# WHOSE CELL LINE IS IT ANYWAY? INTELLECTUAL PROPERTY IMPLICATIONS OF NEW JERSEY'S POLICY ON STEM CELL RESEARCH

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## I. INTRODUCTION

Human stem cells, the most basic cells of the human body, have the unique ability to develop into more sophisticated cells and to repair or replenish defective cells.[1] Scientific research on human stem cells bears enormous potential because "when a stem cell divides, each new cell has the potential to either remain a stem cell or become another type of cell with a more specialized function, such as a muscle cell, a red blood cell, or a brain cell."[2] Indeed, in 2000, the federal government announced for the first time its position that "the potential medical benefits of human . . . stem cell technology are compelling and worthy of pursuit in accordance with appropriate ethical standards."[3] Similarly, despite the relative uncertainty regarding the potential advances derived from stem cell research, significant data indicate that research advocates' initial enthusiasm is justified.[4]

For purposes more relevant to this Comment, New Jersey's lawmakers have declared that "human stem cell research offers immense

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[1] NAT'L INSTS. OF HEALTH, U.S. DEP'T OF HEALTH & HUM. SERVS., STEM CELL INFORMATION: STEM CELL BASICS 1 (2006), http://stemcells.nih.gov/staticresources/info/basics/StemCellBasics.pdf.

[2] *Id.*

[3] Press Release, Nat'l Insts. of Health, NIH Publishes Final Guidelines for Stem Cell Research (Aug. 23, 2000), *available at* http://www.nih.gov/news/pr/aug2000/od-23.htm [hereinafter NIH Publishes Final Guidelines].

[4] AUDREY R. CHAPMAN ET AL., STEM CELL RESEARCH AND APPLICATIONS MONITORING THE FRONTIERS OF BIOMEDICAL RESEARCH 1 (1999), http://www.aaas.org/spp/dspp/sfrl/projects/stem/report.pdf. This report is "endorsed by the Board of Directors of the American Association for the Advancement of Science and by the Institute for Civil Society as a contribution to the public discussion of issues related to stem cell research and applications." *Id.*

promise for developing new medical therapies for . . . debilitating diseases and a critical means to explore fundamental questions of biology. Stem cell research could lead to unprecedented treatments and potential cures for Alzheimer's disease, cancer, diabetes, Parkinson's disease and other diseases."[5] To that end, in January 2004, New Jersey became the second state (after California) to statutorily authorize stem cell research.[6] In December 2005, New Jersey became the first state to publicly fund research of human embryonic cells, including research on certain cell lines which is ineligible for federal funding.[7] The state has committed $8.5 million in public funds to finance the research conducted at the Stem Cell Institute of New Jersey.[8]

Manifested by these legislative assurances, an underlying objective of New Jersey's pioneer stem cell policy is also "[t]o encourage and enable the state's renowned research and life sciences communities to develop quality, innovative treatments for patients."[9] Thus, although New Jersey's policy of encouraging stem cell innovation relies on these private entities, this Comment suggests that existing and pending New Jersey legislation and policy do not adequately clarify to whom the intellectual property rights belong in the case of publicly funded, but privately innovated, stem cell research. This lack of clarity may prove to be a disincentive that hinders the development of the anticipated breakthroughs expected of stem cell research.

Part II of this Comment explains the science involved in stem cell research, then traces federal and state policies concerning that research, and concludes with a detailed description of New Jersey's stem cell policy and legislation. Part III then explains the intellectual property issues that arise in the context of publicly funded stem cell research programs and how these problems are likely to arise under New Jersey's scheme. Finally, Part IV evaluates legislative solutions designed to remedy similar problems in other arenas of publicly

[5] N.J. STAT. ANN. § 26:2Z-1(c) (West 2006).

[6] CAL. HEALTH & SAFETY CODE § 125300 (West 2004) (authorizing stem cell research); *see also* 2003 N.J. Laws 203 (codified at N.J. STAT. ANN. § 26:2Z-1 (West 2004)); *see also* Ella Detrizio & Chris Brennan, *The New Jersey Stem Cell Research Law*, 3 N.J. LIFESCITECH 8–9 (2004).

[7] State of New Jersey Commission on Science & Technology, Stem Cell, http://www.state.nj.us/scitech/stemcell/ (last visited Feb. 6, 2008) (discussing the Commission's awarding of grants totaling $5 million to seventeen research teams) [hereinafter N.J. Sci. & Tech.].

[8] Stem Cell Institute of New Jersey, About the Institute, http://www2.umdnj.edu/scinjweb/about/index.htm (last visited Feb. 18, 2008) ("The mission of the Institute is to carry out research, training, and clinical studies on the application of stem cells to the treatment and cure of human disease.").

[9] *Id.*

funded innovation, ultimately contending that New Jersey has several options at its disposal to alleviate potential intellectual property disputes that would otherwise hinder the development of stem cell research.

## II. BACKGROUND OF THE SCIENCE BEHIND STEM CELL RESEARCH, FEDERAL POLICY, AND STATE POLICY

### *A. Scientific and Technological Understanding*

The advent of human embryonic stem cell research can be traced to 1998, when Drs. James Thompson and John Gearhart each isolated and cultured human embryonic stem cells for research purposes.[10] Understanding the science behind stem cell research begins with the concept that "[t]he stem cell is the alpha cell of all cells. Yet the stem cell is the most basic cell in the human body."[11] Researchers acquire stem cells from embryos that were fertilized in an in vitro fertilization clinic and subsequently donated with the informed consent of the donor.[12] "All stem cells—regardless of their source—have three general properties: they are capable of dividing and renewing themselves for long periods; they are unspecialized; and they can give rise to specialized cell types."[13] As they are unspecialized, stem cells cannot themselves perform specific cellular functions, such as pumping blood or causing bodily movement, but they can bring about specialized cells, such as blood, nerve, or cardiac muscle cells, through a process known as differentiation.[14]

Scientists classify stem cells as belonging to one of three distinct types: totipotent, pluripotent, and multipotent.[15] While both the totipotent and pluripotent cells have the potential to develop into

[10] Heather L. Fowler, Note, *Misapplied Ethical Considerations: U.S. Federal Stem Cell Mandates Lack Global Focus and Market Foresight*, 36 CORNELL INT'L L.J. 521, 523 (2004). It should be noted that Drs. Thompson and Gearhart, although employed by the University of Wisconsin and Johns Hopkins University, respectively, conducted this research in their individual and private capacities. *Id.*

[11] Carly Goldstein, Note, *Dipping into Uncle Sam's Pockets: Federal Funding of Stem Cell Research: Is It Legal?*, 11 B.U. PUB. INT. L.J. 229, 231 (2002) (citing NAT'L INSTS. OF HEALTH, STEM CELLS: A PRIMER (2000)). That is, although the stem cell is the most basic of all human cells, it is considered the alpha cell because of its dominant effect on the future development of the body. *Id.*

[12] NAT'L INSTS. OF HEALTH, *supra* note 1, at 6.

