan recipient. Staff proposes the same flexibility be integrated into the IP regulations, as well, and thus proposes section 100600 be amended to apply IP amendments to the areas described above on a going forward basis unless CIRM and existing Grantees "agree the amendments shall apply to existing Grants."

Staff believes the proposed language strengthens staff's hand to apply important policy calibrations to a broader number of potential grantees.

B. Section 100602 – License Reporting

Part of staff's ongoing responsibility is to gauge the effectiveness of CIRM's IP regulations and assess our Grantees' efforts to exploit CIRM technology. A primary tool at CIRM's disposal is the ability to gain visibility into certain components of licenses and other agreements conveying rights between our Grantees and third parties to CIRM-funded technologies. In addition, the likelihood and amount of revenue generated by CIRM-Funded technologies may impact the tax status of the bond proceeds that fund a given grant. Currently, while Grantees are required to notify CIRM on an annual basis when such agreements are entered into, Grantees are not required to provide CIRM with copies of such documents.

To address this lack of visibility and to make clearer CIRM's requirements going forward, staff initially proposed amendments to section 100602 to require provision of such agreements within 60 days of their execution. Based on feedback from some CIRM grantee institutions, staff narrowed the disclosure requirements to require disclosure only of those terms of licensing agreements that address revenue sharing. Also, to ensure Grantees are comfortable sharing the information with CIRM, the regulation provides flexibility to allow CIRM and the Grantee to find unique procedures to comply with the sharing requirement.

C. Section 100608 – Revenue Sharing.*⁴

In addition to the proposed amendments outlined in the companion memorandum to this agenda item, the additional language be added to section 100608 to address two issues.

First, the amendments as approved previously by the IP subcommittee and Board create new obligations on third party “commercializing entities.” The revenue sharing requirements ensure that third party licensees (who may ultimately be “commercializing entities”) of CIRM-funded technologies have an affirmative obligation to CIRM and the State to abide by these revenue sharing obligations when they apply to the third party licensees. (See proposed subdivision (c).) The amendments clarify the revenue sharing obligations of Section 100608 by indicating that the revenues due under the regulations are payable to the State Treasurer’s Office, Division of Cash Management. (See proposed subdivision (d).)

II. Recommendation

Staff recommends the ICOC approve the proposed language to finalize the amendment process.

⁴ Staff proposes no further changes to what the ICOC and IP subcommittee considered and approved previously.