Intellectual Property Task Force Presentation

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&

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Intellectual Property Task Force Products:

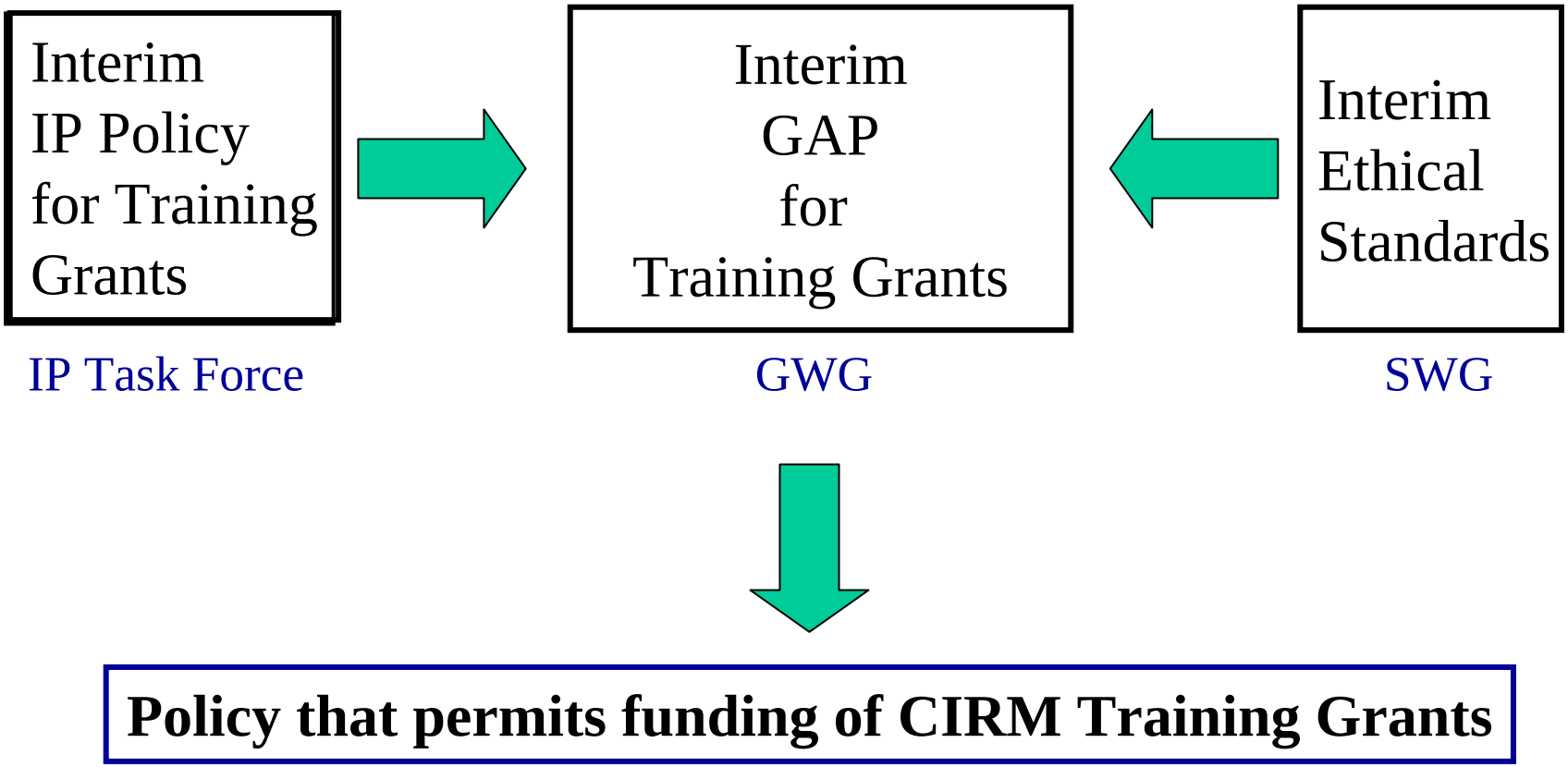
Interim intellectual property policy for training grants

Goal: Dec. 6, 2005

Final intellectual property policy

Goal: Spring, 2006

Multiple Inputs for Interim Training Grant Policy



Forms of Intellectual Property

- Patentable subject matter
  - Composition of matter (“things”)
    - e.g. therapeutics, diagnostics, stem cell lines
  - Process (“technology”)
    - e.g. assays, methods
- Know-how
- Copyrightable subject matter
  - Software
  - Databases
  - Research reports, articles

Why patent?