[13] *Id.* at 4. "Unspecialized" cells are cells that lack tissue-specific structures that enable them to execute any specialized functions. *Id.* "Specialized" cells, to the contrary, are structured to perform specific bodily functions. *Id.*

[14] *Id.*

[15] Goldstein, *supra* note 11 (discussing CHAPMAN ET AL., *supra* note 4).

any cellular structure within the human body,[16] only the totipotent stem cell—formed at the moment when the sperm fertilizes the egg—can develop into a fully functional organism.[17] Conversely, as an already specialized stem cell, the ultimate development of the multipotent stem cell—cultivated from adult stem cells without much controversy—is limited to the certain tissue which it already comprises.[18]

As such, scientists believe that advances in stem cell research will lead to several medical breakthroughs because researchers can tap the substantial potential of stem cells prior to their ultimately limiting transformation into a specific body part.[19] These anticipated breakthroughs include understanding the complexities of human development, safer and more precise testing of new and experimental drugs, and, perhaps most importantly, cell-based therapies. Such therapies include the creation of replacement tissues, renewable sources for organ transplants, and treatment of diseases and conditions, including Alzheimer's disease, Parkinson's disease, diabetes, spinal cord injury, and many more.[20]

### *B. Federal Policy on Stem Cell Research*

Since the inception of stem cell research and technology, policymakers have wrestled with numerous ethical and moral concerns.[21] Most fundamentally, the ethical dilemma surrounding human embryonic stem cell research is rooted in the issue of whether the cells are characterized as embryos or merely specialized body tissue.[22] In order to make the taxing determination of whether stem cells are more analogous to somatic tissue rather than human embryos depends largely on determining the potentiality of a cell—a cell's potential to become a person.[23] Because technically any cell in the hu-

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[16] *Id.* at 231–32.

[17] *Id.* at 232.

[18] *Id.*

[19] Joanna K. Sax, *The States "Race" with the Federal Government for Stem Cell Research*, 15 ANNALS HEALTH L. 1, 5 (2006); *see supra* note 14 and accompanying text.

[20] NAT'L INSTS. OF HEALTH, *supra* note 1, at 15.

[21] *See generally* CHAPMAN ET AL., *supra* note 4.

[22] *Id.* at 11 ("Although the answer to this question will be less important to those who believe that the early embryo has little or no moral status, it will shape the views of those who regard the embryo as significantly protectable."). This distinction is so crucial to the ethical determination because, depending on which perspective one subscribes to, the use of stem cells will either be deemed destruction of life or, less profoundly, morally acceptable scientific research—a debate that evokes many of the concerns associated with the abortion debate. *See id.*

[23] *Id.*

man body could become a person because of breakthroughs in cloning, proponents of stem cell research have circumvented this possible obstacle by focusing their arguments on the *natural* propensity of embryonic stem cells to become a person.[24] That is, "embryos have a natural potentiality to become a person in that the natural development of an embryo, unlike tissue, is to become a human being."[25] Thus, advocates of stem cell research liken stem cells to tissue and avoid the moral dilemmas traditionally associated with issues such as abortion or mammalian cloning.[26]

With these ethical concerns constantly at the forefront of the public discussion of stem cell research, policy regarding this technology has by and large remained conservative.[27] President Ronald Reagan prohibited federal funding of stem cell research through a moratorium that lasted throughout the 1980s.[28] President Reagan rationalized his decision with the theory that embryonic and fetal research would foment abortion and render taxpayers complicit in causing the death of fetuses.[29] President George H.W. Bush preserved the moratorium, maintaining "the pro-life view that any experimentation on a fetus or embryo is equivalent to experimentation on a human being."[30]

However, the tide began to shift in 1993 when, on his first day in office, President Bill Clinton lifted the existing moratorium that had prohibited fetal tissue research for the past decade.[31] Effectively, President Clinton's executive order provided the impetus for federal funding of embryonic and fetal research.[32] Shortly thereafter, the National Institutes of Health (NIH) Embryo Research Panel recommended federal funding of embryo research.[33]

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[24] *See id.* at 11–12.

[25] *Id.* at 11.

[26] *Id.*

[27] *See* Goldstein, *supra* note 11, at 237–42; *see also* Fowler, *supra* note 10, at 523–25, 538–43 (providing a more detailed account of the Clinton and G.W. Bush administrations' stem cell policies).

[28] Nelle S. Paegel, *Use of Stem Cells in Biotechnological Research*, 22 WHITTIER L. REV. 1183, 1199 (2001).

[29] *Id.*

[30] Scott Davison, *Influencing NIH Policy over Embryonic Stem-Cell Research: An Administrative Tug-of-War Between Congress and the President*, 22 J. NAT'L ASS'N ADMIN. L. JUDGES 405, 410 (2002).

[31] Memorandum on Fetal Tissue Transplantation Research, 29 WEEKLY COMP. PRES. DOC. 87 (Jan. 22, 1993); *see also* Debra Rosenberg & Martha Brant, *Taking Aim at Abortion*, NEWSWEEK, Feb. 5, 2001, at 27.

[32] Davison, *supra* note 30, at 410.

[33] Eric Juengst & Michael Fossel, *The Ethics of Embryonic Stem Cells—Now and Forever, Cells Without End*, 284 JAMA 3180, 3182 (2000); *see also* Marjorie Shaffer, *NIH*

Accordingly, on October 3, 1995, President Clinton created the National Bioethics Advisory Commission (NBAC), a diverse panel of scientists and policymakers, and charged it with investigating the controversial issues surrounding stem cell research.[34] Ultimately, the NBAC made broad recommendations to permit federal funding of embryonic stem cell research.[35] The essence of these recommendations was that the federal government should, under appropriate ethical standards, fund research using cells excised from existing cadaveric fetal tissue and research using cells that would otherwise be discarded after infertility treatments, but should not fund research using cells from embryos that were created (either by in vitro fertilization or somatic cell nuclear transfer) solely for research purposes.[36]

In 1996, Congress limited the scope of federal funding used to support stem cell research with the Dickey Amendment, which is a rider to appropriations bills passed every year since its inception.[37] Through this enactment, Congress banned federal funding of:

> (1) [T]he creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero.
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> . . . (b) For purposes of this section, the term "human embryo or embryos" includes any organism, not protected as a human subject under [45 C.F.R. § 46] as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning or any other means from one or more human gametes or human diploid cells.[38]

*Panel Recommends Research on Human Embryos,* BIOTECHNOLOGY NEWSWATCH, Oct. 3, 1994, at 1.

[34] NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH (1999), http://www.bioethics.gov/reports/past_commissions/nbac_stemcell1.pdf.

[35] *Id.* ("[I]n light of public testimony, expert advice, and published writings, we have found substantial agreement among individuals with diverse perspectives that although the human embryo and fetus deserve respect as forms of human life, the scientific and clinical benefits of stem cell research should not be foregone.").

[36] *Id.* at 65–81.

