

REGULATORY PRIORITIES GOVERNING STEM CELL RESEARCH IN CALIFORNIA: RELAXING REVENUE SHARING & SAFEGUARDING ACCESS PLANS

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I. INTRODUCTION

California has taken the lead in domestic support of human embryonic stem cell (hESC) research. This Note evaluates California's stem cell research plan with particular focus on the intellectual property (IP) policies developed by the California Institute for Regenerative Medicine (CIRM). CIRM's IP policies lie at the heart of the State's obligation to ensure taxpayers receive real return on their investment in research in the forms of tangible economic gains and better healthcare for Californians.²

Part II of this Note offers a brief overview of the science and the controversy at the heart of hESC research. Part III introduces the Bayh-Dole Act, which governs IP ownership for federally funded biomedical research. Part III then compares and contrasts the corresponding CIRM and Bayh-Dole IP policies. Part IV evaluates CIRM's revenue sharing policies, which aim to ensure economic return to the State from funded research. Part IV then concludes that revenue sharing is imprudent given the likelihood of much larger economic returns through comprehensive benefits to society such as longer, more productive lives and improved healthcare. Part V evaluates CIRM's access plan policies, which are designed to promote broad access for Californians to therapies developed through CIRM funded research. Part V concludes that because broad access is unlikely without regulatory intervention, access plans are crucial to CIRM's IP policies. Finally, because the obligation to develop access plans only attaches to exclusive licensing agreements, and because the CIRM's licensing regulations contain significant ambiguities, Part V also develops a principle of interpretation for discerning whether licensing agreements are exclusive or nonexclusive.

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1. This paper received support from the California Institute for Regenerative Medicine (CIRM) through the Stem Cell Fellows Program at UC Berkeley.

2. See California Institute for Regenerative Medicine, Initial Statement of Reasons for the Proposed Adoption of Intellectual Property Regulations for For-Profit Organizations, http://www.cirm.ca.gov/reg/pdf/IP_init_stmt.pdf [hereinafter CIRM Initial Statement].

II. STEM CELL RESEARCH: THE SCIENCE AND THE CONTROVERSY

Human stem cells are important for biomedical research because they have the ability to produce a variety of specialized descendant cells.³ The most attractive stem cells to researchers are those from the developing human embryo. Once an egg is fertilized, the process of cellular differentiation begins immediately. Through a series of cleavage divisions, the fertilized egg passes through a two-cell, four-cell, and multi-cellular stage, respectively, before forming a blastocyst at about six days of development. The blastocyst is comprised of two parts: the inner cell mass (ICM) and the surrounding trophectoderm. The ICM cells are pluripotent, meaning that they have the potential to form any type of cell within the human body. The trophectoderm becomes the placenta for the developing embryo and allows the developing embryo to attach to the uterine wall during implantation.⁴

To perform human embryonic stem cell (hESC) research, scientists cultivate ICM cells. This cultivation requires puncturing the outer trophectoderm, which makes the embryo incapable of implantation and further development.⁵ The controversy surrounding hESC research centers on this issue. If the embryo is given rights usually afforded to a person upon fertilization, embryonic stem cell research is murderous. On the other hand, if the embryo is considered primarily as a mass of cells in early development, and only becomes a “person” much later in development, hESC research is largely unproblematic from an ethical standpoint.⁶

A. Federal Policy

The Bush administration prohibits all federally funded hESC research except research using stem cell lines created prior to August 9, 2001,

3. THE HUMAN EMBRYONIC STEM CELL DEBATE, at xvii (Suzanne Holland, Karen Lebacqz & Laurie Zoloth eds., MIT Press 2001).

4. James Thomson, *Human Embryonic Stem Cells*, in THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 3, at 15.

5. Although scientists are looking to find ways of cultivating hESC's without destroying the embryo's capacity for development, this research remains in the very early stages. See Nicholas Wade, *New Stem Cell Method Avoids Destroying Embryos*, N.Y. TIMES, Aug. 23, 2006, available at <http://www.nytimes.com/2006/08/23/science/23cnd-stem.html>.

6. There are, of course, a variety of sophisticated moral positions between these extremes, but the ultimate focus is moral status.

which are lines created prior to adoption of federal policy.⁷ Unfortunately, the policy under the Bush administration is not conducive to meaningful hESC research. Many of the stem cell lines existing prior to President Bush's 2001 decision are contaminated because the lines were cultured in the presence of animal feeder cells causing biological deficiencies in most lines.⁸ Due to such contamination, only about twenty of the sixty lines have proven useful to researchers.⁹ Difficulty in accessing the small number of available stem cell lines has further prohibited much of the scientific community in the United States from engaging in meaningful research.¹⁰

On July 18, 2006, President Bush issued the first veto of his presidency on a bill that would have allowed federal funding for hESC research. The bill comfortably passed both the House and Senate, but the President nonetheless refused to sign it.¹¹ Despite creative policies designed to minimize ethical problems—for example, using only spare embryos from *in vitro* fertilization clinics and prohibiting creation of embryos for research purposes—President Bush refused to compromise.¹²

B. California Steps Out

Faced with the federal impasse, California took the lead in early 2004 and organized a state-funded initiative to support hESC research. In early November of that year, California voters passed a ballot initiative, Proposition 71, authorizing three billion dollars worth of state funded hESC research over a course of ten years. Proposition 71 created the California Institute for Regenerative Medicine (CIRM) to regulate research in the state and to distribute funding for state-sponsored research. Although other

7. Press Release, White House, Fact Sheet: Embryonic Stem Cell Research (Aug. 9, 2001), available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html>.

8. Martin et al., *Human Embryonic Stem Cells Express an Immunogenic Nonhuman Sialic Acid*, 11 NATURE MEDICINE 228 (2005).

9. *Id.* at 228.

10. *Id.* at 228.

11. Charles Babington, *Stem Cell Bill Gets Bush's First Veto*, WASH. POST, July 20, 2006, at A4, available at <http://www.washingtonpost.com/wp-dyn/content/article/2006/07/19/AR2006071900524.html>.

12. Michael Luo, *Stem Cell Bill Clears Senate and Bush Promises a Veto*, N.Y. TIMES, April 4, 2007, at A17, available at <http://www.nytimes.com/2007/04/12/us/12stem.html>.

states have developed state-funding programs, no state provides funds comparable to those available in California.¹³

Initially, the California research program was stalled by legal challenges made primarily on state constitutional grounds. However, on February 26, 2007, the California Court of Appeal for the First District affirmed an Alameda Superior Court holding that the research initiative suffered no defects and could proceed.¹⁴ The California Supreme Court denied review in May of 2007, and research in California is progressing.¹⁵

III. INTELLECTUAL PROPERTY ISSUES IMPLICATED IN HESC RESEARCH

Given California's position as the key domestic leader for hESC research, it will be important for regulators, policymakers, and researchers to pay close attention to how California navigates the complex array of legal issues presented by the new research initiative. As stated by one commenter during the initial comment period for CIRM's for-profit IP policy:

There was a clear promise of public benefit in Proposition 71 . . . About half of all California's families were estimated to have a child or adult who suffers from, or will suffer from, diseases that potentially could be cured with stem cell therapies . . . Proposition 71 also promised the voters who overwhelmingly supported it that the . . . investment was built on a sound economic base. It is the intellectual property rules—in other words, who will control the ownership of Proposition 71 discoveries—that will ulti-

13. Connecticut, Illinois, Maryland, New Jersey, and Ohio have all passed stem cell research initiatives allocating funds for hESC research, although none on the fiscal scale of California's plan. Massachusetts and New York are poised to launch state initiatives relatively soon. See National Conference of State Legislatures, State Embryonic and Fetal Research Laws, <http://www.ncsl.org/programs/health/genetics/embfet.htm> (last visited December 19, 2007).

