CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

M E M O R A N D U M

TO: MEMBERS OF THE INDEPENDENT CITIZENS OVERSIGHT COMMITTEE

FROM: ELONA BAUM, GENERAL COUNSEL

SUBJECT: CONSIDERATION OF AMENDMENTS TO CIRM'S INTELLECTUAL PROPERTY REGULATIONS

DATE: December 4, 2010

Background

On September 30, 2010 Governor Schwarzenegger signed into law Senate Bill No. 1064, which was sponsored by Senator Alquist. The law becomes effective January 1, 2011 and makes a number of amendments related to the California Stem Cell Research and Cures Act, commonly known as Proposition 71. The bill addressed numerous aspects of CIRM's operations. In addition, it codified, with four modifications, CIRM's revenue sharing and access plan regulations.

The four modifications were:

(1) changing the time period for submission of access plans to the ICOC

(2) authorizing the ICOC to waive access plan requirements if certain conditions are met

(3) changing the terminology relating to eligible recipients of access plans from "uninsured Californians" as provided for in CIRM IP regulations to "Californians who have no other means to purchase the drug" and

(4) changing the revenue sharing regulation which levies a 1% royalty on net sales in excess of $500 million annually so that it applies only in instances where more than $5million of CIRM funding generated patented inventions or technologies that "contributed to the creation of the product" generating such revenue. Currently under CIRM's regulations the 1% royalty would apply regardless of whether the CIRM Funded Invention or CIRM Funded Technology "involved in the achievement of" the $500 million in revenue was patented or not.

In instances where CIRM's regulations are not inconsistent with these new statutes, but are rather additive CIRM may, but is not required to, amend its regulations. This would be the case with item #2 and #4 above. However, where there is an inconsistency between CIRM's regulations and the statute, then CIRM's regulations must be changed accordingly to eliminate the inconsistency. This is the case with items #1 and #3 above.

On November 23rd, the Intellectual Property Task Force met and voted to approve the amendments set forth below which address the statutory modifications described above as item #1 (access plan submission date) and #4 (1% royalty provision). This agenda item seeks the ICOC's approval of these two amendments to CIRM's IP regulations. As stated above, the ICOC has discretion to refrain from amending the 1% royalty provision in CIRM's regulations, but it is required to make the timing of access plan proposals consistent with the statute.

Early next year, staff will present to the ICOC and the IP Task Force the two other areas where the statute's revenue sharing and access provisions differ from our regulations.

Proposed Amendments

Summary

1) Proposed Amendment to Section 100607 Access Requirements for Products Developed by Grantees

Both SB 1064 and CIRM's intellectual property regulations require Grantees and Exclusive Licensees to submit drug access plans to CIRM for approval after a "public hearing." CIRM's regulation also applies this requirement to Collaborators and differs in terms of the date upon which this submission must be made. In order to make CIRM's regulations consistent with the SB 1064 statutory provisions, the IP Task Force approved an amendment to Section 100607, which:

(1) Changed the deadline for submitting for the proposed access plans from the existing provision of "no fewer than 90 calendar days prior to the time the Drug is commercialized in California" to "within 10 business days following approval of the drug by the federal Food and Drug Administration," provided within the 10 day period an extension is not requested and granted, and

(2) Required the deadline, even with an extension, to be not more than 30 days after FDA approval.

It should be noted that the proposed amendment did not eliminate the obligation of Collaborators to respond to the access plan requirement even though the statute did not codify this requirement.

2) Proposed Amendment to Section 100608 Revenue Sharing

The IP Task Force also approved an amendment to CIRM's revenue sharing regulation relating to the 1% royalty provision which applies to net commercial revenues in excess of $500 million in a calendar year when grantees receive in excess of $5 million in funding. Under the proposed amendment, approved by the IP Task Force, this provision would apply only in circumstances where patented CIRM Funded Invention or patented CIRM Funded Technology contributed to the product generating the revenue.