[37] Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, H.R. 3043 110th Cong. § 509 (2008) (illustrating the most recent use of the language from the Dickey Amendment in the 110th Congress's appropriations legislation); *see also* Roger G. Noll, *California's Stem Cell Initiative: Converting the Legal and Policy Challenges: Designing an Effective Program of State-Sponsored Human Embryonic Stem Cell Research*, 21 BERKELEY TECH. L.J. 1143, 1144 (2006).

[38] H.R. 3043 § 509.

In 1998, the Department of Health and Human Services (HHS) declared that embryonic stem cells are incapable of developing into a human being,[39] thereby expressly removing embryonic stem cell research from the purview of the 1996 Congressional ban.[40]

Armed with this new declaration from the HHS, the NIH released new guidelines on August 23, 2000 to govern federally funded stem cell research.[41] These guidelines reflect the NIH's new policy that "the potential medical benefits of human pluripotent stem cell technology are compelling and worthy of pursuit in accordance with appropriate ethical standards."[42] In constructing this reformed policy, the NIH distinguished the 2000 Guidelines from the 1994 recommendations that were struck down by Congress. The NIH's distinction between stem cells *derived for* research purposes and those *used for* research purposes permit federally funded scientists to conduct research on existing stem cell lines, but not on cell lines created specifically for research purposes.[43] Thus, since the cells themselves cannot be considered embryos, federally funded scientists are not forbidden from conducting research on them as long as these scientists comport with certain conditions prescribed by the guidelines.[44]

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[39] *Research Using Stem Cells: Before the S. Appropriations Subcomm. on Labor, Health and Human Services, Education and Related Agencies*, 105th Cong. (1998) (statement of Harold Varmus, Director of National Institutes of Health, Department of Health and Human Services), *available at* http://stemcells.nih.gov/policy/statements/120298.asp; *see also* Kathi E. Hanna, *Stem Cell Politics: Difficult Choices for the White House and Congress*, HASTINGS CENTER REP., July–Aug. 2001, at 9.

[40] Extracting stem cell research from the purview of the Dickey Amendment, of course, rests on a presumption in favor of the *natural potentiality* position discussed herein. *See supra* notes 23–25 and accompanying text.

[41] NIH Publishes Final Guidelines, *supra* note 3; *see also* Goldstein, *supra* note 11, at 248–50 (explaining that the NIH guidelines do not violate the Dickey Amendment).

[42] NIH Publishes Final Guidelines, *supra* note 3.

> [Further, t]he *Guidelines* prescribe the documentation and assurances that must accompany requests for NIH funding for research using human pluripotent stem cells from human embryos or fetal tissue. The *Guidelines* state specific criteria for informed consent and establish a Human Pluripotent Stem Cell Review Group to review documentation of compliance with the NIH *Guidelines*. In addition, the *Guidelines* delineate areas of research involving human pluripotent stem cells that are ineligible for NIH funding.

*Id.*

[43] Goldstein, *supra* note 11, at 239 (citing Juengst & Fossel, *supra* note 33, at 3183).

[44] *Id.*; *see also* National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51976, 51979–81 (Aug. 25, 2000). Again, these conditions, in pertinent part, rest on the distinction between cell lines derived for research purposes and those used for research purposes.

In August 2001, President George W. Bush announced the current federal executive policy permitting the use of federal funds solely for research on existing stem cell lines and creating a presidential council for monitoring developments in, and establishing guidelines for, stem cell research.[45] Further, President Bush promised to veto any legislation that allows federal funding for: "(1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) the cloning of human embryos for any purpose."[46] Therefore, the Bush policy effectively rejects the NIH Guidelines insofar as they proscribe federal funding of stem cell research involving any stem cell lines other than those already in existence.[47] The NIH—the government's leading organization on biomedical research—quickly followed the President's lead:

> [F]ederal funds may be awarded for research using human embryonic stem cells if the following criteria are met: The derivation process (which begins with the destruction of the embryo) was initiated *prior* to 9:00 P.M. EDT on August 9, 2001. The stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed. Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements.[48]

### *C. States' Policy on Stem Cell Research*

Notwithstanding federal restrictions on stem cell research, states have exercised their own discretion in forming their individual policies regarding the controversial technology.[49] State policies "range from statutes in California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, New Jersey, and New York, which encourage embryonic stem cell research, to South Dakota's law, which strictly forbids research on embryos regardless of the source."[50] As indicated by New Jersey's and California's policies, "some states so strongly believe in

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[45] Address to the Nation on Stem Cell Research from Crawford, Texas, 37 PUB. PAPERS 32 (Aug. 13, 2001).

[46] Press Release, The White House, President George W. Bush, Fact Sheet: Embryonic Stem Cell Research (Aug. 9, 2001), *available at* http://www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html [hereinafter Fact Sheet].

[47] *See id.*

[48] NIH's Role in Federal Policy: Stem Cell Research, http://stemcells.nih.gov/policy/NIHFedPolicy.asp (last visited Feb. 6, 2008) (emphasis added).

[49] *See* Sax, *supra* note 19, at 21–26.

[50] Nat'l Conf. of State Legislatures, Stem Cell Research, http://www.ncsl.org/programs/health/Genetics/embfet.htm (last visited Feb. 6, 2008).

stem cell research, either for medical, political, or economic reasons, that they are willing to support research that the federal government is not willing to presently fund."[51] The most recent development in this nationwide debate was Missouri voters' ratification of the Missouri Stem Cell Research and Cures Initiative, essentially authorizing any stem cell research programs that meet the federal guidelines.[52]

While some states are still unwilling to authorize stem cell research,[53] California and New Jersey have taken the lead in legislatively permitting and declaring the benefits of stem cell research.[54] Specifically, in becoming the first state to authorize stem cell research within its borders, California declared in 2002 "that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells, including somatic cell nuclear transplantation, shall be reviewed by a stem cell research oversight committee."[55]

California's policy determination is based on a number of findings, such as the legislature's conviction that "[s]tem cell research offers immense promise for developing new medical therapies for these debilitating diseases and a critical means to explore fundamental questions of biology. Stem cell research could lead to unprecedented treatments and potential cures for diabetes, Alzheimer's disease, cancer, and other diseases."[56] Furthermore, scientific advancement and medical breakthroughs were not the only sparks for this revolutionary policy:

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[51] Sax, *supra* note 19, at 20.

[52] MO. CONST. art. III, § 38(d)(1)–(2).

> To ensure that Missouri patients have access to stem cell therapies and cures, that Missouri researchers can conduct stem cell research in the state, and that all such research is conducted safely and ethically, any stem cell research permitted under federal law may be conducted in Missouri, and any stem cell therapies and cures permitted under federal law may be provided to patients in Missouri, subject to the requirements of federal law and [certain named limitations and requirements].

*Id.* § 38(d)(2).

[53] *See, e.g.*, Paul Smaglik, *Stem-Cell State Lines*, 429 NATURE 905, 905 (2004) (discussing Missouri's (currently outdated) and Kansas's specific bans on stem cell research).