14. *Cal. Family Bioethics Council v. Cal. Inst. for Regenerative Med.*, 147 Cal. App. 4th 1319 (Ct. App. 2007) (holding that the State Constitution guarantees a presumption of validity for voter initiatives).

15. Jason Dearden, *California High Court Clears the Way for Stem Cell Grants*, S.F. CHRON., May 16, 2007, available at <http://sfgate.com/cgi-bin/article.cgi?f=/n/a/2007/05/16/state/n171737D93.DTL>.

mately determine whether the bold initiative's promises are kept.¹⁶

This Part discusses the important legal issue of IP policy. Section III.A presents an overview of the federal IP law as it pertains to federally funded research. Section III.B gives an overview of CIRM's non-profit IP policy and CIRM's for-profit IP policy, highlighting key differences with Bayh-Dole.

A. IP Policy Governing Federally Funded Research

Pursuant to the Bayh-Dole Act (Bayh-Dole), the federal government grants ownership of intellectual property to university researchers and small businesses that develop inventions as a result of federally funded research.¹⁷ Prior to Bayh-Dole, multiple funding agencies implemented a variety of ownership schemes for funded researchers.¹⁸ Uniformly, however, agencies retained ownership of intellectual property developed through funded research.¹⁹ Bayh-Dole changed this landscape considerably.

The "policy and objective" section of the Bayh-Dole Act sets forth the goal of the statutory scheme. In short, the scheme is meant to promote publicly beneficial research by academic institutions and small businesses by granting ownership incentives to research institutions.²⁰ 15 U.S.C. § 200 provides in pertinent part that "it is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development."²¹

The most important provisions of Bayh-Dole for purposes of this analysis are those relating to (1) intellectual property ownership, (2) government reserved march-in rights, and (3) the obligation of contractors (academic institutions or small businesses) to license technology with priority for U.S. manufacture.

16. John Simpson, Ensuring All Californians Benefit from Prop. 71 Grants to Businesses: State Should Hold Patents; Attorney General Must Be Enforcer 1-2 (2006), http://test-www.cirm.ca.gov/meetings/pdf/2006/04/042706_item_AM_1.pdf.

17. 35 U.S.C. §§ 200-212 (2000).

18. See Nat'l Institutes of Health Office of Tech. Transfer, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected (July 1, 2001), http://www.ott.nih.gov/policy/policy_protect_text.html [hereinafter NIH Response].

19. *Id.*

20. 35 U.S.C. § 200 (2000).

21. *Id.*

1. *IP Ownership Scheme*

Perhaps Bayh-Dole's most important provision, 15 U.S.C. § 202(a) gives all contractors (defined as any party to a federal funding agreement) the right to retain title to any invention created through federally funded research. In exchange for the right to claim title in inventions, § 202(c) requires contractors to make a number of disclosures including: all inventions resulting from federally funded research; whether the contractor will retain title to the invention; and a promise that the contractor will file any patent applications prior to statutory bar dates.

Additionally, the federal government retains certain rights over and against the contract-inventor, although the contract-inventor holds title to valuable intellectual property.²² Most importantly, the federal funding agency "shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."²³ Additionally, the federal funding agency is entitled to "require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees."²⁴

2. *March-in Rights*

The Bayh-Dole Act vests federal funding agencies with march-in rights for executing licenses from contract-researchers to "responsible applicants."²⁵ Specifically, "the Federal agency under whose funding agreement the subject invention was made shall have the right . . . to require the contractor, an assignee or exclusive licensee of a subject invention to grant . . . [a] license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances."²⁶ Furthermore, if a contractor, assignee, or exclusive licensee refuses to honor such request, the Federal agency is permitted to grant the desired license itself if one of four criteria is met:

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve *practical application* of the subject invention in such field of use;

22. 35 U.S.C. § 202(c) (2000).

23. 35 U.S.C. § 202(c)(4) (2000).

24. 35 U.S.C. § 202(c)(5) (2000).

25. 35 U.S.C. § 203(a) (2000).

26. *Id.*

(2) action is necessary to alleviate *health or safety needs* which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for *public use* specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; *or*

(4) action is necessary because the agreement required by *section 204* has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.²⁷

A federal agency may only exercise its march-in rights within a strict procedural framework requiring the agency to offer a full administrative appeals process.²⁸ Also, any contractors, inventors, assignees, or exclusive licensees who are adverse to the agency's action have a right to petition the U.S. Claims Court within sixty days of an adverse agency ruling.²⁹ Further, all march-in actions will be "held in abeyance pending the exhaustion of appeals or petitions."³⁰

3. *Preference for U.S. Industry*

Finally, the Bayh-Dole framework sets forth an exclusive licensing scheme that promotes U.S. industry. In particular, exclusive licensees must agree to "substantially" manufacture licensed inventions in the United States.³¹

B. CIRM Regulatory Framework

CIRM's IP policies are clearly influenced by the federal IP scheme codified in the Bayh-Dole Act. However, CIRM's policies depart from Bayh-Dole in key respects. Consistent with the California Stem Cell Research and Cures Act, the CIRM IP policies take a more aggressive approach to realizing tangible economic benefits for the State and ensuring

27. 35 U.S.C. § 203(a)(1)-(4) (2000) (emphases added). Although federal agencies are granted considerable power through march-in rights, march-in rights have been seldom exercised. Most agree that federal level march-in rights provide a mostly impotent threat to researchers. See Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?* 43 HOUS. L. REV. 1373, 1391 (2007).

28. 35 U.S.C. § 203(b) (2000).

29. *Id.*

30. *Id.*

31. 35 U.S.C. § 204 (2000).

that research products reach Californians.³² Separate policies govern research conducted by CIRM-funded non-profit entities (e.g., research universities) and research conducted by CIRM-funded for-profit entities (e.g., biotech companies).

1. *IP Policy for Non-Profit Entities*

a) Ownership & Licensing Scheme (Non-Profit Policy)

CIRM's non-profit IP policy mirrors Bayh-Dole by assuming that academic institutions will retain title to IP developed through funded research.³³ In partial exchange for ownership rights, grantee organizations must make a number of disclosures to CIRM.³⁴ Grantee organizations must report all inventions to CIRM³⁵ and inform CIRM annually of all filed patent applications, executed licensing agreements, and efforts to utilize CIRM funded inventions.³⁶ All CIRM-funded researchers must also provide CIRM with an abstract for the public highlighting all CIRM-funded research results published in scientific journals.³⁷

California Code of Regulations Title 17, section 100306 implements a distinct licensing scheme for CIRM-funded research leading to licensable inventions and/or technology. The current scheme, which took effect on July 14, 2007, encourages non-exclusive licensing "whenever possible" but allows exclusive licensing "if such licenses are necessary to provide economic incentives required to enable commercial development and availability of the inventions."³⁸

The most unique part of CIRM's non-profit licensing scheme requires that all exclusive licensees "shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies and diagnostics only to persons that agree to have a plan in place at the time of commercialization to provide access to resultant therapies and diagnostics for uninsured California patients."³⁹ This contrasts significantly with the regime under Bayh-Dole, in which researchers are generally used to non-

32. Roger G. Noll, *Designing an Effective Program of State-Sponsored Human Embryonic Stem Cell Research*, 21 BERKELEY TECH. L.J. 1143, 1170-74 (2006); see also CAL. HEALTH & SAFETY CODE § 125290.30(h) (2007) (codifying mandate to ensure economic returns to California through revenue sharing).

