



MEMORANDUM

TO: Members of the ICOC

FROM: C. Scott Tocher, Counsel to the Chair

RE: **Agenda Item 9:** Consideration of Proposed Amendments to the Intellectual Property Regulations – Additional Amendments To Revenue Sharing and Reporting Requirements

DATE: July 16, 2012

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Executive Summary

Last month the Intellectual Property and Industry Subcommittee met to consider amendments to CIRM’s Intellectual Property (“IP”) regulations. Those amendments were recommended to the ICOC and are discussed in a companion memorandum to this agenda item. The proposed amendments discussed below are in addition to those considered by the IP subcommittee. The purpose of this agenda item is to obtain ICOC consent to initiate a rulemaking with the Office of Administrative Law (“OAL”) to accomplish both sets of changes to the IP regulations. Consistent with prior rulemakings, the ICOC will review final language after public comment has been sought.

I. Regulatory Amendments

A. Section 100600 – Scope of IP Regulations

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 and recommends the ICOC direct staff to initiate the rulemaking process to obtain additional public comment.

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 various license and other agreements conveying rights between our Grantees and third parties to CIRM-funded technologies. 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. Nevertheless, CIRM staff has enjoyed cooperation from some CIRM grantees in seeking further information about such agreements and in some cases Grantees have voluntarily shared the agreements with CIRM.

To address this lack of visibility and to make clearer CIRM’s requirements going forward, staff proposes amendments to section 100602 to require provision of such agreements within 60 days of their execution. CIRM will hold the documents in confidence in accordance with Proposition 71.

C. Section 100608 – Revenue Sharing.

In addition to the proposed amendments outlined in the companion memorandum to this agenda item, staff proposes additional language be added to section 100608 to address two issues. (This language is highlighted in yellow.)

First, the amendments approved by the IP subcommittee create new obligations on third party “commercializing entities.” Staff proposes 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).) Staff also proposes to 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 initiate the formal amendment process.

1 Amend Chapter 6, 17 Cal. Code of Regs. section 100600 to read:

2 **Chapter 6 - Intellectual Property and Revenue Sharing Requirements for Non-Profit and**
3 **For-Profit Grantees**

4 **§ 100600. Intellectual Property and Revenue Sharing Requirements for Non-Profit and**
5 **For-Profit Grantees - Scope.**

6 The regulations of this chapter apply to all California Institute for Regenerative Medicine
7 (“CIRM”) Grants awarded to Non-Profit and For-Profit Grantees on or after the effective date of
8 these regulations. By accepting a CIRM Grant, the Grantee agrees to comply with these
9 regulations. Any new or amended regulations of this Chapter subsequently adopted by the
10 Independent Citizens Oversight Committee (“ICOC”) will apply to CIRM-Funded Project(s) or
11 Activities on the start date of the next Budget Period after the effective date of the regulations.
12 Notwithstanding the foregoing sentence, ~~except~~ amendments to Title 17, California Code of
13 Regulations, sections 100606, 100607 and 100608, shall only apply to Grants awarded after
14 adoption of the new or amended regulations ~~unless the parties agree the amendments shall apply~~
15 to existing Grants. All revisions to CIRM regulations will be posted on the CIRM website at
16 www.cirm.ca.gov, which shall serve as notice to the Grantee or Authorized Organization Official
17 of such revisions. Note: Authority cited: Article XXXV, California Constitution; Section
18 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.

1 Amend 17 Cal. Code of Regs. section 100602 to read:

2 **§ 100602. Invention and Licensing Reporting Requirements.**

3 (a) Prior to an NGA and continuing 12 months after the close of a Grant, a Grantee must
4 have written agreements with Grantee Personnel and Collaborators requiring prompt disclosure
5 to the Grantee of any CIRM-Funded Invention.

6 (b) Within 60 calendar days after a CIRM-Funded Invention has been disclosed to a
7 Grantee, the Grantee must notify CIRM of the CIRM-Funded Invention through the use of the
8 CIRM Invention Disclosure Form, which will be received in confidence by CIRM. The
9 Invention Disclosure Form shall identify the Grant under which the CIRM-Funded Invention was
10 made, the Inventor(s) and the Principle Investigator. The Disclosure shall be sufficiently
11 complete in technical detail to convey a clear understanding, to the extent known at the time of
12 the disclosure, of the nature, purpose, operation, and physical, chemical, biological or electrical
13 characteristics of the CIRM-Funded Invention. If the CIRM-Funded Invention has been
14 submitted for publication or presentation, then the Disclosure shall identify the publication, the
15 date of the abstract or manuscript or presentation, the submission date and if relevant any
16 publication dates, including publication via the internet.

17 (c) Within 60 calendar days after a Grantee executes an exclusive license agreement,
18 non-exclusive license agreement, material transfer agreement, research collaboration agreement,
19 or any other agreement conveying rights in CIRM-Funded Inventions or CIRM-Funded
20 Technology, a Grantee shall notify CIRM of the execution of such agreement(s) and submit to
21 CIRM a copy of the executed agreement. The notification and agreement(s) shall be marked
22 “Confidential” in accordance with Health and Safety Code section 125290.30, subdivision
23 (e)(2)(B).