[54] CAL. CONST., art. XXXV, *amended by* Proposition 71 (2004) (funding stem cell research); CAL. HEALTH & SAFETY CODE § 125290.10 (West 2004); CAL. HEALTH & SAFETY CODE § 125300 (West 2006) (authorizing stem cell research); N.J. STAT. ANN. §§ 26:2Z-1, -2 (West 2004); *see also infra* Part II.D.

[55] CAL. HEALTH & SAFETY CODE § 125300.

[56] *Id.* § 125300(d).

> California's biomedical industry is a critical component of the state's economy that provides employment in over 2,500 companies to over 225,000 Californians, pays $12.8 billion in wages and salaries, invests more than $2.1 billion in research, and reports nearly $7.8 billion in worldwide revenue, and would be significantly diminished by limitations imposed on stem cell research.[57]

Following New Jersey's commitment to fund the technology,[58] the voters of California passed Proposition 71, which created the California Institute for Regenerative Medicine (CIRM)[59] and expressly allocated "an average of $295 million per year in bonds over a 10-year period to fund stem cell research and dedicated facilities for scientists at California's universities and other advanced medical research facilities throughout the state."[60] Proposition 71 also established the Independent Citizen's Oversight Committee (ICOC),[61] a twenty-nine member board comprised of experts from public and private California universities, non-profit and for-profit medical research firms, and disease research advocacy groups, to govern the CIRM.[62] Moreover, as one of the principal authors of Proposition 71 argued, the high costs of funding stem cell research will be offset by the gains enjoyed by California due to the economic growth expected from the promise of the technology.[63]

As it stands, despite the fervor with which Proposition 71 was enacted and promoted, the awarding of research grants has been tempered by litigation brought by challengers of the decision to fund the grants through general obligation bonds.[64] Consequently, in an ef-

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[57] *Id.* § 125300(f).

[58] N.J. STAT. ANN. § 26:2Z-1(f).

> Open scientific inquiry and publicly funded research will be essential to realizing the promise of stem cell research and maintaining this State's leadership in biomedicine and biotechnology. Publicly funded stem cell research . . . offers the most efficient and responsible means of fulfilling the promise of stem cells to provide regenerative medical therapies.

*Id.*

[59] CAL. HEALTH & SAFETY CODE § 125290.10.

[60] 2004 Cal. Legis. Serv. Prop. 71 (West).

[61] CAL. HEALTH & SAFETY CODE § 125290.15.

[62] *Id.* § 125290.20(a).

[63] Sax, *supra* note 19, at 23 (citing Connie Bruck, *Hollywood Science*, NEW YORKER, Oct. 18, 2004, at 70 (discussing how Robert Klein, a California real estate mogul and author of Proposition 71, proposed funding the Institute)).

[64] *See* Press Release, California Institute for Regenerative Medicine, Appellate Court Sets Hearing for Stem Cell Litigation (Jan. 18, 2007), *available at* http://www.cirm.ca.gov/press/pdf/2007/01-18-07.pdf (explaining plaintiffs' appeal from lower court's ruling that funding through general obligation bonds is constitutional and not in violation of any statutes or government oversight duties).

fort to encourage the policy despite the obstacles presented by this litigation, Governor Schwarzenegger ordered a $150 million loan in August 2006, largely provided by a fund comprised of money from private philanthropists and organizations, allowing CIRM to presently solicit proposals for grants.[65]

Other states have since followed California's and New Jersey's lead by at least authorizing, if not also funding, stem cell research.[66] For instance, in 2005, the Connecticut General Assembly established its Stem Cell Research Fund which, not unlike California, consists of "not less than ten million dollars . . . for grants-in-aid to eligible institutions for the purpose of conducting embryonic or human adult stem cell research,"[67] for a ten-year period that began in June 2006.[68]

Similarly, following a 2005 executive order signed by Governor Blagojevich,[69] Illinois maintains that it "is at the forefront of stem cell research as the first Midwest state, and only the fourth state in the nation, to commit public dollars to support this ground-breaking science."[70] Upon creating the Illinois Regenerative Medicine Institute (IRMI), Governor Blagojevich transferred ten million dollars in budget funds to the program.[71] Subsequently, the IRMI awarded its first grants in April 2006, and the health department has appropriated five million dollars from its budget to the stem cell research program for fiscal year 2007.[72]

Taking a smaller but no less significant step, the Indiana General Assembly authorized Indiana University to "establish an adult stem cell research center."[73] Thus far, Indiana has allocated fifty thousand dollars toward establishing the center.[74] In 2006, the Maryland Gen-

[65] Press Release, California Institute for Regenerative Medicine, $181 Million Headed for Stem Cell Institute (Nov. 20, 2006), *available at* http://www.cirm.ca.gov/press/pdf/2006/11-20-06.pdf; *see also* Governor Arnold Schwarzenegger, Discussion of Executive Action to Strengthen Stem Cell Research (July 21, 2006), *available at* http://gov.ca.gov/index.php?/speech/2538/.

[66] *See generally* Nat'l Conf. of State Legislatures, *supra* note 50 (providing a concise summary and chart of state legislation and executive orders permitting and funding stem cell research).

[67] CONN. GEN. STAT. § 19a-32e(c) (2005).

[68] *Id.*

[69] Exec. Order No. 2005-6, Executive Order Creating the Illinois Regenerative Institute for Stem Cell Research (July 12, 2005).

[70] Illinois Regenerative Medicine Institute, About IRMI, http://www.idph.state.il.us/irmi/about.html (last visited Oct. 23, 2006).

[71] Exec. Order No. 2005-6, *supra* note 69; *see also* Nat'l Conf. of State Legislatures, *supra* note 50.

[72] Nat'l Conf. of State Legislatures, *supra* note 50.

[73] IND. CODE ANN. § 21-45-4-1 (West 2007).

[74] Nat'l Conf. of State Legislatures, *supra* note 50.

eral Assembly adopted a similar program when it established the Maryland Stem Cell Research Fund, to distribute grants for research conducted on adult and embryonic stem cells.[75] Maryland has allocated fifteen million dollars for the Stem Cell Research Fund for fiscal year 2007.[76]

Seeking a more developed and expansive policy, the Massachusetts legislature enacted two statutory provisions demonstrating the state's interest in fostering stem cell research.[77] The first establishes a "biomedical research advisory council"[78] that combines the efforts and experiences of several officials from the state's department of health and the University of Massachusetts Medical School.[79] The second provision announces that:

> [T]he purpose of this chapter is to establish a life sciences center . . . intended to: (i) promote the best available research in life sciences disciplines through diverse institutions and to build upon existing strengths in the area of biosciences in order to spread the economic benefits across the commonwealth; and, (ii) foster improved health care outcomes in the commonwealth and the world.[80]

The latter provision also provides funding for the program with the Life Sciences Investment Fund.[81] It is important to note, however, that the general court enacted these provisions after overriding Governor Romney's veto of the proposed pro-stem cell research legislation.[82]

Hesitant states (yet willing nonetheless) continue to contemplate stem cell research, enacting limited legislation that gradually demon-

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[75] MD. ANN. CODE art. 83A, § 5-2B-03 (2006).