33. See CAL. CODE REGS. tit. 17, §§ 100300-100310 (2007).

34. CAL. CODE REGS. tit. 17, § 100302(a)-(e) (2007).

35. CAL. CODE REGS. tit. 17, § 100302(b) (2007).

36. CAL. CODE REGS. tit. 17, § 100302(c) (2007).

37. CAL. CODE REGS. tit. 17, § 100303 (2007).

38. CAL. CODE REGS. tit. 17, § 100306(b) (2007).

39. CAL. CODE REGS. tit. 17, § 100306(d) (2007).

interference from funding sources with respect to licensing and other business activities related to research endeavors.

b) Sharing of Biomedical Materials (Non-Profit Policy)

Also unlike Bayh-Dole, section 100304 requires sharing of biomedical materials resulting from CIRM-funded research. The section provides in pertinent part:

Grantees shall share biomedical materials first created under CIRM funding and described in published scientific articles for research purposes in California within 60 days of receipt of a request and without bias. . . . [E]xceptions to [this rule] are possible [only] with approval by CIRM. . . . Such materials are to be shared without cost or at . . . actual cost.⁴⁰

c) March-in Rights (Non-Profit Policy)

CIRM retains march-in rights under its non-profit IP policy. The march-in framework partially mirrors the Bayh-Dole march-in framework. CIRM has the right to require a grantee organization or an exclusive licensee to grant a license (exclusive, partially exclusive, or non-exclusive) of a CIRM-funded invention to another “in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances.”⁴¹ Further, CIRM reserves the right to license such inventions itself if the grantee organization or exclusive licensee refuses to grant the required license.⁴²

Like Bayh-Dole, the CIRM regulations set forth four criteria, at least one of which must be met to trigger the lawful exercise of march-in rights. However, CIRM’s criteria slightly differ from the federal scheme. For CIRM to exercise march-in rights, it must believe that action is required:

- (1) Because the grantee organization or the licensee has not made responsible efforts in a reasonable time to achieve practical application of a CIRM-funded patented invention;
- (2) Because the licensee has failed to adhere to the agreed-upon plan for access to resultant therapies as described in subdivision (d) of Code of California Regulations, Title 17, section 100306;
- (3) To meet requirements for public use and the requirements have not been satisfied by the grantee organization or its licensee;

40. CAL. CODE REGS. tit. 17, § 100304(d) (2007).

41. CAL. CODE REGS. tit. 17, § 100310(a) (2007).

42. *Id.*

(4) To alleviate public health and safety needs which are not reasonably satisfied by the grantee organization or its licensee and which needs constitute a public health emergency.⁴³

Although CIRM's framework and Bayh-Dole share criteria (1), (3) and (4) in common, criterion (2) is unique to the CIRM policy and highlights the importance of access plans to California regulators.

d) Revenue Sharing (Non-Profit Policy)

CIRM's revenue sharing provisions set forth at section 100408 are also unique to CIRM's policy. CIRM grantee organizations are required to share revenues with California that result from licensing of CIRM-funded inventions.⁴⁴ See Figure 1, *infra*. Specifically, non-profit grantees are required to share 25% of net exclusive licensing revenue in excess of \$500,000 with California.⁴⁵

2. CIRM's for-Profit IP Policy

The for-profit regulations largely mirror the non-profit regulations.⁴⁶ Generally speaking, however, CIRM's for-profit scheme places stricter financial reporting requirements upon for-profit entities and imposes more aggressive revenue-sharing requirements.

a) Ownership & Licensing Scheme (For-Profit Policy)

The for-profit policy, like CIRM's non-profit policy, grants researchers ownership and licensing rights over inventions created through CIRM-funded research.⁴⁷ Further, the for-profit policy, like the non-profit policy, discourages exclusive licensing of technologies that substantially result from CIRM funding. Specifically, "a grantee may negotiate an exclusive license if exclusivity is reasonably believed by Grantee to be an economic incentive necessary to achieve commercial development and availability of the invention."⁴⁸ The for-profit policy also ties exclusive licensing arrangements to access plan requirements.⁴⁹

For-profit grantees that plan to develop and commercialize products themselves are also subject to access plan requirements. The regulations state that "a grantee (or, by terms of an Exclusive License Agreement, its

43. CAL. CODE REGS. tit. 17, § 100310(a)(1)-(4) (2007).

44. CAL. CODE REGS. tit. 17, § 100308 (2007).

45. CAL. CODE REGS. tit. 17, § 100308(b) (2007).

46. *See* CAL. CODE REGS. tit. 17, §§ 100400-100410 (2008).

47. CAL. CODE REGS. tit. 17, § 100405 (2008).

48. CAL. CODE REGS. tit. 17, § 100406(c) (2008).

49. *Id.*

exclusive licensee) must submit a plan [at the time of commercialization] to afford uninsured Californians access to a drug . . . the development of which was in whole or in part the result of CIRM-funded Research.”⁵⁰ The regulations define “drug” broadly as “an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . . [and] this term includes therapeutic products such as blood, blood products, cells, and cell therapies.”⁵¹

The for-profit scheme, unlike the non-profit scheme, also provides that CIRM may make access plans available to the public.⁵²

b) Sharing of Biomedical Materials (For-Profit Policy)

Like their non-profit counterparts, CIRM requires for-profit grantees to share research related biomedical materials at no charge (or at cost) to any party who requests the materials.⁵³

c) March-in Rights (For-Profit Policy)

The for-profit scheme, like the non-profit scheme, grants CIRM march-in rights to compel licensing of CIRM funded inventions.⁵⁴ The for-profit march-in scheme is identical to the non-profit scheme.

d) Revenue Sharing (For-Profit Policy)

Like the non-profit policy, the for-profit policy includes revenue sharing requirements for CIRM-funded research leading to commercially successful inventions.⁵⁵ The for-profit revenue sharing scheme, however, requires much greater paybacks to the State for successful commercial products.

In particular, for-profit companies who elect to commercialize products developed through CIRM-funded research are subject to a four-tiered revenue sharing arrangement. See Figure 2, *infra*. First, companies must share a negotiated percentage of net commercial revenues (between 2% and 5%) up to a maximum of three times the amount of the original CIRM grant.⁵⁶ Second, companies are subject to two sets of blockbuster provisions. When a for-profit grantee’s revenue from a product developed through CIRM funding exceeds \$250 million in one year, the for-profit

50. CAL. CODE REGS. tit. 17, § 100407(a) (2008).

51. CAL. CODE REGS. tit. 17, § 100401(a) (2008).

52. CAL. CODE REGS. tit. 17, § 100407(a)(3) (2008).

53. CAL. CODE REGS. tit. 17, § 100404(a) (2008).

54. CAL. CODE REGS. tit. 17, § 100410 (2008).

55. CAL. CODE REGS. tit. 17, § 100408 (2008).

56. CAL. CODE REGS. tit. 17, § 100408(b)(1) (2008).

grantee must make a “blockbuster” payment to California of three times the initial grant amount.⁵⁷ And when revenue exceeds \$500 million in one year, the for-profit grantee must make a second blockbuster payment to California.⁵⁸ Finally, in addition to early stage revenue sharing and blockbuster payments, a for-profit grantee is subject to late-stage revenue sharing of 1% of all net commercial revenue in excess of \$500 million per year.⁵⁹

For-profit companies that elect not to commercialize developments themselves are required to share 25% of net licensing revenue in excess of \$500,000 with the State.⁶⁰ See Figure 3, *infra*.

