

BY ELECTRONIC MAIL TO FORPROFITPREGS@CIRM.CA.GOV

November 21, 2007

Mr. Scott Tocher
Interim Counsel
California Institute for Regenerative Medicine
250 King Street
San Francisco, CA 94107

RE: Comments to Third Set of Proposed Changes to the CIRM Regulation Entitled: Intellectual Property Policy for For-Profit Organizations (IPPFPO), Issued Nov. 6, 2007

Dear Mr. Tocher:

The California Healthcare Institute (CHI) welcomes this opportunity to comment on the California Institute for Regenerative Medicine's (CIRM) third set of proposed changes to regulations addressing Intellectual Property Policy for For-Profit Organizations (IPPFPO) as released for public comment on Nov. 6, 2007. CHI represents the full biomedical sector of the California economy; our members include more than 260 of California's leading life sciences companies, universities, and academic research institutions.

As the advocate for California's statewide biomedical research and development community, CHI appreciates the time and effort the Independent Citizens' Oversight Committee's (ICOC) has directed towards the development of an intellectual property policy that conforms to the purpose and intent of Proposition 71, the California Stem Cell Research and Cures Act (Prop 71). We especially appreciate the consideration given to comments provided by stakeholders, such as CHI, in the development of this important policy.

Nevertheless, CHI remains opposed to certain provisions in the regulation, as revised, that if enacted are likely to deter industry participation in this important initiative. CHI has consistently held that intellectual property policies regulating transactions among academic institutions and commercial companies should be based on the federal Bayh-Dole Act (P.L. 96-517, Amendments to the Patent and Trademark Act).¹ While Bayh-Dole pertains to federally funded research in non-profit organizations, we suggest its basic principles apply to state funded research.

¹ See Statement of David L. Gollaher, Ph.D., President and CEO, California Healthcare Institute (CHI) before the Joint Informational Hearing of the Senate Health and Human Services Committee and Assembly Health Committee, Sept. 15, 2004

Because commercialization is essential for the development and production of new medicines, CHI maintains that the goal of CIRM intellectual property policies should be to *minimize* barriers to producing innovative new technology. CHI recognizes that Prop 71's language requires CIRM-funded research to provide "an opportunity for the state to benefit from royalties, patents, and licensing fees that result from the research."² Even so, we note that Prop 71 specifically requires that such opportunities be balanced "with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements."³

In their present form, requirements relating to biomedical material sharing, pricing and access, revenue sharing, and march-in rights, we believe, will hinder medical research and product development by creating substantial disincentives to commercial interest in licensing CIRM-funded inventions.

Publication Related Biomedical Materials Requirements – Section 100404

Under Section 100404, any CIRM grantee who publishes research findings must make the biomedical materials described in the publication available to any commercial, not for profit, or academic requester at no cost or at cost, promptly, and without bias. CHI foresees instances when CIRM grantees would use third parties' intellectual property in the course of their CIRM funded work. Should a grantee be required to provide free of charge to all requesters their CIRM funded work, including a third party's IP, then collaboration with the grantee would effectively eliminate patent protections for that third party. CHI believes that this obligation would deter collaborations between research-relevant IP holders and CIRM grantees.

Also, the language under Section 100404(e) is vague and does not provide the certainty necessary for a commercial organization to spend significant resources to develop either a CIRM grant proposal or a new research tools product funded by CIRM. The possibility that the prior approval required from CIRM to exempt a commercial entity from the obligations under this section could be arbitrarily withheld would discourage use of CIRM grant funds. We suggest that the prior approval and pricing reference be removed. Lastly, this section does not protect a grantee's investment should another entity reference or use the grantee's material in a publication prior to the material being made commercially available. To correct these risks to for-profit grantees we suggest item (e) be replaced by the following language: "*The obligations under this regulation cease when the materials are made broadly commercially available or if doing so would endanger the competitive position of the organization by conflicting with the business of the grantee*".

Pricing and Access – Section 100407

Section 100407 states that "a Grantee must submit a plan to afford uninsured Californians access to a Drug, . . . the development of which was in whole or in part the result of CIRM-funded Research." As explained in our previous comments, this provision is ambiguous and will create a great deal of uncertainty. Without specifically defining "access" and qualifying which patients will be eligible to receive therapies at a discount, these provisions are likely to discourage commercial interest in licensing CIRM-funded technologies from for-profit grantees. The long-term result could be that promising state-

² Text of Proposition 71, Sec. 3, Purpose and Intent

³ Prop 71 language establishing California Health and Safety Code, Division 106, Part 5, Chapter 3, Section 125290.30(h)

funded research will remain undeveloped, not producing the “life-saving regenerative medical treatments and cures” that are the core purpose of Prop. 71.