[76] *Id.*; *see also* Nat'l Conf. of State Legislatures, *supra* note 50.

[77] MASS. ANN. LAWS ch. 111L, § 9 (LexisNexis 2006); *id.* ch. 23I, § 1(8)–(9).

[78] *Id.* ch. 111L, § 9(a).

[79] *Id.*

[80] *Id.* ch. 23I, § 1(8)–(9).

[81] Nat'l Conf. of State Legislatures, *supra* note 50.

> The second establishes a life sciences center to promote life sciences research in advanced and applied sciences, including but not limited to stem cell research, regenerative medicine, biotechnology, and nanotechnology and creates the Life Sciences Investment Fund to make appropriations, allocations, grants or loans to leverage development and investments in stem cell research and other areas. $10,000,000 was appropriated to the fund.

*Id.*

[82] *Id.*

strates such states' readiness to permit the controversial experimentation.[83] In sum:

> Even though the federal government is not funding laboratories that want to establish new stem cell lines, public money is still being used to promote this research at the state level. Researchers wishing to engage in frontier science have limited choices. They can either attempt to solicit private funding at the institute where they currently research or move to a state with a commitment to funding the research.[84]

### *D. New Jersey's Stem Cell Research Policy*

New Jersey passed legislation in January 2004 authorizing and encouraging stem cell research.[85] "The New Jersey bill allows all types of stem cell research[,] . . . sets up an institutional review board to review stem cell research, and states that information will be presented to infertility patients about their options to donate unused embryos to research."[86]

A major catalyst for New Jersey's "proclamation"[87] was the state's recognition that "[t]he biomedical industry is a critical and growing component of New Jersey's economy, and would be significantly diminished by limitations imposed on stem cell research."[88] In view of that, in May 2004, New Jersey became the first state to publicly fund stem cell research when Governor James McGreevey signed legislation that established "the nation's first state-supported stem cell research facility."[89] In addition, during his term as Acting Governor of New Jersey, Richard Codey issued an executive order "solidifying New Jersey's position as a scientific leader through the creation of a public umbilical cord and placental blood bank for use in stem cell re-

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[83] *See, e.g.*, WASH. REV. CODE § 43.350.005 (2006) (setting up a rather open ended scheme by which the Washington State Legislature discusses the benefits of stem cell research and authorizes a life sciences discovery fund that may result in future grants for stem cell research); *see also* The Christopher Reeve Stem Cell Research Fund, VA. CODE ANN. § 23-286.1 (2006) (authorizing a fund consisting of money to "be used solely to support medical and biomedical stem cell research conducted in Virginia institutions of higher education that relates to the causes and cures of disease," but not specifically providing any money for the fund).

[84] Sax, *supra* note 19, at 25–26.

[85] N.J. STAT. ANN. §§ 26:2Z-1, -2 (West 2006); *see also* Detrizio & Brennan, *supra* note 6.

[86] Sax, *supra* note 19, at 21; *see generally* N.J. STAT. ANN. §§ 26:2Z-1, -2.

[87] Jeremy Pearce, *Entering a Brave New World, Warily*, N.Y. TIMES, Jan. 18, 2004, at 14NJ1.

[88] N.J. STAT. ANN. § 26:2Z-1(e).

[89] David Kocieniewski, *McGreevey Signs Bill Creating Stem Cell Research Center*, N.Y. TIMES, May 14, 2004, at B5.

search."[90] This measure entrusts all the research and financing to the Stem Cell Institute, instead of spreading the funds throughout the state like California's Proposition 71;[91] it also encourages New Jersey scientists to collaborate with researchers from around the world.[92]

New Jersey took another step as a pioneer in funding stem cell research in December 2005 when its Commission on Science and Technology granted five million dollars to seventeen New Jersey educational, nonprofit, and corporate research teams for cutting-edge exploration of potential cures and treatments for devastating and debilitating conditions.[93] Governor Jon Corzine approved legislation that allocates $270 million to construct and equip several stem cell research laboratories throughout the state.[94] However, New Jersey's efforts to fund the cutting edge research suffered an unexpected setback in November 2007, when voters rejected a measure that would have allowed the state to borrow up to $450 billion over the next ten years to fund stem cell research.[95] Notwithstanding this interruption to New Jersey's momentum, the remainder of this Comment focuses on the intellectual property implications that are likely to arise as New Jersey continues to remain at the forefront of stem cell research.

[90] Press Release, New Jersey Office of the Governor, Codey Announces Pioneering Stem Cell Research Initiative (Oct. 18, 2005), *available at* http://www.nj.gov/cgi-bin/governor/njnewsline/view_article.pl?id=2780.

[91] *See* CAL. CONST. art. XXXV, *amended by* Proposition 71 (2004); CAL. HEALTH & SAFETY CODE § 125290.10 (West 2006); *see also supra* notes 60–65.

[92] State of New Jersey Commission on Science & Technology, The Stem Cell Institute of New Jersey, http://www.state.nj.us/scitech/stemcell/institute (last visited Feb. 21, 2008) [hereinafter N.J. Stem Cell Inst.]; *see also* CAL. CONST. art. XXXV, *amended by* Proposition 71 (2004); CAL. HEALTH & SAFETY CODE § 125290.10; *see also supra* notes 60–65.

[93] N.J. Sci. & Tech., *supra* note 7 ("In December 2005 the Commission awarded the Ellie Katz Umbilical Cord Blood Program and the Coriell Institute for Medical Research $350,000 each to create the nation's first public cord and placental blood bank for stem cell research.").

[94] N.J. Stem Cell Inst., *supra* note 92.

[95] Terrence Dopp, *New Jersey Rejects Stem-Cell Bonds in "Big Defeat,"* BLOOMBERG.COM, Nov. 7, 2007, http://www.bloomberg.com/apps/news?pid=20601087&sid=azGJAFWSMcjs&refer=home.

## III. SIDE EFFECTS OF PUBLICLY FUNDED STEM CELL RESEARCH PROGRAMS AND THEIR LIKELY MANIFESTATION IN NEW JERSEY

### *A. Intellectual Property Implications Encountered Under Other Publicly Funded Stem Cell Research Programs*

"[B]ecause [stem cell] research will most likely proceed under some combination of federal, state, local, non-profit and private for-profit funding sources, the ownership rights will be anything but clear."[96] That is, unlike the simplest scenario, in which a private company is the sole source of funding for its own research, and contractual provisions govern most potential intellectual property disputes with employed scientists, problems may, and often do, arise in the context of state entities funding scientific research.[97]

Generally, the addition of any source of funding—whether state, corporate, or private grant, for example—only further complicates the already hazy question of intellectual property ownership.[98] Yet, unfortunately, it is unlikely that the confusion surrounding intellectual property rights in the arena of stem cell research will lead to strictly private funding, as the requisite amount of funding will hardly be procurable from one source.[99]

The official scholarly rebuttals to California's Proposition 71, released in the election materials shortly before the state-wide vote on the measure, best crystallize the murky intellectual property implications arising under state-funded stem cell research programs.[100] "The *Argument Against Proposition 71* . . . focused largely on the 'boondoggle' aspects of the measure, including a lack of accountability, closed-door meetings, and the funneling of a staggering amount of money

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[96] Sean M. O'Connor, *Intellectual Property Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, 39 NEW ENG. L. REV. 665, 666 (2005).