1 | ~~(de)~~ A Grantee must submit annually to CIRM during, and for 15 years after, the Project
2 | Period of the Grant, an Invention Utilization Report containing the following information:

3 | (1) Grantees must report all patent applications filed which claim, or cite to publications
4 | concerning, CIRM-Funded Inventions, including the countries in which application(s) were filed,
5 | application serial number(s), status and detailed description(s) of the CIRM-Funded Invention(s);
6 | and

7 | (2) Grantees must report the issuance or abandonment of any patent applied for that
8 | claims, or cites to publications concerning, CIRM-Funded Invention, including the patent
9 | number and date of issuance or abandonment and the countries in which the applications have
10 | issued or have been abandoned; and

11 | (3) Grantees must report the total funding from all sources that directly contributed to a
12 | CIRM-Funded Invention disclosed or claimed in the patent application, including each co-
13 | funder's identity, the dollar amounts each contributed and the dates of contribution. CIRM may
14 | audit all such co-funding reports; and

15 | ~~(4) A Grantee must report to CIRM the execution of all Exclusive License Agreements,~~
16 | ~~Non-Exclusive License Agreements, Material Transfer Agreements or Collaborative Agreements~~
17 | ~~conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology; and~~

18 | (5) In the event that a CIRM- Funded Invention or CIRM-Funded Technology generates
19 | revenue or other consideration (whether from a License Agreement or otherwise), a Grantee
20 | must report such revenue or consideration received during the preceding 12 month period or
21 | since the last report, whichever is longer.

22 | (6) A Grantee must report the following key progress toward commercialization of a
23 | CIRM-Funded Invention or CIRM-Funded Technology including the following:

- 1 (A) Initiation of clinical testing;
- 2 (B) Initiation of pivotal studies; and
- 3 (C) Application for marketing approval.

4 (7) Grantee shall have written agreements with its Grantee Personnel, Collaborators,
5 licensees and transferees requiring such third parties to report to the Grantee information
6 described in this subdivision (~~de~~).

7 (~~ed~~) The Invention Utilization Report shall be marked “Confidential” in accordance with
8 Health and Safety Code section 125290.30, subdivision (e)(2)(B).

9 (~~fe~~) CIRM reserves the right to itself and its agents to conduct an audit of the Grantee and
10 Collaborators to ensure compliance with this Chapter. Grantee and Collaborators must maintain
11 and provide such documentation as is necessary to establish compliance. Further, Grantee must
12 ensure that its Collaborators, Grantee Personnel and all Exclusive and Non-Exclusive Licensees
13 maintain such documentation as is necessary to establish compliance.

14 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
15 Safety Code. Reference: Section 125290.30, Health and Safety Code.

1 Amend 17 Cal. Code of Regs. section 100608 to read:

2 **§ 100608. Revenue Sharing.**

3
4 ~~(a) Licensing Revenue.~~ (a) A Grantee and Collaborator must share with the State of
5 California a fraction of Licensing Revenue received under a License Agreement for a CIRM-
6 Funded Invention, CIRM-Funded Technology, or results of CIRM-Funded Research, as follows:

7 (1) ~~InSubject to subdivision (a)(2) of this regulation and to adjustments made in~~
8 ~~accordance with the event that CIRM funds at least one half of the total cost of the CIRM-~~
9 ~~Funded Project resulting in the licensed or transferred CIRM-Funded Invention, CIRM-Funded~~
10 ~~Technology or results of CIRM-Funded Research, then provisions hereof,~~ the amount owed is
11 25 percent of Licensing Revenue received in excess of \$500,000 and shall be payable to the State
12 of California for deposit into the State's General Fund (such payments to be used by the State of
13 California in a manner consistent with Title 35 United States Code, Section 202, subdivision
14 (c)(7)). The threshold amount of \$500,000 (in the aggregate) shall be adjusted annually by a
15 multiple of a fraction, the denominator of which is the Consumer Price Index, All Urban
16 Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the
17 Bureau of Labor Statistics of the United States Department of Labor and published for the month
18 of October 2009, and the numerator of which is such Index published for the month in which the
19 Grantee accepts the Grant. In the event that CIRM funds less than one half of the total cost of the
20 CIRM-Funded Project resulting in the licensed or transferred CIRM Funded Invention, CIRM
21 Funded Technology or results of CIRM-Funded Research then the amount owed is 15 percent of
22 Licensing Revenue in excess of the threshold amount described above.

1 (2) Notwithstanding the forgoing, in the event that a Commercializing Entity is making
2 royalty payments pursuant to subsection (c) below, For-Profit Grantees and For-Profit
3 Collaborators will have no obligation to share with the State of California, any Licensing
4 Revenues they derive as a result of the same commercial revenue stream.

