2006 California Stem Cell Research-Related Active Bill Update
As of March 30, 2006

Assembly Bill (AB) 2721 (Mullin)
Office of Intellectual Property

- Establishes the Office of Intellectual Property in the Department of General Services. The office would be responsible for:
  - tracking intellectual property generated by state employees and by state funded research,
  - monitor how the intellectual property is used,
  - review royalty revenue collection and management reports,
  - develop a database to track intellectual property,
  - establish and update guidelines for use by state agencies in administering their intellectual property,
  - develop an outreach campaign informing state agencies of their rights and abilities concerning intellectual property, and
  - develop sample invention assignment agreements and sample language for licenses or terms-of-use agreements for use by state agencies.
- The bill would define terms that apply to the function of the office, and would make findings and declarations regarding intellectual property.
- This bill would require that intellectual property policies, established on and after January 1, 2008, meet certain requirements regarding rights and uses of the research or invention and any royalties derived there from. It would also require the office to submit a list of all funds where royalties are deposited to the Controller, and would require the Controller to submit an annual report to the office of all specified accounts.
- CIRM exemption – "This chapter shall not apply to intellectual property agreements governed by the California Stem Cell Research and Cures Bond Act (Chapter 3 (commencing with Section 125290.10) of Part 5 of Division 106 of the Health and Safety Code)."

Status: Introduced on February 25, 2006 and referred to Assembly Judiciary Committee; hearing is scheduled for April 18, 2006.

Senate Bill (SB) 401 (Ortiz/Runner)
Amendments to the California Stem Cell Research & Cures Act

This bill, if passed by a majority in both houses and signed by the Governor, would be placed on the next statewide ballot. It would modify the public hearing and conflict-of-interest procedures of members of the ICOC, the Citizen's Financial Accountability Oversight Committee, and the advisory and working groups established to assist these bodies, and would set forth minimum intellectual property licensing conditions applicable to ICOC standards for research and facilities grants and loans.

- Requires that the Bagley-Keene Open Meeting Act, shall apply to all meetings of the Citizen's Financial Accountability Oversight Committee, and any working or advisory group established to assist these bodies.
- Allows for closed session of these committees for:

  - Individually identifiable information regarding the medical history of, mental or physical condition of, or treatment of, a patient or medical subject, except to the extent that the person has waived his or her right to confidentiality regarding that information;
  - Confidential intellectual property or work product, whether patentable or not, including, but not limited to, any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information, which is not patented, which is known only to certain individuals who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives its user an opportunity to obtain a business advantage over competitors who do not know it or use it;
  - Prepublication scientific working papers or research data;
  - The scientific evaluation of any application for research, training, or facility grants or loans submitted for funding. However, any working or advisory group that is charged with reviewing and recommending applications for research, training, or facility grants or loans shall produce a written summary that shall be a public record of the reasons for recommending or not recommending any application for funding;
- Requires that the written summaries shall be posted on the ICOC's Web site at least 10 days prior to the ICOC's consideration for any recommendations for funding and shall include all of the following:
  - In the case of any application that is recommended for funding: the name of the applicant, the title and subject of the application, a description of how the project proposed in the application could benefit the state, a brief summary of the scientific evaluation of the project, the consolidated scientific score for the project, and the final recommendation of the full working or advisory group on the application;
  - In the case of any application that is <u>not</u> recommended for funding: a short description of the project proposed in the application, the disease category addressed by the proposed project, the geographic region represented by that project, and the general reasons for the decision not to recommend the application for funding.
- Requires that appointed members of the ICOC, and the president of the ICOC, to divest themselves of, or place into a blind trust, any financial or real property interest of two thousand dollars ($2,000) or more held by that person in any organization that applies for funding from, or contracts with, the ICOC or in any organization with a substantial interest in stem cell therapy. Defines an organization with a substantial interest in stem cell therapy as one for which, based upon publicly available information, more that 5 percent of the organization's current annual research budget is allocated to stem cell therapy.
- Requires that the ICOC establish and apply minimum licensing conditions to its grants and loans for research and facilities consisting of the following:
  - Every recipient of grant or loan awards for research or facilities that is a research institution provide to the state a portion of net licensing revenues from any invention, research finding or tool, or technology that it develops using funds from the grant or loan award, as follows:
    - The grant or loan recipient will provide 50 percent of net licensing revenues if the state shares in the expenses of developing and protecting any patent on the invention, research finding or tool, or technology.