[97] *Id.* at 667–68 (explaining that private companies employing innovative workforces attempt to avoid such problems with explicit contractual provisions; however, in a situation where a state-funded university uses those funds to finance a researcher and his lab, "any patentable inventions that the researcher invents in the course and scope of his employment with the university must be assigned to the university").

[98] *E.g.*, 17 U.S.C. § 201(b) (2000) (demonstrating copyright issues arising in work-for-hire contexts); *see* O'Connor, *supra* note 96, at 668–69; *see also* DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW: CASES AND MATERIALS 72 n.3 (3d ed. 2004) (explaining similar concerns germane to patent law).

[99] *See* O'Connor, *supra* note 96, at 670.

[100] *See* ATT'Y. GEN., PROPOSITION 71: OFFICIAL TITLE AND SUMMARY, at 72–73, *available at* http://www.ss.ca.gov/elections/bp_nov04/prop_71_entire.pdf; *see also* O'Connor, *supra* note 96, at 676–79.

to 'corporate research' that would ultimately result in windfall profits to private corporations."[101]

For example, Mitch Kapor, a renowned software developer[102] who serves as President and Chair of the Open Source Applications Foundation,[103] applied the aforementioned critiques to the intellectual property context of Proposition 71 in a letter that was widely disseminated days before the vote.[104] Of Kapor's myriad concerns,[105] the most germane to this Comment asserts that Proposition 71 will give rise to ownership disputes between the private venture capitalists who will fund the research and the scientists who will conduct it.[106] Ironically, Proposition 71 evinces this distressing ambiguity in its own provision addressing the intellectual property issues:

> [A]ll grants and loan awards [are] 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.[107]

At least one commentator has argued that such language leaves the intellectual property issues entirely too unresolved.[108] "In the abstract this [statutory provision] sounds reasonable and desirable enough. But, the devil is in the details: Proposition 71 essentially hands off determination of the correct balance *and* the means to effectively achieve that balance to the brand new and untested

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[101] O'Connor, *supra* note 96, at 676–77 (citing ATT'Y. GEN., *supra* note 100, at 73).

[102] Mitchell Kapor, Biography, http://www.kapor.com/bio/index.html (last visited Feb. 6, 2008).

> He is widely known as founder of Lotus Development Corporation and the designer of Lotus 1-2-3, the "killer application" which made the personal computer ubiquitous in the business world in the 1980's. He has been at the forefront of the information technology revolution for a generation as an entrepreneur, investor, social activist, and philanthropist.

*Id.*

[103] Open Source Applications Foundation, http://www.osafoundation.org/ (last visited Feb. 6, 2008) ("OSAF is a non-profit organization working on Chandler Project, a personal information manager designed for small group collaboration.").

[104] Posting of Chris Nolan, *Just Say "No" Says Mitch*, POLITICS FROM LEFT TO RIGHT, http://www.chrisnolan.com/archives/000577.html#more (OCT. 26, 2004, 10:00 PST).

[105] *See id.* Kapor's concerns regarding Proposition 71 range from the potential for conflicts of interest, to insufficient accountability provisions, to the familiar ethical considerations routinely debated nationwide. *Id.*

[106] *Id.*

[107] CAL. HEALTH & SAFETY CODE § 125290.30(h) (West 2004).

[108] O'Connor, *supra* note 96, at 678–79.

ICOC."[109] The crux of this concern is that "Californians were asked to vote blindly for a $3 billion investment gambit whose IP rights and return on investment rules and procedures have yet to be established in any effective or binding manner."[110]

Comparing the unease created by Proposition 71 and the ICOC to the context of such blind-faith investing of taxpayers' dollars in cutting-edge research, one reporter hypothesized:

> Imagine that a partnership of scientists and Hollywood moguls urged you to invest in a promising but controversial field of medical research.
>
> The partnership would control how your money is spent, based on recommendations from appointed "working groups" whose meetings would be kept secret from you.
>
> Would you accept such a deal? Probably not.[111]

Thus, without an effective intellectual property structure in place clearly allocating intellectual property rights before the promise of stem cell research is realized, "the nightmare tussles over ownership and control will begin . . . [and] [t]his clamor will increase proportionally to the success of the therapies."[112] That is, "stem cell research will be a victim of its own success"[113] when public access is obstructed by either a chilled incentive for researchers because of an unfair share in ownership, or exorbitant prices for the therapies that arise from the work of innovators with too much private control.[114]

### *B. Manifestation of Intellectual Property Implications Likely to Arise Under New Jersey's Stem Cell Research Policies*

New Jersey's stem cell research policy, although motivated by the desire to spark innovation and maintain the state's status as a biomedical leader,[115] is ominously quiet regarding allocation of intellectual property rights.[116] While New Jersey expressly recognizes important governing principles of its stem cell research policy including "standards of open scientific exchange, peer review[,] and public

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[109] *Id.* at 678.

[110] *Id.*

[111] Stuart Leavenworth, *The Opaque Petri Dish*, SACRAMENTO BEE, Jan. 9, 2005, at E1.

[112] O'Connor, *supra* note 96, at 689.

[113] *Id.* at 687.

[114] *Id.* at 687–89.

[115] N.J. STAT. ANN. § 26:2Z-1(f) (West 2006) ("Open scientific inquiry and publicly funded research will be essential to realizing the promise of stem cell research and maintaining this State's leadership in biomedicine and biotechnology.").

[116] *See id.*; *see also* N.J. Sci. & Tech., *supra* note 7.

oversight,"[117] the state's purported aspirations such as "develop[ing] innovative treatments for patients and generat[ing] economic opportunity and job growth in New Jersey"[118] fail to provide any assurances to the innovators that they will receive adequate ownership rights.[119] As such, despite these good intentions, New Jersey's stem cell research policy may regrettably suffer the consequences that the aforementioned critics of California's Proposition 71 predicted.[120]

Such infirmities are present throughout New Jersey's statutes, as well as in other substantive policy statements, evidencing the potential for intellectual property murkiness.[121] Primarily, in its apparent mission statement, New Jersey declares its stem cell initiative's commitment to "advance New Jersey's position as a leader in scientific research . . . encourage . . . *innovative* treatments . . . support *groundbreaking* research . . . [and] generate economic opportunity and job growth."[122] Of course, in the United States, such goals are best achieved "by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries."[123]

Despite this vagueness, New Jersey has at its disposal two measures that at least provide a foundation upon which to build an adequate intellectual property scheme.[124] First, unlike the relative silence throughout the statutes authorizing stem cell research,[125] the Stem Cell Research Grant Program expressly provides that "[r]ecipient organizations will be required to share with the State of New Jersey a percentage of any income received from the intellectual property that might be developed with the State's grant support."[126] While this "guarantees that the state will receive a direct financial benefit from any commercial licensing,"[127] it does little to clarify the quantity of that benefit, or what portion of the commercial benefits the grantee

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[117] N.J. STAT. ANN. § 26:2Z-1(f).

