Summary of Major Comments & Recommendations
On the CIRM Intellectual Property for Non-Profit Organizations Regulations

Prepared by CIRM to support the Intellectual Property (IP) Task Force Subcommittee of the Independent Citizens Oversight Committee

7/14/2006

Sections:

The following digest is divided into three categories, identified above. The grouping of comments is based on a general assessment of the complexity of the policy entailed in the comment, as well as the technical nature of the comment. Comments which appear purely technical, such as suggestions to help clarify undisputed meaning and which implicate no policy debate or discussion, are not included in this document, although such recommendations may be accepted in final drafting of the regulations. Effort was made to distill comments to their essence while attempting to avoid extended quoting of material. The description of the comments is not influenced by any evaluation as to their merit or accuracy, and should be regarded solely as the opinions of the respective authors. Each comment is followed by a parenthetical reference to its source. The source materials may be found on CIRM's website, www.cirm.ca.gov, under the agenda materials posted for the July 14, 2006, IP Task Force Subcommittee meeting. The "Notes" section contains background information and, where appropriate, recommendations by staff.

CATEGORY A

1	**ISSUE:** Revenue Sharing – Abolish or Modify?

REGULATION: 100308
CIRM seeks to obtain a financial return on the public's research investment through the recovery of 25% of revenues from the grantee organization's (not the inventor's) share of revenues from licenses for CIRM-funded patented inventions. Consistent with their Bayh-Dole obligations, grantee organizations must share a fraction of revenues with the inventor(s). To defray administrative costs associated with patent expenses, CIRM will recover funds from a grantee organization when net revenues from a license or licenses of a CIRM-funded patented invention exceed $500,000 in the aggregate. In the event that CIRM partially funds research that leads to a licensed patented invention with revenues in excess of $500,000, the return to the State of California will be proportionate to the CIRM financial support.

COMMENTS: Abolish RS:
1. As demonstrated on federal level, benefits to state from research and tech transfer and product commercialization will come from job creation, exports, income/payroll/capital gains/corporate taxes. Recoupment policy will divert grantees' financial resources from additional research. (Ref. 2, pp.6-7)
2. RS makes CIRM funding less attractive to researchers; puts Cal at disadvantage as compared to other states and countries. (Ref. 7, p.3)

COMMENTS: Modify:
3. Define "revenues" to exclude equity: - such as stock, stock options, et cetera, due to difficulty of evaluation. (Ref. 2, p.6)

4. Cap RS to total investment by state: Support recoupment but should seek only repayment money lent or granted as opposed to an "equity" stake (proportional). Equity or proportional stake significantly chills downstream investment who can't/won't take on CIRM as equity partner in investment. (Ref. 13, p.3)

5. Increase RS from 25% to 50%: (Ref 15)

6. Lower threshold from $500k to $100k: Return on higher threshold is insufficient, esp since it's a percentage of "net" instead of "gross" revenue. Exclusive licensees usually reimburse the institution for patent costs. (Ref 2, p.2; 15)

NOTES:
1. Generally: Prop 71: "The ICOC shall establish standards that require that all grants and loan awards by subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements." (H&S Code § 125290.30, subd. (h).)

2. In re Comment 6: Precedence - other granting agencies have settled on $500,000 as a sharing trigger with their non-profit grantees.

2	**ISSUE:** Should the Research Use Exemption (RUE) be Abolished or Modified?

REGULATION: 100307

"Grantee organizations agree that California research institutions may use their CIRM-funded patented inventions for research purposes at no cost. Grantee organizations shall ensure that such use is preserved in their licenses of CIRM-funded patented inventions."