        - The grant or loan recipient will provide 25 percent of the net licencing [sic] revenues if the state does not share in the expenses of developing and protecting any patent on the invention, research finding or tool, or technology.
    - For any grant or loan for research or facilities that is to be financed with taxable bonds, the ICOC shall require a higher level of royalties than set forth above, if a higher level is necessary to offset the additional cost of using taxable bonds.
    - For any grant or loan for research or facilities that is financed with nontaxable bonds, the ICOC may require that the royalties required by this subdivision be paid directly to a nonprofit organization that is dedicated to enhancing access to clinical trials and therapies for low-income populations, rather than being paid to the state, if the institute determines for tax reasons that receipt of the royalties by the state would preclude the use of nontaxable bonds.
    - For every recipient of a grant or loan award for research or facilities that is a research institution, requires every licensee who develops a product, drug, or therapy using any invention, research finding or tool, or technology developed with funds from the grant or loan award to agree to sell the product, drug, or therapy to state and county health programs at the best price the licensee sells it to any purchaser.
    - For every recipient of a grant or loan award for research or facilities that is a commercial entity agree, as a condition of accepting the funds, to sell any product, drug, or therapy that it develops using grant or loan funds to state and county health programs at the best price the recipient sells it to any purchaser.
    - For any recipient of a grant or loan award for research or facilities that is a commercial entity, to provide royalty payments to the state at a rate that is consistent with the rates historically received by the University of California for research agreements with biotechnology and pharmaceutical commercial entities for that type of research.
- Requires that the ICOC seek licensing conditions that would provide greater financial benefits to the state than those required above where it is possible to do so without hindering research and development of promising stem cell therapies and treatments.
- Requires that the ICOC impose any licensing conditions in its grants and loans for research that are necessary to ensure the free and open dissemination of basic research tools and findings, including research exemptions, open source and nonexclusive licensing ,compulsory licensing, development of patent pools, and other provisions the ICOC finds are necessary to ensure open dissemination.
- Requires that the ICOC require a grantee or licensee to grant a nonexclusive, partially exclusive, or exclusive license to a responsible applicant if the ICOC determines that the grantee or licensee is violating the terms of licensing conditions, or if the grantee or licensee is not making efforts in a reasonable period of time to achieve practical application of an invention developed with grant or loan funds, or if it is necessary to alleviate health and safety needs. Requires, with the exception of actions to address health and safety needs, prior to exercising this authority, the institute to give the grantee or licensee an opportunity to bring its actions into compliance with the licensing conditions.
- Defines "net licensing revenue" as to include all forms of financial consideration from licensing, including cash and corporate equity, and shall be defined as gross licensing revenues, less a reasonable administrative and licensing allowance, patent expenses, and reasonable payments to inventors.

- Requires that any proposed intellectual property agreement between the ICOC and a grantee or loan recipient to be reviewed by the Attorney General prior to its approval by the ICOC, and the ICOC shall consider any comments by the Attorney General prior to approving the agreement.
- Requires that each member of a working or advisory group appointed to assist the institute or its governing body shall disclose to the ICOC any income, real property, and investments they or a close family member has in all of the following:
    - A California-based academic or nonprofit research institutions.
    - A biotechnology or pharmaceutical company.
    - Real property interests in California.
- Requires that Facilities Working Group members to disclose all construction, real estate, and development firms from which they or a family member receives or has received economic benefits.
- Requires that the ICOC to provide the disclosures to the State Auditor and that the State Auditor will review at least annually the disclosures, in addition to the voting record of each working or advisory group member regarding recommendations for applications for research and facility grants and loan awards and regulatory standards, and submit an annual report to the Legislature containing findings on conflicts of interest. .
- Defines "financial conflict of interest" as that the working or advisory group member, or a close relative or professional associate of the member, has a financial or other monetary interest in an application or standard that is known to the member, including a direct benefit of any amount deriving from an application or standard, or a financial benefit of any type from an applicant institution of over five thousand dollars ($5,000) per year, including honoraria, fees, stock, or other benefits.
- Requires that this measure will become effective only upon approval by the voters at a statewide election, and that the Secretary of State will submit the measure to the voters at the next statewide election.

Status: Amended to current focus on March 7, 2006 of a measure that previously focused on other subject matter. In 2005, the bill (with the earlier focus) passed the Senate. SB 401 is currently in Assembly Health and a hearing is scheduled for April 18, 2006.

Senate Bill (SB) 1260 (Ortiz/Runner)
Human Egg Donation Consent

- Requires that prior to providing assisted oocyte production for research or development of medical therapies, a physician to provide to his or her patient a standardized written summary of health and consumer issues associated with assisted oocyte production. The summary shall include, but not be limited to, disclosures concerning the potential risks of assisted oocyte production and oocyte donation.
- Requires physicians to provide to potential donors the patient guide published and updated by the American Society for Reproductive Medicine entitled, "Assisted Reproductive Technology: A Guide for Patients."
- Requires the physician to obtain written consent from his or her patient prior to providing assisted oocyte production for research. Consent must include:
    1. A statement that the patient has received and reviewed the summary of health and consumer issues.

2. A statement informing the patient that oocytes may not be sold or transferred.
3. A summary of the arrangements the procuring entity has made for coverage or payment for medical care related to ovarian stimulation and oocyte retrieval.
4. Disclosure, if the physician and surgeon is participating in the medical research for which the oocytes will be used.

- Provides that no human oocyte or embryo may be acquired, sold, received, or otherwise transferred for valuable consideration for the purposes of medical research or development of medical therapies, excluding reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of oocytes or embryos.
- Prohibits payments in excess of the amount of reimbursement of expenses to any research subject to encourage her to produce human oocytes for the purposes of medical research.
- Encourages the ICOC to review existing studies concerning the health risks and benefits of ovarian stimulation drugs used for assisted oocyte production, identify gaps in existing knowledge concerning health risks and benefits, and undertake further research as necessary to characterize the risks and benefits of those drugs.

Status: Hearing in Senate Health Committee scheduled for April 19, 2006.

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