More than 200 years ago, the Constitutional Convention included in the U.S. Constitution the power "to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Almost 90 years later, President Lincoln addressed the importance of patenting, when he said, "the patent system has added the fuel of interest to the fire of genius."

- **To force the inventor to disclose the invention to enable the work of others**
- **To allow the inventor to enjoy financial benefits of the invention after disclosure**

Technology Transfer: two routes

- Licensing: the process by which an owner of the invention permits a second party to use the invention
  - Can by accompanied by payment
  - Licenses can be exclusive or non-exclusive
  - Is not a transfer of ownership
- Informal sharing of know-how
  - In aggregate, much larger than licensing
  - Principle route is publication

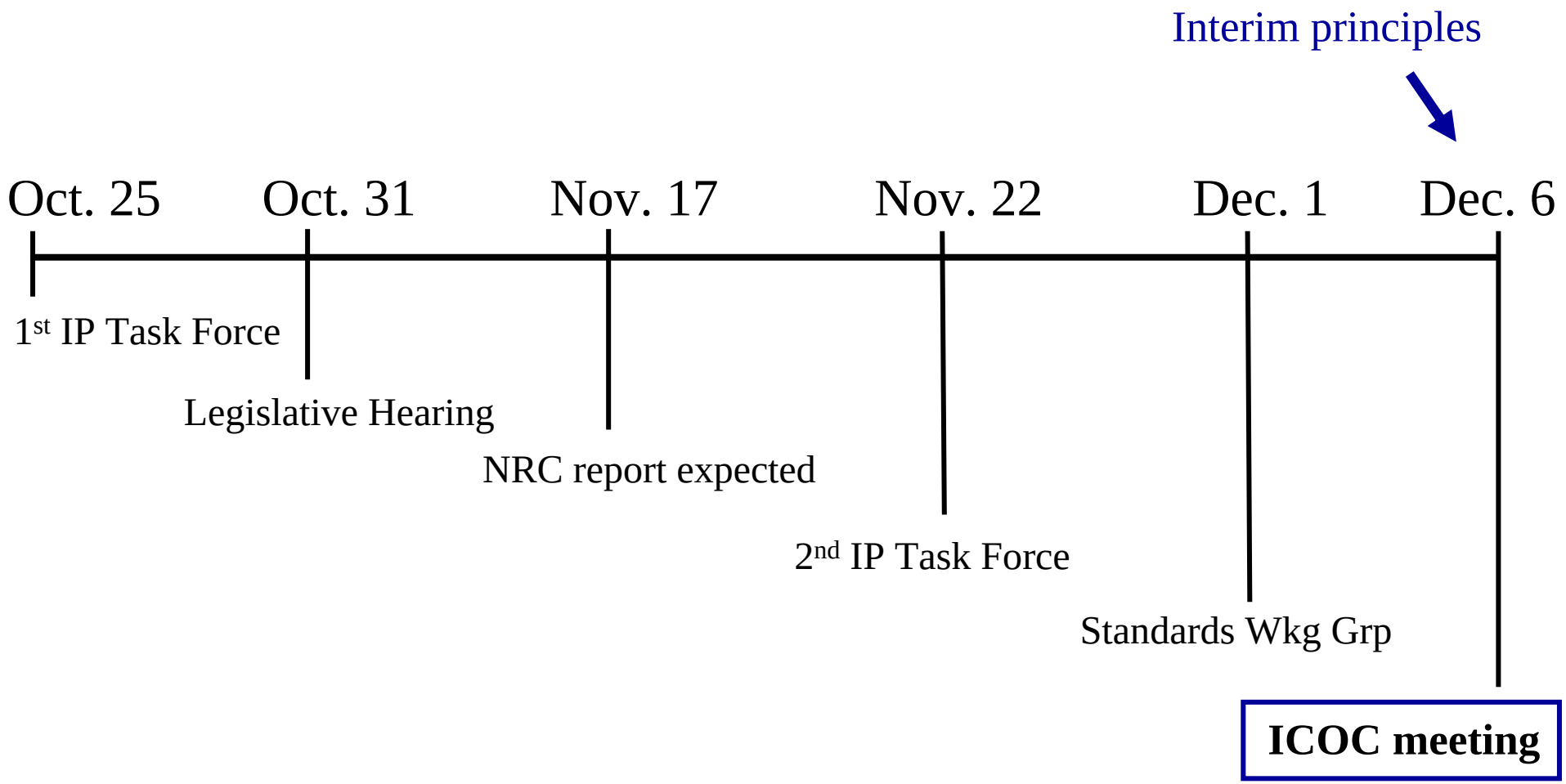
California Stem Cell Research and Cures Act
(Proposition 71)

125290.30. Public and Financial Accountability Standards

(h) Patent Royalties and License Revenues Paid to the State of California

The ICOC shall establish standards that require that all grants and loan awards be 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.

