



M E M O R A N D U M

To: Governing Board
From: Elona Baum
Subject: Proposed Amendments to Intellectual Property Regulations
Date: August 27, 2012

The agenda for the Governing Board's meeting on July 26, 2012 included consideration of proposed amendments to CIRM's intellectual property regulations. Due to time constraints the matter was not heard and is not being considered. The Memorandum which was posted in July in support of this item is being reposted and is attached as Exhibit A. A mark up of the regulations showing the proposed amendments in track changes is posted separately. Except for recent proposed changes which are highlighted in yellow, the Intellectual Property and Industry Subcommittee considered all proposed amendments and recommended them for approval. The highlighted changes made to the Definition of Commercializing Entity and to section 100608(a) are intended to ensure that California's licensing revenue sharing regulations are not dependent on the specific form of any licensing or contractual arrangement but rather arise when licensing revenue is generated in whole or in part from CIRM Funded Research, a CIRM-Funded Invention or CIRM-Funded Technology.

Exhibit A



M E M O R A N D U M

TO: Intellectual Property and Industry Subcommittee

FROM: Elona Baum, Matt Plunkett, Scott Tocher

SUBJECT: Proposed Amendments to IP Regulations – Revenue Sharing and Definitions

DATE: May 31, 2012 – Revised June 19th, 2012

I. Background:

Attached are a set of proposed amendments to the Intellectual Property and Revenue Sharing Requirements for Non-Profit and For Profit Grantees Title 17, California Code of Regulations Sections 100601 (definitions) and 100608 (revenue sharing).

Under CIRM's regulations, there are two revenue sharing provisions. Section 100608(a) requires Grantees and Collaborators to share 25% of their licensing revenue in excess of 500,000. This rate is reduced in accordance with the proportional share of CIRM funding which contributed to the licensed invention and technology as compared to the total project costs incurred during the project period (the "Proportionality Reduction"). The other revenue sharing provision is set forth in section 100608(b). It provides that Grantees and Collaborators must share revenues resulting from CIRM Funded Research as follows: after revenues exceed \$500,000, three times the grant award, paid at a rate of 3% per year, plus upon earning \$250M in a single calendar year, a onetime payment of three times the award, plus upon earning revenues of \$500M in a single calendar year, an additional onetime payment of three times the award and finally in the instance where a patented CIRM Funded Invention or CIRM Funded Technology contributed to the creation of Net Commercial Revenue greater than \$500M in a single calendar year, and where CIRM awarded \$5 million or more, an additional 1% royalty on revenues in excess of \$500 million annually over the life of the patents.

The one time payments triggered at \$250 million and \$500 million in annual revenues, create an uneven payment obligation which is characterized as being "lumpy" and could be a disincentive for the engagement of industry. In addition, the Proportionality Reduction provided for in Section 100608(a) creates administrative challenges and uncertainty. The following proposed amendments seek to address these issues while at the same time ensuring a comparable economic return to California.

SB 1064, which was enacted by the Legislature in 2010 with CIRM's support, codified the revenue sharing formulas into law. In recognition of the relatively early stage of the research and need to partner with industry in order to commercialize CIRM-funded discoveries, SB 1064 authorized CIRM's Governing Board to modify the formulas if it determined that it was necessary to do so either to ensure that research and therapy development are not unreasonably hindered as a result of CIRM's regulations or to ensure that the State of California has an opportunity to share in the revenues derived from such research and therapy development. The proposed amendments re-strike the balance both to ensure that industry will partner with CIRM and to ensure that the State has the opportunity to benefit from successful therapy development.

1. Following posting of this Memorandum on May 31, 2012, non-substantive, technical edits were made to the last bullet of this Memorandum (p.2) as follows: (i) changed Net Commercial Sales to Net Commercial Revenue (the term used in the proposed amendment) and (ii) consistent with the proposed amendment, eliminated reference to “patented CIRM Funded Technologies” which appeared at the end of the bullet (note: from a practical perspective, patented CIRM Funded Technologies would fall within definition of CIRM Funded Inventions.)

II. Objectives

The proposed amendments:

- Smooth out payment obligations in order to facilitate industry investment and engagement in CIRM programs which, in turn, will leverage CIRM's funding and provide access to industry know how
- Extend the revenue sharing obligations to commercializing entities to ensure the State realizes revenues from successful therapy development
- Simplify the proportionality calculation relating to CIRM's existing licensing revenue sharing regulation
- Maintain the existing revenue sharing scheme as it pertains to non-profit grantees (except with respect to the simplification of the licensing revenue sharing proportionality calculation)
- Maximize the amount of funding that companies can re-invest in product development, by exempting pre-commercial revenues from CIRM's revenue sharing
- Maintain the requirement that funds generated from CIRM's revenue sharing regulations are deposited in the California's General Fund

III. Proposed Changes

Licensing Revenue Sharing (Section 100608(a)):

- The amendments to section 100608(a) simplify the calculation of the Proportionality Reduction. Instead of tracking dollar for dollar other funding sources to determine the proportionality of CIRM funding for a given invention, the amendments provide that in the event that CIRM funds 50% or more of a CIRM Funded Project then the State of California will receive 25% of the Grantee's licensing revenue which rises from the licensing of CIRM Funded Technology (e.g. data) or CIRM Funded Inventions resulting in whole or in part from the CIRM Funded Project. In the alternative, if CIRM funded less than 50% of the Project, the State will receive 15% of the Grantee's licensing revenues.
- By virtue of an amendment to the definition of Licensing Revenue, For-Profit Grantees will not be required to share pre-commercial revenues such as upfront payments and development milestone payments. This is consistent with recent amendments to the Loan Administration Policy which recognize that pre-commercial revenue is akin to a payment in arrears for prior investments.
- For-Profit Grantees and Collaborators will be required to share licensing revenues with California which, for example, arise from the licensing of methods, but in order to avoid double payments arising from the same income stream, For-Profits will not have an obligation to share with CIRM any royalty income they receive if CIRM is receiving a royalty on the same revenue stream from a Commercializing Entity pursuant to section 100608(b).

Royalty on Net Commercial Sales (Section 100608(b)):

The "self-commercialized" revenue provisions of the current regulatory scheme are revised to smooth out the payment obligation and to extend the obligation to commercializing entities. This provision will apply to commercial sales revenues (not licensing revenues) received by a "Commercializing Entity" to the extent the CIRM funded Drugs, products or services resulted in whole or in part from CIRM grants to a For-Profit Grantee. It amends the revenue sharing formula as follows:

- Sets the rate of payout owed to California to one-tenth of one percent (0.1%) per one million dollars (\$1Million) in Grants provided to For-Profit Grantee(s) for the lesser of (i) 10 years or (ii) nine times (9x) the Grant; and

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- o Includes a follow on 1% royalty where Net Commercial Revenue exceed \$500 million per year and where CIRM grant(s) aggregate more than \$5 million and involve a patented CIRM- Funded Invention.