

CALIFORNIA COUNCIL ON
SCIENCE AND TECHNOLOGY

Sustaining Members •

*University of California
California Institute of Technology
California State University
Stanford University
University of Southern California
California Community Colleges*

May 25, 2005

The Honorable Senator Ortiz
California State Senate
State Capitol Building, Room 5114
Sacramento, CA 95814

RE: **Status of IP Study Requested by ACR 252 and ACR 24**

Dear Senator Ortiz:

We are writing to provide a brief update on the status of the California Council on Science and Technology's (CCST) project to examine intellectual property (IP) arising from state supported agreements, contracts, and grants. This project is being conducted at the request of the California Legislature.

In September 2004, Assembly Concurrent Resolution 252, authored by Assembly Member Gene Mullin, was passed in both the Assembly and Senate. ACR 252 (attachment 1) asks CCST to consider promoting the utilization of intellectual property arising from state supported agreements, contracts and grants and requests CCST to work with the State Department of General Services as well as state and federal government experts in contract and licensing, research and development practitioners, experts in technology transfer, and individuals representing the public interest.

As a consequence of the state's new stem cell initiative, created by Proposition 71, an amendment to ACR 252 was authored by Assembly Member Gene Mullin (ACR 24) requesting CCST extend this work and provide specific recommendations on handling IP derived from stem cell research. ACR 24 (attachment 2) requests that the IP Study Group produce an "interim report" tailored to the needs of the nascent California Institute for Regenerative Medicine (CIRM) by the end of June.

CCST has responded to this legislative request by developing a project plan, identifying a main Study Group and a supporting Working Group. The interim report on IP derived from stem cell research is on track to be completed by the end of June.

CCST's IP Study Group consists of 17 experts who represent a diverse set of skills, including industry, academic research institutions (both S&T experts and IP/tech transfer experts), national laboratories, private sector lawyers, government agencies, and public interest/economic development.

The members are:

Co-Chairs

Alan B. Bennett, Associate Vice Chancellor for Research, Office of Research, Technology-Industry Alliances, University of CA, Davis
Stephen D. Rockwood, Executive Vice President, Science Applications International Corporation

Members

Susan Bryant, ICOC member and Dean, School of Biological Sciences, University of California, Irvine

Ronald W. Cochran, Executive Officer, Lawrence Livermore National Laboratory

Lawrence B. Coleman, Vice Provost for Research, University of California

Cynthia Curry, Senior Staff Counsel, Office of Legal Services, Department of General Services

Michael Goldberg, ICOC member, Mohr, Davidow Ventures, Silicon Valley Office

Ginger Graham, President and CEO, Amylin Pharmaceuticals

Wayne Johnson, Vice President, University Relations Worldwide, Hewlett-Packard Company

Katharine Ku, Director, Office of Technology Licensing, Stanford University

Meyya Meyyappan, Director, Center for Nanotechnology, NASA Ames Research Center

Roger G. Noll, Morris M. Doyle Professor of Public Policy, Stanford University

James Pooley, Partner, Milbank, Tweed, Hadley & McCloy LLP

Pamela Samuelson, Professor, School of Information Management & Systems, University of California, Berkeley

Robert J. Spinrad, Consultant

Richmond A. Wolf, Director, Office of Technology Transfer, California Institute of Technology

Julie Meier Wright, President and CEO, San Diego Economic Development Corp.

In addition to the Study Group, there are 11 members of a Working Group, which consists of subject matter experts familiar with IP issues and with the policy interface between the state government and the research community.

The IP Study Group has met three times to date. At its first meeting on March 16th at the Office of Technology Licensing at Stanford University, the committee defined the scope of the project, described elements needed in the final report to meet the request of the state, and identified information that needed to be gathered and reviewed in order to be responsive to the Legislature's requests in both ACR 252 and ACR 24.

The second meeting was held on April 19th in Oakland at the UC Office of the President. The focus of this meeting was to explore the matters related to IP within the biomedical research enterprise. Invited presenters were Dr. Zach Hall, Interim President, California Institute for Regenerative Medicine; David Mowery, Professor of New Enterprise Development at the Haas School of Business, UC Berkeley, who provided history and background on the Bayh-Dole Act and its effects; Vern Norviel, Partner, Wilson Sonsini Goodrich & Rosati, a law firm that specializes in IP counseling and patents; and Dr. David Martin, a former academic biomedical researcher who has senior executive and leadership experience in several biotechnology firms.

The third meeting was held on May 17th at the California Institute of Technology. That meeting focused on review of a preliminary draft of the Study Group's interim report.

The IP Study Group is now actively working on revisions of the draft report. Although it is too early in the process to share the report, we can describe in general what it will contain.

Draft Outline of CCST IP Study Interim Report on IP Derived from Stem Cell Research

- An Introduction to Biotechnology R&D - how it works
 - This section will provide background on the typical timeline and investment involved in bringing a biotech product to market from the initial research concept.

Page 3

The Honorable Senator Ortiz

May 25, 2005

- Background on the federal Bayh-Dole Act
 - This section will describe the basic provisions of the Bayh-Dole Act, with a brief history of the circumstances leading to its enactment, subsequent discussion, and a comparison to California's current situation.
- Proposition 71 and the benefits of biomedical research
- Elements a CIRM IP policy may want to consider
- Issues that need to be considered by CIRM
 - This section will describe some issue that cannot be examined fully in the interim report, and may require further, in-depth study.
- California's return on investment
 - This section will define the kinds of direct and indirect return California can expect from its investment, and discusses the pros and cons of different revenue structures.
- Recommendations
 - A short list of recommendations that the Study Group feels will be important for CIRM to consider.
- Appendix: Bayh-Dole Act - a more detailed analysis
 - A more detailed explanation of Bayh-Dole history and effects on a national level.
- Appendix: Databases and research tools
 - Exploration of the specific issues relevant to these particular areas of IP, which involve different degrees of public access.
- Appendix: IP Study Group Information, Meeting Agendas, Bios, References

As noted above, this report is on track to be delivered to the Legislature and to CIRM by the end of June 2005. We believe it will be an important tool for those who are charged to develop policies for the handling of intellectual property developed with state funds, especially issues related to stem cell research. We offer to brief you in more detail as soon as the report is completed.

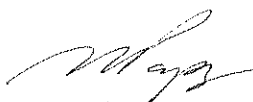
Sincerely,



Stephen D. Rockwood
Co-chair, IP Study Group



Alan B. Bennett
Co-chair, IP Study Group



Lawrence Papay
Chair, CCST



Susan Hackwood
CCST Executive Director

Enclosures: ACR 252
 ACR 24

cc: Robert Klein, Chair, Independent Citizens Oversight Committee
 Ed Penhoet, Vice Chair, Independent Citizens Oversight Committee
 Zach Hall, Interim President, California Institute for Regenerative Medicine