Important IP Task Force Dates



Partial List of Relevant Reports

- 1998 Guidelines for Licensing of Genomic Inventions
- 1999 Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources
- 2002 Association for University Technology Managers: Annual Report
- 2003 Sharing Publication-Related Data and Materials
- 2003 Independent Evaluation of the International AIDS Vaccine Initiative
- 2003 Association for University Technology Managers: Annual Report
- *2004 A Patent System for the 21st Century
- 2004 IAVI Annual Report
- *2004 California's Biomedical Industry
- 2005 Patents, Material Transfers, and Access to Research Inputs in Biomedical Research
- 2005 Considerations in Developing an Intellectual Property Model for Research Grants Awarded by the California Institute for Regenerative Medicine
- *2005 Policy Framework for Intellectual Property Derived from Stem Cell Research in California
- *2005 Implementation of Proposition 71: Options for Handling Intellectual Property Associated with Stem Cell Research Grants
- *2005 Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation and Public Health

Presentations considered by IP Task Force

October 25th IP Task Force Meeting

- CCST presentations by:
  - Susan Hackwood
  - Steven Rockwood
  - Alan Bennett
  - Pamela Samuelson
- Biotechnology/IP presentation:
  - Fred Dorey (Cooley Godward)

October 31st Legislative Hearing

- State Treasurer's Office/ Orrick Bond Counsel
- James Pooley (CCST)
- Rebecca Eisenberg (U of Michigan)
- Merrill Goozner (Center for Science in the Public Interest)
- Jennifer Washburne (New America Foundation)
- Labeeb Abboud (IAVI)
- Carol Mimura (UC Berkeley)

November 22 IP Task Force Meeting

- James Harrison (APA reulations)
- State Treasurer's Office
- Orrick, Herrington and Sutcliffe
- Brian Wright (NRC report committee)
- Rebecca Eisenberg's testimony
- Richard Klausner (former Head Global Health Programs Gates Foundation)

IP Models: CCST interim report

A Bayh-Dole based model proposed for CIRM

- Grantees own IP rights
- Require that grantees plan for IP management to advance science in California
- Do not require remuneration from any resultant revenue stream
- Require that researchers make tools available to other researchers
- Require that CIRM-funded IP is developed into therapeutics and diagnostics
- Retain march-in rights
- Reserve the right to use CIRM-funded IP by or on behalf of CIRM

IP Models: IAVI

Two models with individually tailored IP plans

- Research
  - IAVI research consortium retains exclusive IP rights
- Development
  - Grantees own IP rights
  - Individually negotiated IP agreements require that vaccines be provided at reasonable cost in developing countries
  - Return on investment linked with collaborators to sell vaccines at affordable costs in developing world
  - Encourages grantees to commercialize discoveries to greatest extent possible
  - Retains march-in rights

IP models: Eisenberg Recommendations

- Allow grantees to own IP rights
- Reserve the right for CIRM researchers to use CIRM-funded IP
- Evaluate the “exceptional circumstances” aspect of federal law (for invention title ownership) for a non-proprietary approach to furthering CIRM technology transfer goals
- Encourage the dissemination of data and biomedical materials
- Avoid a “tax” on any revenues generated by CIRM-funded inventions
- Avoid a patent-pooling approach as a foundational principle but reserve the right to enable one if a need arises

Questions to guide policy discussions:

1. Who should own any inventions that may arise from CIRM funding?
2. How shall CIRM require the sharing of data, tools, technology, and intellectual property?
3. Should CIRM create a research exemption for the use of intellectual property for basic research purposes?
4. What licensing requirements should be adopted by CIRM grantees?
5. Should CIRM retain “march-in” rights?

Sharing policy: non-patented and patented subject matter categories under discussion

a) Data

b) Technologies: processes

c) Biomedical materials –

broadly defined by NIH to include:

- cell lines
- monoclonal antibodies
- reagents
- animal models
- combinatorial chemistry libraries
- clones and cloning tools
- databases and software

Interim IP Policy Concepts for Training Grants

- Grantees own technology
- Data sharing: we want to push the envelope of current practice toward much more open, etc.
  - We strongly support the widest possible sharing
- Create research exemption
- Licensing:
  - Royalties: tax?
    - "We anticipate there might be a tax"
  - Preference for companies with a plan for patient therapy access
- March-in Rights: CIRM would maintain march in rights for:
  - Failure to develop
  - For public health and safety reasons