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SB 1064

The pertinent provisions of SB1064 are set forth as follows:

"The intellectual property standards that the ICOC develops shall include:

a) A requirement that each grantee or the exclusive licensee of the grantee submit a plan to CIRM to afford access to any drug that is, in whole or in part, the result of research funded by CIRM to Californians who have no other means to purchase the drug. The access plan must be consistent with industry standards at the time of commercialization in California, accounting for the size of the market for the drug, and the resources of the grantee or exclusive licensee.

b) A requirement that the grantee or exclusive licensee either submit the plan required by subdivision (a), seek an extension from CIRM, or notify CIRM of its intention to seek a waiver, within 10 business days following final approval of the drug by the federal Food and Drug Administration. If the grantee seeks an extension, the plan must be submitted within 30 business days following final approval of the drug by the federal Food and Drug Administration. The plan shall be subject to the approval of CIRM, after a public hearing and opportunity for public comment. [Emphasis added]

c) A process by which the ICOC may waive the requirement in subdivision (a) if the ICOC determines, after a public hearing, that in the absence of the waiver, development and broad delivery of the drug will be unreasonably hindered or that the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to subdivision (a). The process shall include the requirement that a request for a waiver shall be posted on CIRM's Internet Web site for a minimum of 10 business days in advance of the public hearing and that CIRM shall notify the legislature if the ICOC grants a waiver request, including the reasons that justified the waiver request.

d) Procedures to protect from public disclosure proprietary information submitted by grantees and exclusive licensees to CIRM pursuant to this section.

[Emphasis added]

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"(iv) In addition to the payments required by clauses (i), (ii), and (iii), the first time that net commercial revenues earned by the grantee from the product equal or exceed five hundred million dollars ($500,000,000) in a calendar year, the grantee shall pay the General Fund 1 percent annually of net commercial revenue in excess of five hundred million dollars ($500,000,000) for the life of any patent covering the invention or technology, if the grantee patented its invention or technology and received a CIRM grant or grants amounting to more than five million dollars ($5,000,000) in support of the research that contributed to the creation of the product.

(3) The ICOC shall have the authority to adopt regulations to implement this subdivision. The ICOC shall also have the authority to modify the formulas specified in subparagraphs (A) and (B) of paragraph (2) through regulations if the ICOC determines pursuant to paragraph (1) that a modification is required either in order to ensure that essential medical research, including, but not limited to, therapy development and the broad delivery of therapies to patients, is not unreasonably hindered, or to ensure that the State of California has an opportunity to benefit from the patents, royalties and licenses that result from basic research, therapy development, and clinical trials. The ICOC shall notify the appropriate fiscal and policy committees of the Legislature 10 calendar days before exercising its authority to vote on the modification of the formulas specified in subparagraphs (A) and (B) of paragraph (2)."

Track Changes

ICOC IP Task Force Meeting
November 22, 2010

Exhibit A

§ 100607. Access Requirements for Products Developed by Grantees.

(a) A Grantee, a Collaborator or an Exclusive Licensee that is commercializing a Drug, as defined in Title 17, California Code of Regulations, section 100601, subdivision (i), that resulted in whole or in part from CIRM-Funded Research must submit a plan to afford uninsured Californians access to such a Drug.

(b) A Grantee, a Collaborator or an Exclusive Licensee that commercializes a Drug must submit the access plan described in subdivision (a) of this regulation to CIRM **within 10 business days following final approval of the drug by the federal Food and Drug Administration unless within that timeframe, the Grantee, Collaborator or Exclusive Licensee seeks an extension from CIRM. If CIRM grants an extension, the access plan must be submitted no later than 30 business days following final approval of the drug by the federal Food and Drug Administration.**

(d) The access plan must be consistent with industry standards at the time of commercialization accounting for the size of the market for the Drug and the resources of the Grantee, the Collaborator or its Exclusive Licensee. Grantees, Collaborators and/or their Exclusive Licensees shall have the burden of establishing that the proposed access plan satisfies the requirements of this Section.

(e) The access plan shall be subject to the approval of CIRM after a public hearing conducted by CIRM that provides for receipt of public comment. CIRM may adopt appropriate procedures to protect proprietary information submitted by Grantees, Collaborators and Exclusive Licensees in connection with said public hearing. Approval shall not be unreasonably withheld. Overall, CIRM shall not require that proposed Access plans exceed industry standards for such plans at the time of commercialization in California.