IV. ENSURING TANGIBLE ECONOMIC RETURN

CIRM has sought to ensure return on investment for taxpayers through its IP policies. Tangible economic return on investment is most likely to be realized through improvements to the “overall well-being of society” from increased life spans and healthcare savings,⁶¹ benefits the CIRM policy may have underestimated.⁶² However, the likely return through revenue sharing, a much contested but central aspect of CIRM’s IP policy, will be comparatively small.⁶³ Taken together, the tremendous returns likely to be realized apart from revenue sharing and the resistance expressed by industry and researchers weigh in favor of relaxing or abandoning revenue sharing provisions. This Part concludes that CIRM’s revenue sharing policies are likely imprudent given possible disincentives for industry and the likelihood of large economic returns through broader societal benefits.

A. Projected Economic Benefits of Revenue Sharing

In contrast to Bayh-Dole, CIRM has decided to “take a piece of the pie,” from researchers and others who develop valuable products as a result of CIRM-funded research. Requiring researchers and commercial developers to share the financial rewards they reap with the State (revenue sharing) is a relatively simple way to ensure tangible economic return on investment.

57. CAL. CODE REGS. tit. 17, § 100408(b)(2) (2008).

58. *Id.*

59. CAL. CODE REGS. tit. 17, § 100408(b)(3) (2008).

60. CAL. CODE REGS. tit. 17, § 100408(a)(1) (2008).

61. Michael Longaker et al., *Proposition 71 and CIRM: Assessing the Return on Investment*, 25 NATURE BIOTECHNOLOGY 513, 514 (2007).

62. *Id.*

63. *Id.* at 520.

For example, assume first that a for-profit firm obtains a \$10 million grant from CIRM.⁶⁴ Assume further that the for-profit firm develops a patented product that generates \$5 billion in revenue during the life of the patent.⁶⁵ The for-profit firm will be obligated to pay CIRM between 2% and 5% of revenue for any years in which net revenue is more than \$500,000 but less than \$250 million, up to \$30 million in total payments.⁶⁶ On the first year the for-profit firm reaches \$250 million in net revenue, it will owe CIRM another \$30 million.⁶⁷ Then, if the product reaches \$500 million in revenue in one year, it will owe CIRM another \$30 million.⁶⁸ After the second blockbuster payment is made, the for-profit company is further obliged to pay 1% of net revenue in excess of \$500 million for the life of the patent.⁶⁹ The State would recover approximately \$135 million from one blockbuster product (\$30 million in early stage revenue sharing, plus \$60 million in blockbuster payments, plus another (possible) \$45 million in late stage revenue sharing).⁷⁰

Assume also that non-profit institutions license ten highly successful patents, developed through CIRM funded research, to for-profit firms.⁷¹ Assume further that each patent generates \$100 million in revenue over its lifetime. The State would recover approximately \$250 million from the ten licenses, and \$385 million overall (\$135 million from the for-profit firm with a blockbuster product and \$250 million from the non-profit institutions).⁷²

B. Projected Economic Benefits through Betterment of Society

Professor Longaker and colleagues conducted a hypothetical analysis of the likely societal impact (to the United States at large) of a treatment reducing the impact of juvenile onset diabetes mellitus (JODM) by half (in terms of mortality rate, annual healthcare costs of individuals with the disease, and direct costs of a new therapy).⁷³ As they point out, current therapies require a life-time of insulin replacement therapies resulting in “an enormous medical burden, eventually causing clinical problems in organs

64. *Id.*

65. *Id.*

66. CAL. CODE REGS. tit. 17, § 100408(b)(1) (2008).

67. CAL. CODE REGS. tit. 17, § 100408(b)(2) (2008).

68. *Id.*

69. CAL. CODE REGS. tit. 17, § 100408(b)(3) (2008).

70. Longaker, *supra* note 61, at 520.

71. *Id.*

72. *Id.*

73. *Id.* at 514.

and tissues.”⁷⁴ Researchers hope that hESC research will lead to creation of functional pancreatic cells that will “physiologically sense glucose [levels] and secrete insulin” as needed for proper metabolism.⁷⁵ Cells like these would present a real possibility of a cure for JODM. In order to add credibility to their economic assessment, however, Longaker’s group notes that “stem cell therapies that would lead to complete cures for JODM are commonly discussed [and hold great economic promise], but we develop our model around a more conservative scenario in which a new therapy reduces the impact of JODM by half.”⁷⁶

Further, Longaker’s model conservatively assumes that Proposition 71 leads to an earlier realization of therapies for JODM—not that the JODM therapies would never be developed in absence of Proposition 71. Longaker states that “policies like Proposition 71 do not generate discoveries that would otherwise never have been made, but rather they can help by shortening the time that elapses before the therapies become available.”⁷⁷

The most significant potential economic benefits of CIRM-funded research will arise from increased life years, and in particular, quality adjusted life years (QALYs).⁷⁸ In the context of JODM, under currently accepted estimates (where one QALY amounts to \$50,000), the economic gain attributable to the hypothesized advance for individuals with JODM, as a result of CIRM-funded research, would amount to \$28 billion undiscounted current dollars.⁷⁹ Longaker’s group also estimates that individuals with JODM could add upwards of \$12 billion in added productivity in the workplace, if the modest hypothesized advance in treatment for JODM results in increased QALYs for these individuals.⁸⁰

Developments in JODM treatment would also likely lead to healthcare savings.⁸¹ Assuming the therapeutic advance would lead to an overall decrease in the amount of healthcare resources devoted to persons with JODM (due to reduced complications, better disease management, etc.), and before accounting for costs associated with introducing the new therapy, Longaker and colleagues have calculated that decreased health care consumption would amount to \$2.3 billion in current undiscounted dol-

74. *Id.* at 515.

75. *Id.* at 515.

76. *Id.*

77. *Id.*

78. *Id.* at 516.

79. *Id.* at 516.

80. *Id.*

81. *Id.*

lars.⁸² These overall savings would be eroded by costs associated with introduction of the new therapy, resulting in net health care savings of \$368 million.⁸³

It is important to acknowledge the assumptions underlying Longaker's group's results. JODM is a highly prevalent condition.⁸⁴ For a developed therapy to benefit society in the ways Longaker's group has suggested: the therapy must be widely accessible/affordable; the therapy must be actually hastened by CIRM-funded research; the conditions addressed by the research must be serious and affect many people (e.g., JODM); and the conditions addressed by the research must be conditions that affect people relatively early in life as opposed to near the end of life when additional life years are unlikely.⁸⁵

C. Returns through Revenue Sharing Are Too Small to Justify Added Burdens to Researchers and Industry

The above evaluation of the benefits from revenue sharing and from the betterment of society yields the conclusion that it is unwise for CIRM to risk discouraging participation by researchers and others through revenue sharing, given that comparatively larger economic returns will be realized in other, non-controversial ways.

1. Revenue Sharing in Context

Although the possibility of California receiving \$385 million through revenue sharing as a result of CIRM-funded research is significant in real terms, "direct returns from IP from CIRM funding . . . pale [in comparison to] other anticipated returns from Proposition 71."⁸⁶ In particular, \$385 million is relatively small when compared to more than \$40 billion in gains likely to be seen as a result of increased quality of life, decreased mortality, increased productivity, and health care savings resulting from a single therapeutic advance.⁸⁷

The hypothetical \$385 million in revenue sharing is even less significant in comparison to broader economic benefits, considering that \$385 million in revenue sharing requires creation of at least one blockbuster therapy in addition to at least ten patents collectively worth \$1 billion dollars in primary licensing revenue. It is reasonable to assume that a single

82. *Id.* at 517.

