



MARCH-IN RIGHTS under CIRM Regulations effective September 6, 2018

March-In Rights (Section 100650, Part X). An Awardee, its Collaborator, Exclusive Licensee and eventual Commercializing Entity are all subject to CIRM's march-in rights. The march-in rights parallel federal march-in rights under Bayh-Dole, which apply to discoveries arising from NIH funding and which are intended to prevent a useful drug discovery from being shelved. Like federal march-in rights, CIRM's march-in rights are designed to be used rarely (e.g., a licensee's refusal to use a discovery to address a public health emergency) and only after the exclusive licensee has had an opportunity to cure or appeal CIRM's determination to its Board.

March-In Rights

Section 100650, Part X of the CIRM IP Regulations covers March-In Rights. It was drafted to be similar in concept to the federal march-in rights established in the 1980 Bayh-Dole Act where the US government may require such a license where "action is necessary to alleviate health or safety needs which are not reasonably satisfied,"¹ or where the benefits of the [government-funded] invention are not being made "available to the public on reasonable terms."²

Under the Bayh-Dole Act there have been five petitions to exercise the march-in rights and the NIH has denied all the petitions.

Though the CIRM and its Board are not bound by these NIH determinations, they do provide guidance regarding the intent behind the Bayh-Dole Act.

Further information on March-In Rights can be found in the Intellectual Property FAQ -

https://www.cirm.ca.gov/sites/default/files/files/funding_page/IP_FAQ_9.6.2018.pdf

[17.] Are there circumstances where CIRM will force an Awardee to share CIRM-funded intellectual property?

Answer: In rare circumstances, perhaps. Like the federal government, upon the satisfaction of certain conditions (including failure of the Commercializing Entity/Awardee/Collaborator/Exclusive Licensee to cure) CIRM may intercede in certain circumstances on behalf of the State and grant exclusive or nonexclusive licenses if the Awardee/exclusive licensee:

- Fails to make reasonable efforts to achieve practical application of the invention or research data;
- Fails to comply with the access plan;
- Fails to use the data or invention to address a public health emergency declared by the Governor.

[18.] What if there is disagreement between the Awardee and CIRM over the exercise of march-in rights?

Answer: Prior to exercising march-in under the very limited circumstances described above, Awardees will be notified of CIRM's intentions and will have at least one year to comply before CIRM exercises its march-in rights, except in the case of health emergencies (which may be exercised at any time). If after this period the parties remain in dispute, the Awardee may appeal to the ICOC.

¹ Section 35 U.S.C. § 203(a)(2)

² Section 35 U.S.C. § 201(f)