(f) Access plans approved hereunder shall make Grantees, Collaborators and Exclusive Licensees that commercialize a Drug responsible only for providing the Drug itself. Nothing herein shall require the Grantee, Collaborator or Exclusive Licensee to be

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responsible for any costs of administering the Drug nor for any associate costs of medical procedures or protocols for the Drug therapy, nor for any costs for attendant care.

(g) A Grantee, Collaborator, or an Exclusive Licensee that is commercializing the Drug must provide a Drug, that resulted in whole or in part from CIRM-Funded Research, at a price as provided in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) (or a successor statewide prescription drug discount program) to eligible Californians under said program.

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(h) A Grantee, Collaborator or its Exclusive Licensee that is commercializing the Drug must sell a Drug, that resulted in whole or in part from CIRM-Funded Research, and which is purchased in California with Public Funds (as defined in Title 17, California Code of Regulations, section 100601, subdivision (q)) at any benchmark price described in the California Discount Prescription Drug Program or a successor statewide prescription drug discount program.

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(i) This regulation is not intended, and this regulation shall not be construed, to preempt or prevent any other requirement under state or federal law or regulation, or agreement or contract, that would result in selling a Drug at a lower price than provided hereunder.

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§ 100608. Revenue Sharing.
(a) A Grantee and Collaborator must share with the State of California a fraction of Licensing Revenue received under a License Agreement for a CIRM-Funded Invention, CIRM-Funded Technology, or results of CIRM-Funded Research, as follows:

(1) Subject to subdivision (a)(2) of this regulation and to adjustments made in accordance with the provisions hereof, the amount owed is 25 percent of Licensing Revenue received in excess of $500,000 to the State of California for deposit into the State's General Fund (such payments to be used by the State of California in a manner consistent with Title 35 United States Code, Section 202, subdivision (c)(7)). The threshold amount of $500,000 (in the aggregate) shall be adjusted annually by a multiple of a fraction, the denominator of which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the Bureau of Labor Statistics of the United States Department of Labor and published for the month of October 2009, and the numerator of which is such Index published for the month in which the Grantee accepts the Grant.

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

(b) A Grantee and Collaborator must share with the State of California a fraction of any Net Commercial Revenue it receives from a self-commercialized product it commercializes itself and which resulted from its CIRM-Funded Research (regardless of whether a CIRM- Funded Invention or CIRM-Funded Technology is involved) as follows:

(1) Grantees and Collaborators must pay royalties to the State of California for deposit into the State's General Fund on Net Commercial Revenue exceeding the threshold amount described in subdivision (a)(1) of this regulation. Total payments under this subdivision (b)(1) shall equal and not exceed three times the total amount of the CIRM Grant or Grants that led to the product. The rate of payback of the royalty shall be at a rate of three (3) percent of the annual Net Commercial Revenue from the product.

(2) In addition, if Net Commercial Revenue from a product commercialized by the Grantee, or Collaborators and which resulted from its CIRM-Funded Research exceeds the milestone of $250 million in any calendar year, a one-time payment of three times the total amount of the Grant(s) awarded shall be paid to the State of California. In addition, if Net Commercial Revenue exceeds the milestone of $500 million in any calendar year, an additional one-time payment of three times the total amount of the Grant(s) awarded shall be paid to the State of California.

(3) In addition to any amounts due under any other provision of this regulation, where a patented CIRM-Funded Invention(s) or patented CIRM-Funded Technology is involved in the achievement of Net Commercial Revenue realized by a Grantee or Collaborator equivalent to or greater than $500 million in any year, and where a CIRM Grant or Grants amounting to more than $5 million (in the aggregate) were made in support of CIRM-Funded Research that contributed to the creation of Net Commercial Revenue, the Grantee or Collaborator will pay the State of California one percent

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annually of Net Commercial Revenue in excess of $500 million for the life of any patent covering such patented CIRM-Funded Invention or patented CIRM-Funded Technology.
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