83. *Id.*

84. *Id.* at 515.

85. *See id.* at 518.

86. *Id.* at 520.

87. *Id.* at 516.

blockbuster product would probably lead to even more significant societal benefits (increased quality of life, decreased mortality rates, health care savings, etc.) than the modest advance in JODM treatment discussed above. It is also reasonable to assume that ten valuable patents would lead to multiple therapeutic advances comparable, at the least, to the JODM example. The gap between economic returns through revenue sharing and economic returns through broad societal benefits only increases if CIRM research is as successful as California predicts.

2. *Revenue Sharing Is Likely to Discourage Participation by Important Players*

A key question for the propriety of revenue sharing is whether the risk of discouraging researchers and investors from participating is worth the relatively modest sum at stake. On balance, it seems unlikely that university researchers will be discouraged by CIRM's revenue sharing provisions despite loss of licensing revenue. No other state within the United States is offering research funding comparable to the levels available in California.⁸⁸ Even if researchers or universities more generally do not like the idea of sharing revenues, they have little bargaining power given the lack of suitable state funding alternatives.

It remains possible that concerns about lost profits or State-imposed burdens for university entrepreneurs will discourage universities from engaging in CIRM funded research. Dr. Michelle Cai argued persuasively that "pure academic research devoid of commercial implications is becoming a rarity in an era of federal incentives to turn the fruits of government-funded basic research into commercial applications."⁸⁹ Given the political (and scientific) cachet associated with hESC research, however, and given the general commitment of most academic researchers to advancement of science, university non-participation appears unlikely for the foreseeable future. California is proud of its status as a biotechnology leader, and dissatisfaction with revenue sharing seems unlikely to overtake the desire for biotechnological advancement in the State, at least among researchers in the university setting.⁹⁰

88. Monya Baker, *Industry Concerns Mount Over CIRM Grants*, 25 NATURE BIOTECHNOLOGY 1063, 1064 (2007).

89. Michelle Cai, Note, *Madey v. Duke University: Shattering the Myth of Universities' Experimental Use Defense*, 19 BERKELEY TECH L.J. 175, 175 (2004).

90. See Baker, *supra* note 88.

The for-profit sector, however, appears far more likely to resist participating in research with revenue sharing requirements.⁹¹ Industry resistance is not surprising given that a \$10 million grant, for example, could result in as much as \$135 million in required payments back to the State.⁹² The California Healthcare Institute (CHI), an advocacy group for the biomedical research and development community within the State, interviewed its members regarding CIRM's IP policies. CHI's members include "more than 250 of California's leading life sciences companies, universities, and academic research institutions."⁹³ The CHI interviews revealed that "over 80% [of members] . . . would be much less likely to consider licensing a technology, or investing in a start-up company based on a technology carr[ying] [the revenue sharing and access requirements in the regulatory policy]."⁹⁴ CHI worries that "the likely consequences of these provisions . . . will be fewer new medicines and therapies to the citizens of California."⁹⁵

Others besides CHI have also highlighted industry reluctance to participate in CIRM funded research under the current IP policies.⁹⁶ For example, Geron CEO Tom Okarma has noted that "his company is unlikely to apply for any science grants [from CIRM], but would [ordinarily] welcome funds for clinical research. Geron's investors have already done the 'heavy lifting' to generate the company's technologies . . . and grants that might siphon away revenues don't appeal."⁹⁷ Simply put, "CIRM needs to figure out how many restrictions it can have in place and still attract quality companies for its grants."⁹⁸

In addition to burdens from direct revenue sharing, industry members may face increasing licensing fees from researchers. Research institutions, whether non-profit or for-profit, may increase licensing fees to account for revenues they lose through revenue sharing. This creates further disincentives for industry members who might otherwise be inclined to license technologies developed through CIRM-funded research.

91. See Letter from David Gollaher, President and CEO of California Healthcare Institute, to C. Scott Tocher, Interim Counsel to CIRM (Oct. 4, 2006), available at http://www.chi.org/uploadedFiles/Legislative_Action/State_Issues/CHI%20comments%20to%20revised%20IPNPO_100406.pdf [hereinafter Gollaher letter].

92. See *supra* Section IV.A.

93. Gollaher letter, *supra* note 91, at 1.

94. *Id.* at 2.

95. *Id.*

96. See Baker, *supra* note 88, at 1063.

97. *Id.* at 1063.

98. *Id.*

3. *The NIH Has Rejected Revenue Sharing Requirements Twice*

At numerous points in the past, federal legislators and officials at the National Institutes of Health (NIH) have explicitly rejected revenue sharing regulations for federally funded medical research. These officials have based their decisions in part, on (1) concerns about discouraging participation by research and industry communities and (2) recognition that the most significant economic returns on research will be from advances in health care and increased productivity of citizens.⁹⁹

In 1980, prior to passage of Bayh-Dole, legislators debated the question of return on investment for taxpayers.¹⁰⁰ However, revenue sharing provisions were removed prior to passage of Bayh-Dole, due in part to concerns about negative incentives to researchers and industry.¹⁰¹ In 2001, the NIH reconsidered the issue of revenue sharing and concluded again that “requiring direct financial recoupment of the federal investment in biomedical research can potentially impede the development of promising technologies by causing industry to be unwilling to license federally funded technologies.”¹⁰²

The NIH also rejected revenue sharing requirements because the potential economic return through revenue sharing is small, relative to returns resulting from general benefits to society such as improved quality of life and increased longevity.¹⁰³ The NIH concluded that the risk of discouraging participation in research was not worth the modest returns foreseeable through revenue sharing.¹⁰⁴ The NIH also highlighted direct economic returns from taxes on profits, job creation, and overall economic growth, all of which California is likely to experience as a result of CIRM funded research. As summarized in a 2006 report by the Congressional Research Service,

While the idea of [revenue sharing] was considered by the Congress in hearings on [Bayh-Dole] legislation, it was rejected as an unnecessary obstacle. . . . Instead, Congress accepted as satis-

99. NIH Response, *supra* note 18.

100. *Id.* at Section C.5 (capping the total proposed revenue sharing at the amount provided by the government under the particular funding arrangement, so that the most any researcher would share with the federal government was the actual amount granted).

101. WENDY SCHACHT, CRS REPORT FOR CONGRESS: THE BAYH-DOLE ACT: SELECTED ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY 14 (2006), available at <http://www.ncseonline.org/NLE/CRSreports/07Jan/RL32076.pdf>.

102. NIH Response, *supra* note 18, at Section F.

103. *Id.* at Section C.7.

104. *Id.*

factory the anticipated payback to the country through increased revenues from taxes on profits, new jobs created, improved productivity, and economic growth . . . [in addition to] the emergence of the biotechnology industry and the development of new therapeutics to improve health care.¹⁰⁵

Of course, unlike the NIH, CIRM is charged with regulating research for the sake of primarily *Californians*, not all U.S. citizens more generally. Revenue sharing allows regulators to ensure that California in particular receives a share of economic gains resulting from CIRM-funded research. Otherwise, CIRM must worry about the possibility that although research will be conducted in California, industry growth and therapeutic developments may ultimately be widely distributed both nationally and internationally. Unfortunately for CIRM, however, dispersion problems exist whether revenue sharing is required or not. Revenue sharing alone cannot make up for the possibility that industrial growth might be siphoned away from California. CIRM has the difficult task of balancing the need to attract industry with the need to ensure that benefits to Californians are maximized. Revenue sharing creates a risk of lack of participation by industry in exchange for small economic gain.