In the Fall of 2006 CHI surveyed its members to determine what impact the pricing and access requirements proposed by the IPPNPO (and similar language as contained in the IPPFPO) would have on companies and venture capital interest in potential licensing opportunities. The results were dramatic – over 80% indicated that they would be *much less likely* to consider licensing a technology, or investing in a start-up company based on a technology that carried such pricing and access mandates.

At a minimum, the IPPFPO should specify a funding threshold that would limit its access and pricing provisions to products for which CIRM funding represents a substantial portion of a product’s total development costs. Such a trigger should apply to CIRM funding whether it involves an invention developed by a company in part through direct CIRM funding to the firm or part of an invention licensed by a company from a CIRM grantee. The principle behind the trigger should be the *proportion* of CIRM funding in the total cost of bringing a product to market, not the *process* by which CIRM funding is provided. Failure to incorporate a threshold function in the IPPNPO will, we believe, make licensing and technology transfer of CIRM-funded inventions considerably less attractive in many instances where CIRM funding would be but a small part of any downstream commercialized product.

Revenue Sharing – Section 100408

Section 100408 provides that for self-commercialized products that result from CIRM-funded patented inventions, awardees must share net revenues in excess of \$500,000 with the State of California at a royalty rate between 2-5% (to be negotiated with CIRM), capped at three times the total awarded money. CHI acknowledges and appreciates the inclusion of language allowing for a threshold and maximum amount of revenue to be returned to the State. However, CHI would recommend that funding sources should explicitly include self-funding (i.e., if a company funds a project, that company should get credit for it). The current approach, taken largely from academic settings, substantially underestimates the expenses of drug development to arrive at “net revenue.” Should CIRM maintain a revenue-sharing provision in the IPPFPO, we suggest that the definition of net revenues be revised to more closely reflect private sector experience. We would also maintain, similar to our suggestions for the pricing and access provisions, that the revenue sharing regulations be clarified to apply only to instances where CIRM grant money is tied directly to a developed product.

As reflected in past decisions made at the federal level, CHI believes that direct revenue sharing and royalty provisions could create unnecessary obstacles for commercial enterprises working with the government. The greatest financial benefits to the state from CIRM-funded research and subsequent technology transfer and product commercialization will come from a broad range of economic factors including job creation, exports, increased income taxes, payroll taxes, capital gains taxes, and corporate income taxes.

March-In Rights – Section 100410

CHI is also concerned with the IPPFPO’s grounds for termination of licenses and “march-in” rights, especially as these provisions pertain to the pricing and access requirements addressed above. While based on provisions in Bayh-Dole, the IPPFPO differs notably by including among the circumstances for triggering march-in rights failure by licensees to adhere to pricing and/or access plans as described in the proposed Section 100410(b)(2). CHI maintains that these provisions, by increasing the risk of

litigation, add another layer of risk and uncertainty to commercial transactions. CHI therefore suggests that the ICOC remove pricing and access as grounds for both the triggering of CIRM march-in rights and the termination of licenses.

CHI also requests, consistent with Bayh-Dole, that “public use” requirements addressed in Section 100410(b)(3) be clearly specified to minimize uncertainty.

Conclusion

To promote technology transfer and commercial collaboration on CIRM-funded inventions and to limit barriers to stakeholder participation in research, licensing and commercialization, CHI suggest that the ICOC:

- Remove requirements in Section 100404 that would deter applicants from developing a CIRM grant proposal or a new research tools product funded by CIRM. Alter language requiring the disclosure of third party IP following the publication of research findings by a CIRM-grantee.
- Remove the pricing and access requirements in Section 100407. Recognizing that removal is unlikely, we suggest a well-defined threshold to limit these provisions to products for which CIRM funding is a significant and substantial portion of a product’s overall development costs. Provide clarity on the definition of access and how a company will identify patients that are to receive access to their product.
- Amend Section 100408 to provide that self-funding be included as a funding source in determining the threshold and maximum amount determination of revenue to be returned to the state. Alter the definition of “net revenue” to more closely reflect private sector experience.
- Remove pricing and access as ground for triggering march-in rights as contained in Section 100410.

CHI appreciates this opportunity to comment on the third revision to the CIRM Intellectual Property Policy for For-Profit Organizations. We believe a strong IPPFPO will advance CIRM-funded stem cell research and, ultimately, treatments for millions here in California and worldwide. This, in turn, will improve California’s health care system, benefit the California economy, and further promote the state’s biotechnology industry as a global leader. We hope that the ICOC will give careful consideration to our comments and incorporate them into the final IPPFPO.

We look forward to working with the ICOC as it finalizes this policy, and we would be happy to further discuss these comments in additional detail.

Thank you for your attention to this important matter.

Sincerely,



David L. Gollaher, Ph.D.
President and CEO