5 ~~(b) Net Commercial Revenue.(2) If any funding sources other than CIRM (including~~
6 ~~those of the Grantee or Collaborator, as the case may be) directly contributed to the development~~
7 ~~of said CIRM-Funded Invention or CIRM-Funded Technology, then the return to the State of~~
8 ~~California on Licensing Revenue in excess of the threshold amount described in subdivision~~
9 ~~(a)(1) of this regulation shall be proportionate to the support provided by CIRM, as follows: The~~
10 ~~amount of CIRM funding of the CIRM-Funded Invention or CIRM-Funded Technology shall be~~
11 ~~divided by the total of funding provided by all sources, and that fraction shall be multiplied by~~
12 ~~25. That numeral is the percentage due to the State of California of Licensing Revenue.~~

13 ~~(b) A Commercializing EntityGrantee and Collaborator~~ must share with the State of
14 California for deposit in the State's General Fund a fraction of ~~any~~ Net Commercial Revenue
15 that results in whole or in part it receives from ~~a self-commercialized product it commercializes~~
16 ~~itself and which resulted from its~~ CIRM-Funded Research (regardless of whether a CIRM-
17 Funded Invention or CIRM-Funded Technology is involved) as follows:

18 (1) ~~A royaltyGrantees and Collaborators must pay royalties to the State of California for~~
19 ~~deposit into the State's General Fund~~ on Net Commercial Revenue ~~exceeding the threshold~~
20 ~~amount described in subdivision (a)(1) of this regulation. Total payments under this subdivision~~
21 ~~(b)(1) shall equal and not exceed three times the total amount of the CIRM Grant or Grants that~~
22 ~~led to the product. The rate of payback of the royalty shall be at a rate of 0.1% per \$1 million of~~

1 ~~CIRM Grant(s) for the earlier of Ten (10) years~~~~three (3) percent of the annual Net Commercial~~
2 ~~Revenue from the date of First Commercial Sale; or nine times the product.~~

3 ~~(2) In addition, if Net Commercial Revenue from a product commercialized by the~~
4 ~~Grantee, or Collaborators and which resulted from its CIRM Funded Research exceeds the~~
5 ~~milestone of \$250 million in any calendar year, a one-time payment of three times the total~~
6 ~~amount of the Grant(s); (By way of example, Grants totaling \$15 million) awarded shall be paid~~
7 ~~to the State of California. In addition, if Net Commercial Revenue exceeds the milestone of~~
8 ~~\$500 million in any calendar year, an additional one-time payment of three times the total~~
9 ~~amount of the Grant(s) awarded shall be paid to the State of California.~~

10 ~~(3) In addition to any amounts due under any other provision of this regulation,~~
11 ~~where a patented CIRM Funded Invention(s) or patented CIRM Funded Technology is~~
12 ~~involved in the achievement of Net Commercial Revenue realized by a Grantee or~~
13 ~~Collaborator equivalent to or greater than \$500 million in any year, and where a CIRM~~
14 ~~Grant or Grants amounting to more than \$5 million (in the aggregate) were made in~~
15 ~~support of CIRM Funded Research that contributed to the creation of Net Commercial~~
16 ~~Revenue, the Grantee or Collaborator will result in royalty payments of 1.5% of Net~~
17 ~~Commercial Revenues.) pay the State of California one percent annually of Net~~
18 ~~Commercial Revenue in excess of \$500 million for the life of any patent covering such~~
19 ~~patented CIRM Funded Invention or patented CIRM Funded Technology.~~

20 ~~(2) In addition, upon satisfaction of the obligation in subsection (b)(1) above, a~~
21 ~~1% royalty shall be owed on Net Commercial Revenues in excess of \$500 million per~~
22 ~~year, until the last to expire patent covering a CIRM Funded Invention, if any, that~~
23 ~~generates, or plays a role in the generation of, in whole or in part said Net Commercial~~

1 Revenue; provided at least \$5 million in CIRM Grant or Grants were made in support of
2 such CIRM-Funded Research, CIRM Funded Technology or CIRM Funded Inventions

3 (3) For purposes of subdivision (c) of this section, the royalty rate calculation
4 shall apply only to Grants made to For-Profit Grantees and which were awarded
5 subsequent to the effective date of this section, as amended.

6 (4) Royalty payments owed pursuant to this section shall be paid 60 days
7 following the end of each calendar quarter.

8 (c) Grantees and Collaborators shall include provisions within any license of a CIRM-
9 Funded Technology or CIRM-Funded Invention ensuring that a Commercializing Entity,
10 whether a licensee or sub-licensee, directly owes payments to the State pursuant to subdivision
11 (b) of this Section, where applicable.

12 (d) Revenues due the State according to this Section shall be paid to the California State
13 Treasurer's Office, Division of Cash Management.

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15 Note: Authority cited: Article XXXV, California Constitution; and Section 125290.40(j), Health
16 and Safety Code. Reference: Section 125290.30, Health and Safety Code.