Some may argue that revenue to California derived from revenue sharing is more secure (i.e., easier to measure) than economic gains associated with broader societal benefits. However, it is reasonable to assume that gains from revenue sharing are only likely to be seen if discoveries with strong potential to lead to therapeutic advances are actually made. Further, when these discoveries are made, much greater economic benefits should accrue in broader benefits to society.

Therefore, given that the return to California taxpayers will be greatest from improvements to “the overall well-being of society,” that the relative return through revenue sharing is likely to be comparatively small, and that there is significant resistance to revenue sharing within the biotechnology and investment communities, CIRM should de-emphasize (or eliminate) revenue sharing as a way of generating economic return for taxpayers.¹⁰⁶

105. SCHACHT, *supra* note 101, at 14-15.

106. *See* Longaker, *supra* note 61, at 513-21.

V. THE IMPORTANCE OF ACCESS PLAN REQUIREMENTS AND THE NEED TO RESOLVE REGULATORY AMBIGUITY

The access plan provisions contained in CIRM's IP policies are designed to ensure that benefits of state-funded research reach socio-economically disadvantaged Californians.¹⁰⁷ Unlike the goal of tangible economic return, CIRM's regulatory policies are likely to be a necessary step to realize the goal of broad access to health benefits. Therefore, CIRM's access plan requirements are crucial to ensuring that Californians, especially socio-economically vulnerable Californians, have access to healthcare improvements that result substantially from CIRM-funded research.

A. Broad Access is Unlikely Without Policy Intervention

As Professor Ruth Faden points out, "it [is] . . . of serious moral concern, that there will be significant economic barriers to access to new therapies utilizing stem cells. New technologies are usually expensive and thus the earliest (and sometimes only) beneficiaries of medical advances are the economically privileged."¹⁰⁸ In its stated rationale for requiring exclusive licensees to create access plans, CIRM explains that it "seeks to ensure that licensees of CIRM-funded patented inventions obtain the appropriate scope of rights . . . to develop potential applications of the invention while optimizing public good through . . . widespread use."¹⁰⁹ Furthermore, as many in California agree "it is essential that the policy controlling ownership of any valuable medical discoveries that result from Proposition 71-funded research by businesses . . . be crafted so that all Californians . . . benefit from the research paid for by [all] taxpayers."¹¹⁰

Access plan requirements, like revenue sharing requirements, pose disincentives to researchers and industry alike. Unlike the case of revenue sharing where economic return is likely to occur in other, far more significant ways, the policy objectives underlying access plan requirements, access for uninsured and low income Californians, are unlikely to be met by alternate means.¹¹¹

107. See CIRM Initial Statement, *supra* note 2.

108. Ruth Faden, *Public Stem Cell Banks: Considerations of Justice in Stem Cell Research and Therapy*, 33 HASTINGS CENTER REP. 13, 25 (2003).

109. CIRM Initial Statement, *supra* note 2, at 7.

110. Simpson, *supra* note 16, at 1.

111. In fact, there may be other ways to better ensure broad access. Future work should assess the likely success or failure of access plans.

B. Exclusive and Non-Exclusive Licensing: Industry Practice and Regulatory Ambiguity

The non-profit regulations define an exclusive license as “any license agreement for a CIRM-funded patented invention that permits the licensee to exclusively exercise any commercial right within the state of California or the United States, or within any field of use.”¹¹² Broadly stated, domestic geographic exclusivity and all forms of field exclusivity impose access plan requirements upon exclusive licensees of technologies developed by non-profit grantees.

The for-profit regulations provide an even broader definition, defining an exclusive license as “any license agreement for a CIRM-funded patented invention that authorizes the licensee to exclusively exercise one or more of the rights (or a portion of the rights) belonging to the patent holder under the patent.”¹¹³ Exclusive licensees of technologies developed through CIRM-funded research by for-profit grantees and all for-profit entities that self-commercialize products resulting from CIRM-funded research must provide access plans to the CIRM.¹¹⁴

Ambiguities in both licensing policies leave a number of important questions unanswered: What about international exclusivity? Precisely what counts as field exclusivity in the non-profit policy? What about other forms of exclusivity: temporal, technique, method of use, etc.? Are these forms of exclusivity covered by the broader for-profit policy? Are they covered by the non-profit policy?

Given ambiguities in the licensing policies, CIRM should be prepared to confront licensees (and licensors) who may attempt to strategize around access plan requirements. A full analysis of licensing issues related to CIRM’s access plan requirements is beyond the scope of this Note. However, this Note develops a principle of interpretation based upon licensee intent by which CIRM regulators and others should evaluate whether access plan requirements attach to licensing arrangements: access plan requirements should attach when, at the time of licensing, a licensee intends to use technology resulting from CIRM-funded research directly to exploit market opportunities.

112. CAL. CODE REGS. tit. 17, § 100301(f) (2007).

113. CAL. CODE REGS. tit. 17, § 100401(f) (2008).

114. CAL. CODE REGS. tit. 17, § 100407 (2008).

1. *The Difficult Distinction Between Exclusive and Non-Exclusive*

The distinction between an exclusive and a non-exclusive license is not easy to draw in practice.¹¹⁵ As one treatise author points out, “commercial practice yields a wide variety of differing transactional frameworks . . . mak[ing] drawing a simple distinction between exclusive and nonexclusive licenses difficult.”¹¹⁶ Some courts define a non-exclusive license as one in which a licensor waives the right to sue the licensee.¹¹⁷ Exclusive licenses thus entail giving rise to the right to sue when other rights conveyed are violated.

Whether a license is deemed to be exclusive or non-exclusive also depends on the *scope* of the rights conveyed. If the scope of rights is too narrow, the license is effectively non-exclusive.¹¹⁸ For example, a license for one year is far less exclusive than a license extending for the entire term of the licensor’s IP right.¹¹⁹ Additionally, a license with national exclusivity is far more excluding than a license limited to a narrow geographic area.¹²⁰ As Nimmer and Dodd argue, “as the scope of exclusivity becomes more narrow, its effect[s] reach the point where describing the license as exclusive becomes more analytically cumbersome than useful.”¹²¹ Exclusivity in general, and the extent of exclusivity within particular agreements, is a matter of interpretation.¹²²

In its definition of exclusive license in the non-profit policy, CIRM specifically notes field of use and geographic exclusivity.¹²³ With respect to field of use, there are a variety of ways to interpret exclusivity. For instance, Nimmer and Dodd note that “[field of use] is best understood as referring to those portions of the licensed scope that deal with the location, area of technology, market, and other attributes of the permitted use of the subject matter.”¹²⁴ Thus, there are a variety of ways in which parties can contract for exclusive rights related to “field of use.” CIRM has yet to offer guidance as to types of field exclusivity that fall within its definition of

115. See *Exxon Corp. v. Oxxford Clothes, Inc.*, 109 F.3d 1070 (5th Cir. 1997).

116. RAYMOND NIMMER & JEFF DODD, *MODERN LICENSING LAW* § 5:1 (2007).

117. *Suessen v. Schubert*, 829 F.2d 1075, 1081 (Fed. Cir. 1987).

118. NIMMER & DODD, *supra* note 116, at § 5:7.

119. *Id.*

120. *Id.*

121. *Id.*

122. *Id.*

123. See CAL. CODE REGS. tit. 17, § 100310.

124. NIMMER & DODD, *supra* note 116, at § 6:15.

exclusive license, but this question should be anticipated. Furthermore, given the much broader definition of exclusive license contained in the for-profit policy, CIRM should be prepared to clarify what types of exclusivity it considers relevant.