COMMENTS: Abolish RUE

1. Eliminates any incentive for private industry to make investments necessary to bring research to fruition. If all California customers must be served free, no commercial opportunity for research tools. Academic and non-profits don't have capabilities to commercialize fundamentally essential research tools. (Ref. 2, pp.7-9)

2. By blocking commercialization, CIRM-funded research tool will languish on university shelves and be distributed only through informal research networks; All non-commercial research is already covered by an existing RUE; Commercial licenses generally available to researchers; focus on goal of broad access for researchers, not the means. (Ref 3, pp.1-3)

3. Research tools are core enabling technologies – companies take the tool IP from universities and enhance and commercialize = enhanced biological understanding and faster, more repeatable tools and techniques. Opportunity to patent and commercialize is powerful incentive that is interrupted by RUE and incentive lost b/c Cal research market must be served at no cost; repeats early Bayh Dole era mistakes. (Ref. 4, pp. 4-5.)

4. Fulfillment of Prop 71 goal leading to innovative cures requires private cooperation. Primary value of life science companies is patents. RUE reduces ability of VC and investors to mitigate risk through licensing and royalty, resulting in fewer discoveries and less advancement in treatments. Overly broad: research institution may use invention to develop successor therapy, and partner into tech transfer agreement resulting in monetary benefit, leaving out the company that invested in developing original concept. Fewer companies will choose to participate in tech based on CIRM funded discoveries. (Ref 6)

5. RUE extends far beyond common law doctrine which allows otherwise illegal infringement when conduct is purely for philosophical and non-commercial inquiry; policy effectively reaches entire research market since market will be in California; considerable work done to research-related IP before its broadly available and useful – where companies come in; NAS analysis concludes patents not limiting biomedical research – when licenses sought for research purposes are generally easy to get and not costly; goal of broad dissemination already achieved through IP policies requiring licensing on reasonable terms and march-in for failure to keep inventions accessible to public for research. (Ref. 8,9,10)

6. IP protection encourages investment and disclosure – RUE fails here. (Ref. 9,10)

COMMENTS: Modify

7. RUE may negatively impact tools industry and research entities who may be victims of own success when large numbers of requests for access pour in. (Ref. 13, p.2) Suggest:

> *"Grantee organizations agree to provide unbiased access to CIRM-funded patented inventions to California research institutions for use in their internal non-commercial research at reasonable cost. If a grantee's CIRM-funded patented invention is made broadly commercially available at reasonable cost to California research institutions, then the grantee's obligation shall cease."*

COMMENTS: Support Existing Regulation:

8. CIRM improved upon Bayh-Dole by explicitly providing for RUE. (Ref. 14, p.4)

9. Extend RUE to reciprocate for out-of-state providers who make inventions available to Cal research institutions at no cost. (Ref. 1, p.3)

NOTES:

1. Redraft Suggestion: To clarify scope and intent.

"Grantee organizations agree that California research institutions *are free to practice the art of the grantee's* CIRM-funded patented inventions for research purposes *without requirement for a license* and at no cost. Grantee organizations shall ensure that such use is preserved in their licenses of CIRM-funded patented inventions."

1. In re Comments 1-6: January 23 IP Task Force meeting:
Policy strikes balance between wide public use of inventions and possible negative impact on tools patenting and commercialization. Suggested language likely not feasible.

2. In re Comment 7: Under the RUE, no requests would be needed for patented invention use. Because of how patents are written, anyone "skilled in the art" should be able to reconstruct the invention.

3. In re Comment 8: National Research Council of the National Academies, American Intellectual Property Law Association, the European Union and Japan support some form of RUE at the national and California level.

4. In re Comment 9: Reciprocity with out-of-state providers is problematic from a monitoring standpoint (how does state know the practice of third parties?), jurisdictional reach (out-of-state parties not subject to enforcement) and proportionality of sharing.

5. See section 125290.30, subd (h), quoted below in Note 1 to Issue 1.

6. Core CIRM IPPNPO Principle #3: "Patented inventions that are made in the performance of CIRM-funded research are to be made freely available for research purposes in California research institutions." This policy will allow researchers to experiment with state-of-the-art technology generated as a consequence of CIRM funding without constraints which might otherwise apply under patent law.

