CIRM Intellectual Property Information Session
For-Profit Regulations

September 11th and 12th, 2008

These materials and the accompanying presentations are provided solely for purposes of facilitating the September 11 and 12, 2008 Workshops. They are not intended to provide legal advice regarding any particular issue or circumstance. Recipients and participants are encouraged to seek advice as they may deem appropriate from independent counsel.

Governing Principles:

Ensuring Innovation and Fair Return

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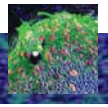
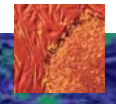
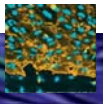
Proposition 71 requires the CIRM to balance competing benefits to California from:

1) patents, royalties and licenses, while

2) assuring that essential research is not unreasonably hindered by IP agreements.

Intellectual Property Policy Development

- Fifteen public meetings devoted to intellectual property policy development
- 18 presentations by experts and stakeholders
- Best practices survey of 20+ funding entities
- More than 100 interviews
- 12 Public Comment Rounds
- Almost 100 formal comment letters responded to under the Administrative Procedure Act

- Scope

Trigger: First CIRM dollar

"In Whole or in Part":

CIRM's For-Profit IP regulations generally apply to:

1) CIRM Grantees

and

2) A Grantee's Exclusive Licensee

Compatible with other funding sources

- Overall structure of For Profit IP Regulations

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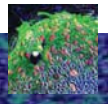
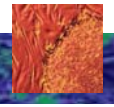
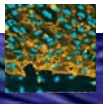
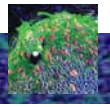
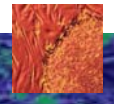
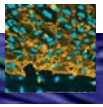
- Scope and Definitions
- Invention and License Reporting Requirements
- Publication and Press Release requirements
- Biomedical Materials Requirements
- Patents
- Licensing Patented Inventions
- Access Requirements
- Revenue Sharing
- March-In Rights

- CIRM-Funded IP – Rights and Responsibilities
  Regulations 100405 and 100406 (Slide 1 of 2)

Requirements:

- Encourage development by grantee or by non-exclusive licenses.
- If not going to self-develop, Grantee must make commercially reasonable efforts to negotiate non-exclusive licenses, unless it would put a grantee at a disadvantage with a competitor or if necessary to provide economic incentive to commercialize invention.
- Exclusive Licensees must agree to abide by the access and pricing provisions of section 100407.
- Grantee must take reasonable action to enforce the terms of license.

• CIRM-Funded IP – Rights and Responsibilities (Slide 2 of 2)

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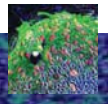
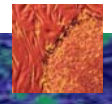
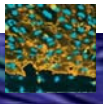
Balance:

- **Inventions and related IP Owned by Grantee**
- **Grantee Controls Patent Prosecution**
  - Choice of counsel
  - Selection of claims
  - Prosecution decisions
- **Licensing Controlled by Grantees**
  - Identify potential licensees
  - Establish terms
  - Negotiations
- **Grantee determines and executes strategy for exploitation**
- Exclusive licenses ok if exclusivity provides the economic incentive necessary to achieve development and availability of the invention.

  1) Must document licensee development and commercialization capabilities;

  2) Must include terms addressing all reasonably anticipated therapeutic and diagnostic uses;

  3) Must include terms describing a commercial development plan with appropriate benchmarks, remedies for failure to develop, and grounds for modification or termination

- March-In – 100410

Requirement: Like the federal government, CIRM reserves the right to intercede in certain circumstances on behalf of the State and grant exclusive or nonexclusive licenses if the grantee/exclusive licensee:

- Fails to make commercially reasonable efforts to achieve practical application of the invention or research data;
- Fails to comply with the access plan;
- Fails to satisfy requirements under section 100407, other than price;
- Fails to use the data or invention to address a public health emergency declared by the Governor.

Balance:

- Cure Period: Grantees have at least one year to comply before exercise of march-in, except for health emergencies. Right of appeal to ICOC.
- Parallels obligation in private exclusive license arrangements
- Limited circumstances

- Revenue Sharing: Different formulas for Grantee Licensing Revenues

Requirement: Where a grantee elects to license a CIRM-funded patented invention (instead of self-commercializing), it must share 25% of Grantee's revenue from the license.

Balance:

- Proportional Payout: Where funding sources additional to CIRM contributed to the development of the invention, then the return to the State is proportional to CIRM's participation.

- Sharing not triggered until after $500,000 in revenues.

• Licensing Revenues – Examples

1) Grantee accepts CIRM grant and patents a discovery resulting from the CIRM-funded research. No funds from other sources were used in the development of the patented invention. Grantee licenses the invention to a third party and receives 1 million dollars in licensing revenue the first year.