Generally, geographic exclusivity articulates the market for the licensed product or technology.¹²⁵ Because CIRM defines geographic exclusivity—California or the United States more generally—there is less room for ambiguity in geographic limitations.¹²⁶

2. *An Intention-Based Principle of Interpretation for Scrutiny of Licensing Arrangements*

Given lack of consensus as to what constitutes an exclusive licensing agreement, and given industry incentives to avoid access plan requirements, CIRM should address the question of how licensing arrangements will be scrutinized. This Note suggests the following principle for analysis of licensing arrangements: where there is ambiguity regarding exclusivity (e.g., where it is somewhat unclear whether there is field or geographic exclusivity in the agreement or any other meaningful exchange of rights), if a licensing arrangement appears to be based upon expectation of immediately marketable therapeutic (or other) uses, this expectation favors finding exclusivity.

If, on the other hand, there is no clear exchange of substantial rights and “significant further research and development efforts to realize the commercial application of the invention” are required post-license, a finding of non-exclusivity is likely favored.¹²⁷ Finally, if CIRM finds that a particular licensing arrangement is exclusive, the licensee should have the burden to show non-exclusivity since licensees have clear economic incentives to so demonstrate.

Legislators and regulators alike believe that access plans are crucial for accomplishing the distributive intent of California taxpayers who voted for Proposition 71. In its statement supporting proposal of the for-profit IP regulations, CIRM provides that:

125. *Id.*

126. One open question relates to international exclusivity. Will access plan requirements fall upon an exclusive licensee who takes an exclusive license to practice a technology in a foreign country?

127. California Institute for Regenerative Medicine, Working Draft: CIRM Intellectual Property Policy for Non-Profit Organizations 32 (Jan. 18, 2006), http://www.cirm.ca.gov/meetings/pdf/2006/01/012306_item_3.pdf (See discussion entitled “Licensing Policy Elements”) [hereinafter Working Draft].

As a consequence of expenditure of the ‘first dollar’ of CIRM funding, the for-profit awardee organization agrees to provide a plan (at the time of commercialization) to provide to uninsured California residents access to resultant therapies. . . . This will ensure that Californians without insurance are able nonetheless to have improved access to therapies developed with the financial assistance of California’s taxpayers.¹²⁸

Legislators and regulators also expect that licenses will be exclusive when technology is licensed on the basis of expectations of immediate marketability of therapeutic or other uses. CIRM provides the following discussion supporting location of the exclusive/non-exclusive distinction in the intent of the licensee:

For inventions with [direct] potential preventive, diagnostic, or therapeutic uses, where some type of exclusivity (and therefore patent protection) is necessary for product development, [exclusive] licensing of the patent rights is the primary vehicle for transferring the technology to commercial partners.¹²⁹

Taken together, (1) the importance of access plans for making therapies available to uninsured Californians, and (2) the expectation that licenses for technologies expected to lead directly to marketable products will be exclusive, amounts to the interpretive principle noted above—licenses based on expected marketable uses favor finding exclusivity.

The interpretive principle is also supported by industry practice. Companies will pay handily for non-exclusive licenses, but probably only where significant research and development will be required after a license is granted.¹³⁰ This is because the companies believe that their own researchers will discover and develop new products. Exclusive licenses, on the other hand, are generally sought when a company intends to use a particular technology that with limited direct competition is either itself a marketable product or that will develop quickly into a marketable product.¹³¹

128. CIRM Initial Statement, *supra* note 2, at 7-8.

129. Working Draft, *supra* note 127, at 32.

130. See Christopher Scott Thomas, *Mice with a Human Touch*, 25 NATURE BIOTECHNOLOGY 1075 (2007).

131. John Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 307 (Wesley Cohen & Stephen Merrill eds., National Research Council 2003).

Along similar lines, one member of CIRM's IP regulatory council pointed out that the exclusive/non-exclusive distinction is best viewed in light of the intent of the licensee.¹³² When industry licensees take non-exclusive licenses, the license usually serves a research function that will hopefully lead to a marketable product downstream.¹³³ Exclusive licenses, on the other hand, are usually taken with the intention of directly exploiting market opportunities through the license.¹³⁴

Like access requirements for exclusive licensees and self-commercializers, CIRM's express preference for non-exclusive licenses promotes broad access to health benefits. Non-exclusive licenses allow multiple companies to work with the licensed technologies, thereby increasing the possibility of developing useful therapies.¹³⁵ In fact, there is "a belief on the part of some holders of target patents that by giving several firms a nonexclusive license they increase the chances that one will discover a useful drug."¹³⁶

Although non-exclusive licensing may increase the possibility of significant research developments, problems will still arise in terms of delivery to broad socioeconomic groups. This issue has not yet been addressed by CIRM.

VI. CONCLUSION

California is the key domestic leader of stem cell research in the United States. CIRM's IP policies for non-profit and for-profit organizations are important contributions to the national research landscape.

CIRM's IP policies aim to assure two chief goals promised by the legislation authorizing the research initiative: tangible economic return and broad access to benefits. Requiring grantees to share revenues with the State is an imprudent policy strategy because major economic returns will materialize in other ways, and revenue sharing may discourage key players from participating. Access plan provisions, on the other hand, are worth possible negative incentives given that broad access is unlikely to be achieved without regulatory intervention by CIRM. Finally, given the centrality of licensing agreements to attachment of access plan require-