3	**ISSUE:** March-In Rights

REGULATION: 100310

CIRM maintains a mandatory licensing provision commonly referred to as the march-in authority, the purpose of which is to prevent the underutilization of CIRM-funded inventions. March-in would apply only to those research tools that could be defined as patentable inventions. Prior to exercising march-in rights, CIRM must determine that such action is necessary because of the failure of the grantee organization or its licensees to take effective steps to achieve practical application of the inventions in a particular field of use, to satisfy health or safety needs, or to meet requirements for public use. Unlike the research exemption license retained by CIRM, the march-in provision is not limited to use for research purposes. CIRM march-in rights may be exercised in the event of (but are not limited to) failure to license CIRM-funded patentable inventions, failure to meet plans outlined in license agreements, or failure to provide adequate availability of resultant products for the public use.

COMMENTS:

- **1. Abolish – Not a State's Right**: Federal government has proper authority and expertise to determine a public health emergency. For CIRM to assert right and expertise to suspend patent rights is inappropriate exercise of authority of CIRM. (Ref 6, p.2)
- **2. Clarify or omit "public use" trigger:** Subd. (a)(3): "To meet requirements for public use and the requirements have not been satisfied by the grantee organization or its licensee." Fed system refers to "public use specified in federal regulations. (Ref. 2, p.6; 7, p.4)
- **3. Omit pricing and access triggers:** Even though Bayh-Dole does not so provide, has been pressured to march in for price reasons. Feds have resisted and CIRM would find similar pressures, adding another layer of risk and uncertainty to academic-commercial transactions. (Ref. 2, p.5)
- **4. Add trigger for "reasonable pricing":** Needs to be more explicit: "*failure to make the resultant therapies available to the public at a reasonable price.*" (Ref 1, pp.1-2; 14, pp. 6-7; 15)
- **5. Establish detailed procedures.** (Ref 2, p.6)
- **6. Support march-in provisions:** Bayh-Dole model cumbersome due to appeals and agency system for determinations – deterring enforcement – 100310 provides clear indication rights won't be exercised until notice given and time for cure elapsed. (Ref. 14.p.5)

NOTES:

1. In re Comment 1: CIRM is within its rights to make agreements as a condition of funding research which provide for circumstances where patent rights are surrendered. Voluntary agreements circumscribing or affecting patent rights are commonplace.

2. In re Comment 5: Establishment of detailed procedures may or may not be necessary. Given the rarity that march-in is exercised at the federal level, presumably this issue might benefit from awaiting CIRM's experience with these provisions before prescribing set methods in advance, thus allowing for flexibility in the future.

3. In re Comment 4: "Public use" mirrors federal march-in language, which is undefined.

4. Federal government established a "reasonable pricing" clause for CRADA (Cooperative Research and Development Agreements) but abolished in 1997 after its demonstrated chilling effect on translation of research discoveries to public utility via the commercial sector.

CATEGORY B

4	**ISSUE:** Define Criteria for/Remove Termination of Licenses Due to "Failure to Keep Licensed Invention Available to the Public for Research Purposes"

REGULATION: 100306, subd. (f)
"(f) Grantee organizations shall negotiate relevant and specific grounds for modification or termination of the license. Examples would include failure to meet agreed-upon commercialization benchmarks, failure to keep the licensed invention reasonably accessible to the public for research purposes, and failure to reasonably meet the agreed-upon plan for access to resultant therapies as described in subdivision (d) of this regulation."

COMMENTS:
- Provision is vague and ambiguous. Language not consistent with initial requirement of 100307, pertaining to California research institutions. (Ref 2, p.9)

NOTES:
Recommendation: Accept suggestion. Can delete language regarding failure to keep accessible for research purposes, as likely redundant with RUE.

5	**ISSUE:** Remove the Requirement for Exclusive Licensees to Have "Plan for Access"

REGULATION: 100306, subd. (d):
"(d) Grantee organizations shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies and diagnostics only to organizations with plans to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, such licensees will agree to provide to patients whose therapies and diagnostics will be purchased in California by public funds the therapies and diagnostics at a cost not to exceed the federal Medicaid price. The CIRM may make access plans available for review by the ICOC on an annual basis."