[118] N.J. Sci. & Tech., *supra* note 7.

[119] *See id.*; *see also* N.J. STAT. ANN. §§ 26:2Z-1, -2 (West 2006).

[120] *See supra* Part III.A.

[121] *See* N.J. STAT. ANN. §§ 26:2Z-1, -2; N.J. Sci. & Tech., *supra* note 7.

[122] N.J. Sci. & Tech., *supra* note 7 (emphasis added).

[123] U.S. CONST. art. I, § 8, cl. 8.

[124] *See* State of New Jersey Commission on Science & Technology, Stem Cell Research Grant Program, http://www.state.nj.us/scitech/stemcell/grants/faqs.html (last visited Feb. 6, 2008) [hereinafter Stem Cell Research Grant Program]; State of New Jersey Commission on Science & Technology, Entrepreneur Assistance, http://www.state.nj.us/scitech/entassist/ (last visited Feb. 6, 2008) [hereinafter Entrepreneur Assistance].

[125] N.J. STAT. ANN. §§ 26:2Z-1, -2.

[126] Stem Cell Research Grant Program, *supra* note 124.

[127] *Id.*

can expect; yet it at least provides a starting point within the statutory framework.

Within New Jersey's intellectual property toolbox is its Edison Innovation R&D Fund ("Edison Fund").[128] The Edison Fund was designed to fund companies involved in early, high-risk stages of scientific and technological research and development.[129] Pertinent to this Comment, a main goal of the Edison Fund is to "increase[] the amount and value of intellectual property"[130] created by such companies. Underlying the Edison Fund are the familiar goals to "promote[] collaboration between universities and companies . . . and grow[] technology businesses in New Jersey"[131]—further evidence of New Jersey's commitment to remain a leader in biotechnology.

Unlike the concerns presented by the aforementioned policies,[132] the Edison Fund materials provide some quantitative guidance as to royalty distribution using language similar to that of the Stem Cell Research Grant Program, but taking it one step further:

> The Commission shall receive a percentage of royalty payments from any intangible property awarded to the grantee awarded assistance from the Commission and which assistance led to the awarding of the intangible property pursuant to New Jersey Statutes, P.L. 2005, c.272 as follows:
>
> - 1% of net sales resulting from IP developed under the grant—up to the original amount of the grant.
> - 1% of royalty payments received by the company for licensing IP developed under the grant—up to 10 times the original amount of the grant[.][133]

Under this administrative scheme, the Edison Fund caps the maximum amount of royalties payable to the State by the innovator at ten times the amount of the original grant, thereby providing clear guidelines for allocation of royalties to all interested parties.[134]

Nevertheless, all regulation of stem cell research in New Jersey falls under the rubrics of the Stem Cell Institute of New Jersey and the Stem Cell Research Grant Program because the Edison Fund is primarily a competition-encouraging mechanism designed to foster

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[128] Entrepreneur Assistance, *supra* note 124.

[129] *Id.*

[130] *Id.*

[131] *Id.*

[132] *See supra* Part III.A.

[133] STATE OF N.J. COMM'N ON SCI. & TECH., EDISON INNOVATION R&D FUND APPLICATION GUIDELINES 5 (2007), *available at* http://www.state.nj.us/scitech/pdf/entassist/edisonrdguidelines07.pdf.

[134] *Id.*

technological innovation by private companies that may or may not collaborate with a state research institution.[135] Consequently, the Edison Fund's unique clarity regarding intellectual property rights and royalty allocation can presently serve in no more than an advisory capacity.

In attempting to discern their intellectual property rights when funded by these programs, researchers must look to existing New Jersey intellectual property law applicable to work funded by the state's science and technology grant program.[136] Not surprisingly, this provision offers a quantitatively nebulous explanation of allocation of intellectual property rights to royalties:

> [The New Jersey Commission on Science and Technology] shall have authority to receive a percentage of royalty payments from any intangible property . . . awarded to any science and technology company that received assistance from the commission and which assistance led to the awarding of the intangible property [in exchange for certain financial and other obligations.][137]

Thus, while New Jersey's intentions, coupled with foundational intellectual property plans, provide a benevolent and fertile environment in which to develop the state's budding stem cell research frontier, the state needs specific and clear provisions addressing these issues. "This crisis, and its concomitant challenge to the social order and existing IP ownership structure, must be averted by taking proactive measures now. In fact, some sorting and planning of ownership claims that correspond to funding sources can be effected today for new stem cell research initiatives."[138]

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[135] Entrepreneur Assistance, *supra* note 124. "The Edison Innovation R&D Fund will provide grants on a competitive basis." *Id.* "Companies are encouraged to partner with any New Jersey PhD granting universities or with any company or institution with primary business location in New Jersey." *Id.* Moreover, to be eligible, companies must be "[o]rganized as a C Corp or an LLC." *Id.*; *see also supra* Part II.D.

[136] *See* N.J. STAT. ANN. § 52:9X-9 (West 2006). Thus, in crafting a regulatory scheme for state-funded stem cell research, New Jersey lawmakers cannot simply rely on the Edison Fund to govern these concerns since it only affects state institutions if they are partnered with an eligible "lead company." *See supra* note 135 and accompanying text.

[137] *Id.* § 52:9X-9(u). That is, the Commission does little to provide notice to potential innovators regarding the actual amount of royalties they should expect to share with the state. *See* Stem Cell Research Grant Program, *supra* note 124. While this seems to leave open only the question of the amount of royalties, other, more comprehensive, policy regimes demonstrate that there are a number of other concerns—including surrendering, relaxing, and guaranteeing certain rights—that must be addressed by a successful policy. *See infra* Part IV.

[138] O'Connor, *supra* note 96, at 666.

## IV. APPLICATION OF OTHER LEGISLATIVE AND REGULATORY SCHEMES: TOWARD A PROPOSAL TO AVOID CONFLICT IN NEW JERSEY

As suggested above, New Jersey must delineate clearer guidelines regarding intellectual property rights as the state begins to realize the burgeoning potential of stem cell research. New Jersey's policies regarding budding technologies such as stem cell research—with all the benefits that it promises—should provide more clarity rather than simply acknowledging that the state will receive some indefinite percentage of the income generated through intellectual property royalties. This clarity should come in the form of not only a precise royalty distribution framework, but also a satisfactory balance of rights and compromises between innovators and the state in exchange for both parties' surrendering of certain exclusivities.