132. Telephone Interview with Michael Goldberg, Partner, Mohr Davidow Ventures (Oct. 24, 2007).

133. *Id.*

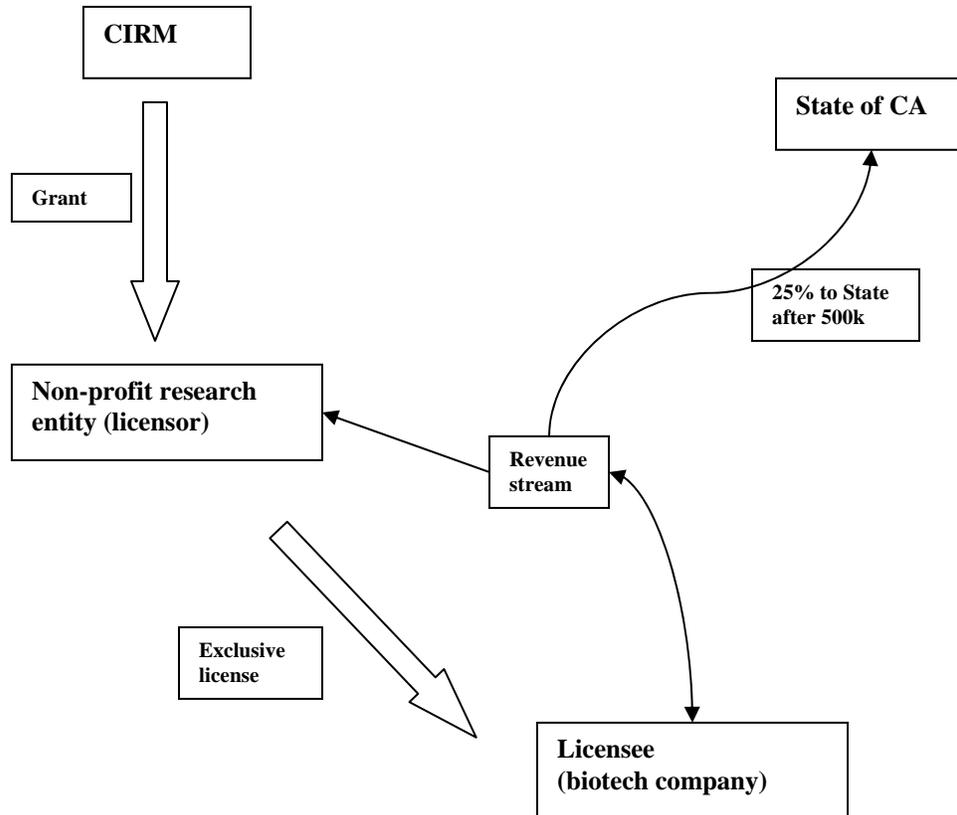
134. *Id.*

135. Walsh, *supra* note 131, at 323.

136. *Id.*

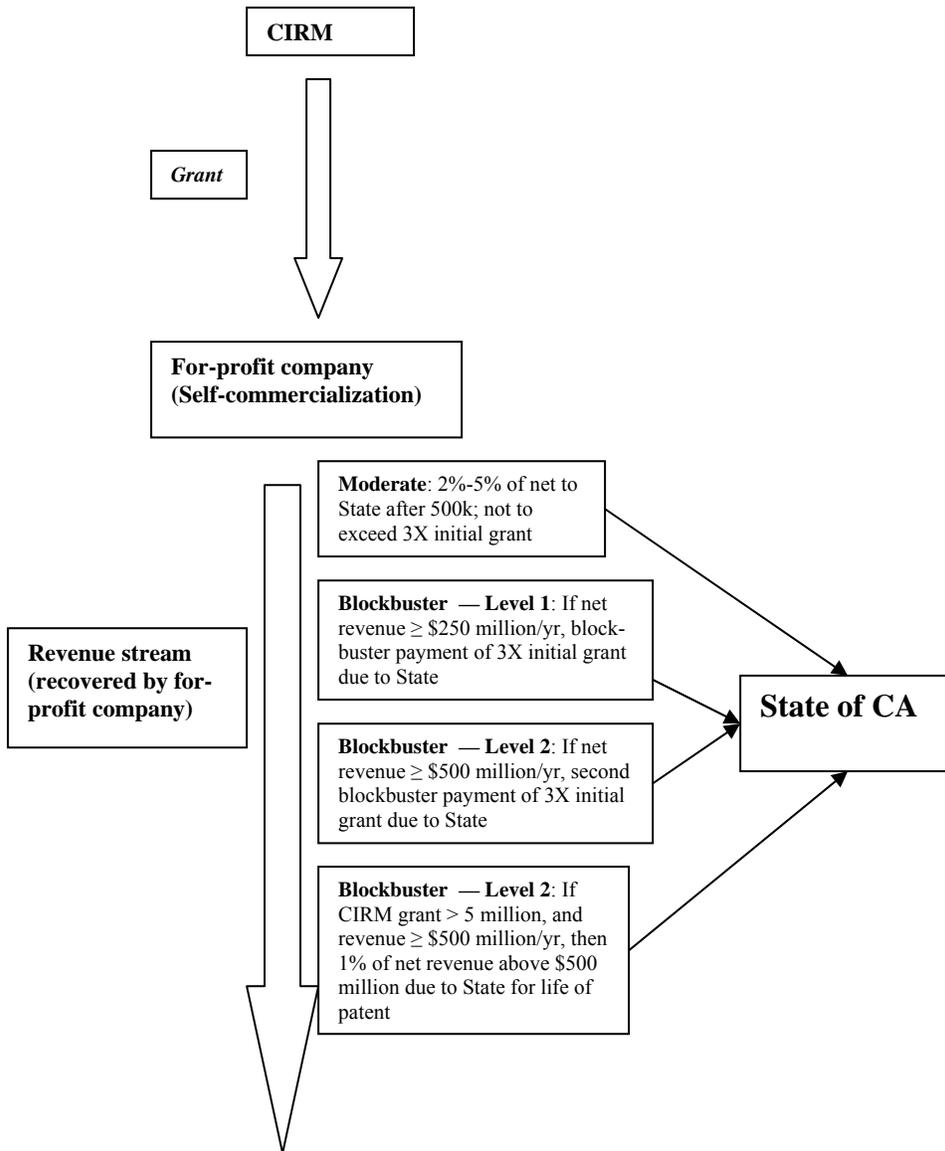
ments, CIRM should interpret licensing agreements on the basis of licensee intent and find exclusivity when licensees expect technologies to allow immediate market exploitation.

Figure 1: Non-Profit Revenue Sharing Scheme¹³⁷



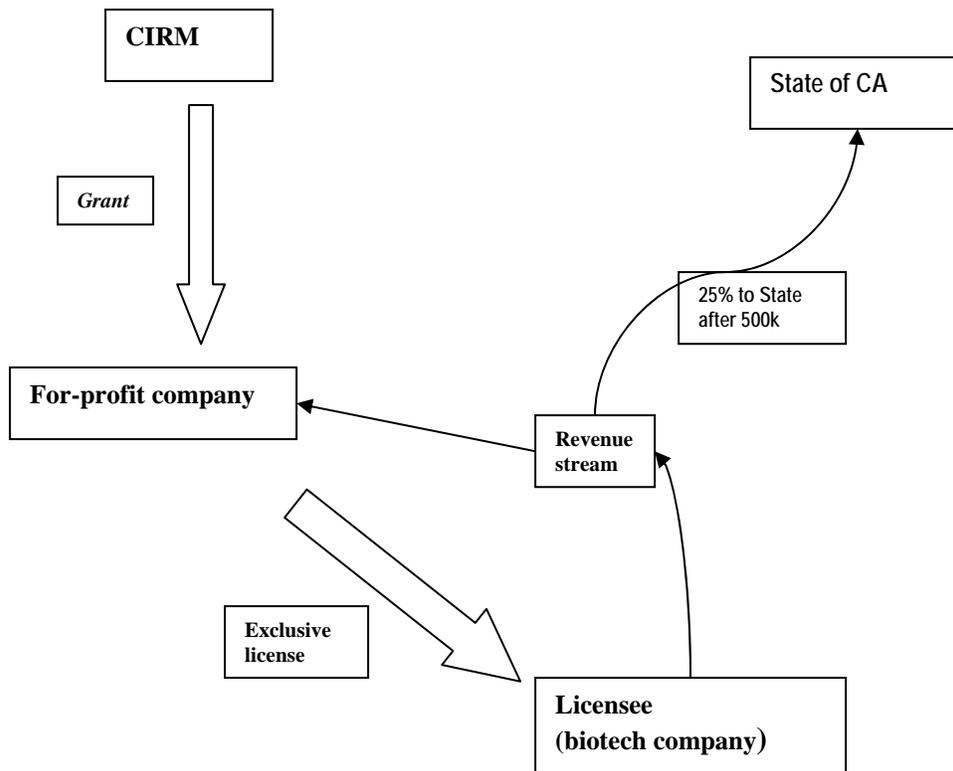
137. See CAL. CODE REGS. tit. 17, § 100408 (2007).

Figure 2: For-Profit Revenue Sharing Scheme (self-commercialization)¹³⁸



138. See CAL. CODE REGS. tit. 17, §§ 100408(b)(1)-(3) (2008).

Figure 3: For Profit Revenue Sharing Scheme (exclusive licensing)¹³⁹



139. See CAL. CODE REGS. tit. 17, § 100408(a)(1) (2008).