COMMENTS: Abolish
1. IPPNPO wrong place to address health care access and affordability – not objectives

of Prop 71. Considering biotech's long product lead times, price regulation makes it more difficult to project return on investment. NIH attempts at fair pricing lead to poor results. (Ref 2, pp.4-5)
2. Restricts free markets. Without flexibility in pricing and structure of licenses, ability to secure private funding to support development of innovative products would be severely hindered. (Ref. 4, pp.3-4)

NOTES:
November 22, 2005 IP Task Force transcript:
The IP Task Force discussed a provision for a unique benefit to Californian "underserved" patients whereby public sector purchasers would be allowed to acquire resultant therapies at the same price as the federal government (p. 145).
January 23, 2006 IP Task Force transcript:
The IP Task Force originally discussed having the "plan for access" apply to all licenses, not just exclusive ones (p. 55 "All licenses" discussion). Compromise narrowed scope to include exclusive licenses as approved by ICOC 2/10/06.

6	**ISSUE:** Open Access

REGULATION: (no pre-existing regulation specifically on point)

COMMENTS: Mandate 6-month open access requirement for scientific articles:
1. Requirement of short abstract is incomplete to meet principle of sharing data and knowledge broadly and promptly. Making abstracts available does little to remove barriers to access. (Ref 5, pp.1-3) SUGGEST ADDITIONAL SUBDIVISION:

"*Within 6 months of publication of CIRM-sponsored research results in a scholarly journal or conference proceedings, PIs must place the scholarly work in a trusted non-commercial open-access online repository. This will require that the PI either a) retain copyright and license to a publisher only the right of first commercial publication or b) retain a license for this purpose if he/she transfers copyright for the scholarly work to a publisher. If the publisher refuses to allow the retention of such a license, the PI may apply to CIRM for a one-time exception to the requirement in the form of either a) a waiver of the requirement, or, preferable, b) an extension of the delay of open-access deposit of the work from 6 to 12 months.*"

COMMENTS: Mandate deposit of manuscript in open access library and data in database:
2. Publishers of scientific and tech articles insist on transfers of copyright as condition of publication. Abstract is insufficient, so final manuscripts should be deposited in an open-access library. Researchers should be encouraged to deposit data in an open-access database. (Ref. 14, pp. 7-8)

NOTES:
Recommendation: The proposal is beyond the intended scope of existing provisions

regarding information sharing. If Task Force desires, idea can be evaluated further for possible regulatory amendment at a later date.

7	**ISSUE:** Mandate Contribution of Patented Invention Use to Patent Pool

REGULATION: 100306, subd. (b)
"(b) Grantee organizations shall negotiate non-exclusive licenses of CIRM-funded inventions whenever possible. Nevertheless, grantee organizations may negotiate and award exclusive licenses for CIRM-funded inventions if such licenses are necessary to provide economic incentives required to enable commercial development and availability of the inventions. …"

COMMENTS:

- A patent pool would better promote rationale cited for this section, "optimizing the public good through widespread use of the invention." (Ref 1, p. 2; 15)
  SUGGESTED ADDITIONAL LANGUAGE:

" (b) Grantee organizations shall negotiate non-exclusive licenses of CIRM-funded inventions whenever possible. *To facilitate such licensing, grantees shall place CIRM-funded inventions in a patent pool unless an exclusive license is* necessary to provide economic incentives…."

NOTES:
Advised in November 2005 Joint Legislative Hearing by Professor Rebecca Eisenberg against patent pool at this stage given nascent stage of CIRM involvement in field. Advise against patent pool without knowing what the patents are about and how they relate to other existing patents in the field.

