

§ 100610. March-In Rights.

(a) CIRM may request that a Grantee, Collaborator or an Exclusive Licensee enter into a nonexclusive, partially exclusive, or Exclusive License Agreement with respect to a CIRM-Funded Invention or CIRM-Funded Technology, in any field of use or territory with a responsible applicant or applicants, upon terms that are reasonable under the circumstances.

(b) If a Grantee, Collaborator or an Exclusive Licensee refuses CIRM's request to enter into a License Agreement to a CIRM-Funded Invention or CIRM-Funded Technology as provided by this regulation, CIRM shall have the right to enter into such a license with an applicant on behalf of the Grantee or its Exclusive Licensee (march-in) if:

(1) the Grantee, Collaborator or an Exclusive Licensee has not made reasonable efforts to achieve practical application of a CIRM- Funded Invention and/or CIRM-Funded Technology, as applicable;

(2) the Grantee, Collaborator or an Exclusive Licensee have failed to provide or comply with a plan for access to a Drug in accordance with Title 17, California Code of Regulations, section 100607;

(3) the Grantee, Collaborator or Exclusive Licensee has unreasonably failed to use a CIRM- Funded Invention or CIRM- Funded Technology to alleviate public health and safety needs that constitute a public health emergency as declared by the Governor.

(c) One consideration in taking the action described in subdivision (b) of this regulation will be whether doing so will impinge on the Grantee's, Collaborator's or Exclusive Licensee's academic freedoms.

(d) CIRM will promptly notify a Grantee, Collaborator or an Exclusive Licensee of any adverse determination under this provision and the basis therefore, as well as its intention to exercise march-in rights ("March-In Notice").

(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.

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