   Result: CIRM receives 25% of the grantee's share in excess of $500,000 = $125,000.

2) Same scenario above, but CIRM's funding represents 1/10th of the total funding the grantee used to develop the invention.

   Result: The state receives 1/10th of the 25% of the licensing revenue, or $12,500.

- Revenue Sharing – Self-Commercialization
- Non-Blockbuster

When revenues exceed $500,000 in a year for a self-commercialized product, then:

- Return 3 times the total grant paid back at a rate of 2-5% of annual revenue.

Example 1: Grantee with $1 million grant commercializes drug that earns $400,000 in year one.

Return to the state: $0.

Example 2: Same as above: drug earns $10,000,000 in year two.

Return to the state: $3 million paid at rate of 2-5% of annual revenues.

- Revenue Sharing – Self-Commercialization
- Blockbuster

In addition to any payments just described, additional 3x grant payments are due at each of the following triggers:

1) When annual revenues exceed $250,000,000; and
2) When annual revenues exceed $500,000,000.

Example: Prior scenario, but grantee receives $300 million in third year.

Result: In addition to the earlier payments, an additional $3 million now due.

In the event a CIRM-funded patented invention is involved and the revenue exceeds $500,000,000, then an additional 1% royalty due on amounts over $500,000,000 where CIRM funding exceeds $5 million.

Example: Same scenario above, but grantee receives $600 million in year four and used a CIRM-funded patented invention.

Result: CIRM receives additional $3 million, but no royalty because the grant is less than $5 million.

Access Plans for Uninsured Californians

Requirement:

- Grantees and their exclusive licensees must submit a plan to afford uninsured Californians access to a Drug.
- Plan is subject to approval by CIRM after a public hearing providing for receipt of public comment.

Balance:

- Plans already prevalent in industry as “patient assistance programs.”
- Standard: “consistent with industry standards” at the time of commercialization.
- Plans may account for the size of the market and the resources of the grantee/licensee.
- Grantee pays only for Drug, not peripherals, related costs or other care.
- Small percent of overall market

• Pricing Requirements for Californians – 100407

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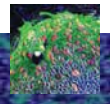
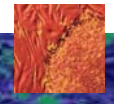
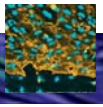
Requirement:

- Grantee/Exclusive Licensees must participate in the CalRx program for underinsured Californians and provide a drug, the development of which was in whole or in part the result of CIRM-funded research, to those eligible at the CalRx prices.
- Grantee /Exclusive Licensees must also provide Drugs to publicly-funded purchasers at one of the benchmarks described in CalRx.

Balance:

- Only if self-commercialized or exclusively licensed.
- Limited to duration of patent.
- Small percent of overall market

- Publishing and Press Release Requirements: Sections 100403 & 100409

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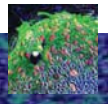
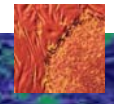
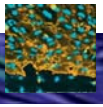
Requirements:

- Copies of articles regarding CIRM-funded research published in scientific journals must be given to CIRM along with an abstract.
- Articles must acknowledge CIRM funding.
- Provide notice in advance of press releases discussing CIRM-funded research.

Balance:

- Grantee determines publishing schedule and contents.
- Notification and acknowledgment are common features in grant agreements.

Administrative Elements: Invention and Licensing Reporting: 100402

A Grantee must make annual reports during and for 15 years after the project period regarding:

- 1) all patent applications regarding inventions arising from the research and detailed description of the invention;
- 2) issuance or nonissuance of patent applications;
- 3) at time of patent application, the percentage of support provided by CIRM and all other sources that contributed to the discovery of the invention;
- 4) licensing agreements for CIRM-funded inventions and related performance
- 5) revenues received from any CIRM-funded patented invention.
- 6) CIRM has audit rights

Balance:

- Elements are familiar components of research funding agreements

Sharing of Publication-Related Biomedical Materials - Regulation 100404

Requirement: When a Grantee publishes a scientific paper describing tangible research material of biomedical relevance first produced in CIRM-funded research (except for therapeutic products or diagnostic products), such materials must be shared for research purposes for free or at actual cost to a requestor in California within 60 days.

Balance:

- CIRM may approve **alternatives** if:
  - The financial burden becomes onerous
  - The sharing request is in direct conflict with the business of the grantee
  - The material or its transfer could pose a public health risk
  - The request is otherwise inappropriate, as determined by the CIRM.
- In lieu of sharing, grantee may **provide requestor with the information** necessary to reconstruct or obtain the material
- With CIRM's prior approval, the obligations to share **cease when the materials are broadly commercially available**
- **No obligation to share third party materials** described in publications such as raw materials use to develop the published biomedical material, or materials covered by third party IP rights