CATEGORY C

8	**ISSUE:** Add Statement Regarding Attorney General March-In Rights

REGULATION: 100310
(see Issue 2)

COMMENTS:
- Because of limited CIRM staff and emphasis on research, march-in rights should be assigned to the California Attorney General. (Ref 1, p.2; 11; 15)

NOTES:
Staff recommendation against this suggestion. First, the Attorney General's law enforcement jurisdiction is not a matter for the CIRM to regulate. The Attorney General's ability to enforce the state's march-in rights exists with or without the suggested language. Accordingly, it is unnecessary and without effect.

9	**ISSUE:** Define "Research Institution"

REGULATION: "Grantee organizations agree that California research institutions may use their CIRM-funded patented inventions for research purposes at no cost. Grantee organizations shall ensure that such use is preserved in their licenses of CIRM-funded patented inventions."

COMMENTS:
The term should include a clarification of whether the institution must be exclusively, primarily, or minimally involved in research, and what level of presence in California is necessary for the research institution to be a CRI. If only a minimal contact is required, any entity could rent a mail drop in California while conducting all of the exempt research out of state. (Ref 12, p.3)

NOTES:
On its face, a CRI is an institution that performs research in California. The "drop box" scenario described above would fall outside this term. Possible clarification:

"Grantee organizations agree that California research institutions may use their CIRM-funded patented inventions for research ~~purposes~~ *in California* at no cost. Grantee organizations shall ensure that such use is preserved in their licenses of CIRM-funded patented inventions."

10	**ISSUE:** Require Reciprocal Sharing of Publication-Related Biomedical Materials

REGULATION: 100304
"Grantees shall share biomedical materials described in published scientific articles for research purposes in California within 60 days of receipt of a request and without bias as to the affiliation of the requestor unless legally precluded. Under special circumstances, exceptions to the above are possible with approval by CIRM. Alternatively, authors may provide requestors with information on how to reconstruct or obtain the material. Materials are to be shared without cost or at cost."

COMMENTS:
- CIRM has stressed importance of widespread sharing; should recognize that valuable research will take place outside of California and should foster exchange of information with scientists around the world. (Ref 1, p.3) SUGGEST ADDING FOLLOWING:

"*…Following the principle of reciprocity, grantees shall share biomedical materials on the same basis with any non-California research institution that shares biomedical materials with California institutions.*"

NOTES:
Problematic for reasons outlined in Note #4, to Issue #2. Would require reporting to

CIRM of third party conduct regarding unregulated non-CIRM entities. Nothing in current policies prevent grantees from doing so.

11	**ISSUE:** Buttressing Exclusive Licensing Provisions

REGULATION: 100306

COMMENTS:

1. Discretion not to patent: Bayh-Dole presumes patents are always needed but this isn't always so. Makes little sense for patents on broadly enabling upstream research technologies that are ready for dissemination to researchers in both the public and private sectors and may be put to use in the lab without further investment in developing them as products. Grantees should have discretion not to patent. (Ref 14, p.5)

2. Create Explicit Presumption for Non-Exclusive Licenses: 100306b's requirement of non-exclusive licenses "whenever possible" should be strengthened to require grantees to justify deviations from an explicit presumption in favor of them. (Ref 14, p.6)

3. CIRM Revocation of Licenses: Subdivision (h) directs grantees to take action to modify or revoke license rights. CIRM should expressly reserve the right to do so to prevent egregiously unfair practices of licensees (where CIRM is in better position to make such a determination. (Ref 14, pp.6-7)

NOTES:

1. CIRM IPPNPO Policy, at p.35: "CIRM does not encourage patent protection for "upstream inventions", those that require significant further research and development efforts to realize the commercial application of the invention. For example, CIRM does not encourage patent protection for research tools, such as transgenic mice, receptors, or cell lines for research use (as opposed to therapeutic or diagnostic uses). For such research tools, the public interest is served primarily by ensuring that the research tool is widely available to both academic and commercial scientists to advance further scientific discovery."

2. In re Comment 2: Would likely require new regulation defining criteria and procedures for CIRM evaluation of grantee departure.

3. In re Comment 3: Staff recommends maintaining existing provision due to staff resource constraints.