Accordingly, while these measures are a significant starting point,[139] this Comment advocates that learning from other legislative and policy schemes will provide valuable assistance in addressing this problem. These schemes are California's Intellectual Property Policy for Non-Profit Organizations,[140] the National Science Foundation's (NSF) grant policy[141] governed by the Bayh-Dole Act,[142] and the Federal Orphan Drug Act.[143]

### *A. CIRM's Intellectual Property Policy for Non-Profit Organizations*

As New Jersey's chief fellow pioneer on the frontier of stem cell research, CIRM functions as the west coast equivalent to the Stem Cell Institute of New Jersey. As such, California's policy addressing these issues is of particular significance. In pertinent part, CIRM's policy declares its "core principles"[144] to be: "1. Ownership; 2. Broad Sharing; 3. Research Exemption; 4. Licensing; [and] 5. March-in rights."[145]

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[139] *See supra* Part II.B.

[140] CAL. INST. FOR REGENERATIVE MED., INTELLECTUAL PROPERTY POLICY FOR NON-PROFIT ORGANIZATIONS (2006), http://www.cirm.ca.gov/policies/pdf/ippnpo.pdf. CIRM is also developing a separate policy applicable to for-profit organizations. *Id.* *See also supra* Part III.A.

[141] Policies and Procedures for Inventions and Patents Resulting from Grants, Cooperative Agreements, and Contracts, 45 C.F.R. § 650 (1982); *see also* NAT'L SCI. FOUND., GRANT POLICY MANUAL 95–102 (2005), http://www.nsf.gov/pubs/manuals/gpm05_131/gpm05_131.pdf; *infra* Part III.B.

[142] Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–210 (2000)); *see also infra* Part IV.B.

[143] Orphan Drug Act, 21 U.S.C. §§ 360aa–ee (2000) (originally enacted as Pub. L. No. 97-414, 96 Stat. 2049 (1983)).

[144] CAL. INST. FOR REGENERATIVE MED., *supra* note 140, at 22.

[145] *Id.* at 22–23.

These provisions allow all grantees of CIRM funds to own the intellectual property arising from the Institute's financing, while encouraging a liberal sharing policy throughout the scientific and educational communities.[146] Although the owner-inventors will maintain ownership of all intellectual property, certain patented inventions will remain freely available to California research institutions.[147] Such grantees of CIRM funds "are expected to negotiate non-exclusive licensing agreements where possible . . . to encourage the successful commercial development of the invention into products and services that can benefit the public."[148] In an effort to balance the ownership interests of the inventors with CIRM's public welfare interests, the policy provides a march-in rights provision, which grants CIRM the ability to practically apply a patented invention when the inventor demonstrates underutilization of licensing amounting to waste.[149]

Thus, as a state with a comparable policy and attitude concerning stem cell research, New Jersey would be well-served to implement a similar intellectual property policy. The California policy "is intended to meet the dual goals of academic openness and the need to bring scientific advances to the public via commercialization" while also "facilitate[ing] the commercialization of CIRM-funded discoveries without impeding the progress of stem cell research."[150] This intellectual-property-geared language seems strikingly consistent with New Jersey's goals for its stem cell research program:

> New Jersey's stem cell research initiative is committed [t]o advanc[ing] New Jersey's position as a leader in scientific research and bring[ing] the benefits of stem cell research to New Jersey residents[; t]o encourage[ing] and enable[ing] the state's renowned research and life sciences communities to develop quality, innovative treatments for patients[; t]o support[ing] groundbreaking research that contributes to the understanding of stem cells and their potential and the translation of such research to patient treatment[; and t]o generat[ing] economic opportunity and job growth in New Jersey by accelerating commercialization

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[146] *Id.* at 22.

[147] *Id.*

[148] *Id.* at 23.

[149] *Id.* at 23, 37–38.

> Prior to exercising march-in rights, CIRM must determine that such action is necessary because of the failure of the grantee organization or its licensees to take effective steps to achieve practical application of the inventions in a particular field of use, to satisfy health or safety needs, or to meet requirements for public use.

*Id.* at 37.

[150] CAL. INST. FOR REGENERATIVE MED., *supra* note 140, at 4–5.

> of new therapies and new technologies related to stem cell research.[151]

Thus, as the Stem Cell Institute of New Jersey formulates its intellectual property policy, it should consider what CIRM, its co-pioneer in the arena of stem cell research, has adopted in California. Such a clear description of ownership rights, coupled with even clearer royalty allocation language as that found in New Jersey's Edison Fund,[152] demonstrates an ideal foundation on which to build a suitable intellectual property framework.

### *B. The NSF Grant Policy and the Bayh-Dole Act*

As the main governmental agency charged with funding scientific innovation with federal money,[153] the NSF is an ideal reference point from which New Jersey can model its intellectual property policies regarding stem cell research. In 1982, the NSF updated its regulations governing inventions and patents borne from NSF-granted federal funds.[154] The impetus for this policy revision was the NSF's objective to align its treatment of such intellectual property with the governmental interests set forth in the Federal Bayh-Dole Act.[155]

With the passage of Bayh-Dole, Congress sought to strike a balance—similar to that envisioned by this Comment—by altering the federal patent policy in order to reconcile the government's ownership interest with that of fostering modern technological innova-

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[151] N.J. Sci. & Tech., *supra* note 7.

[152] *Supra* note 133 and accompanying text.

[153] National Science Foundation, http://nsf.gov/about/ (last visited Mar. 17, 2008).

> The National Science Foundation . . . is an independent federal agency created by Congress in 1950 "to promote the progress of science; to advance the national health, prosperity, and welfare; [and] to secure the national defense . . . ." With an annual budget of about $6.06 billion, [the NSF is] the funding source for approximately 20 percent of all federally supported basic research conducted by America's colleges and universities.

*Id.*

[154] National Science Foundation Patent Policy, 45 C.F.R. § 650.2 (2000).

[155] *Id.* "The regulation replaces all current NSF patent regulations and brings NSF patent policies and procedures into compliance with the Bayh-Dole Act. The policies and procedures set forth apply to all grants and cooperative agreements awarded by the Foundation since July 1, 1981 . . . ." *Id.*; *see also* NAT'L SCI. FOUND., *supra* note 141, at 95. "The disposition of rights to inventions made by small business firms and non-profit organizations, including universities and other institutions of higher education, during NSF-assisted research is governed by . . . the Bayh-Dole Act." *Id.*

tion.[156] As a practical matter, the Bayh-Dole Act served to grant "universities and small businesses the right to own their inventions made with federal funds."[157] The provisions set forth by Bayh-Dole provide valuable insight to New Jersey as such a regulatory scheme seems to be a healthy approach to realizing governmental aspirations while balancing the interests of award grantees.[158]

More specifically, Congress struck this balance by granting certain minimum rights to the government while simultaneously imposing certain requirements on grantees, namely businesses and universities.[159] For instance, regarding governmental rights, Bayh-Dole requires that all such funding contracts include a clause granting the government a paid-up license to use the patented invention.[160] Under this provision, neither the government nor any of its contractors could be held liable for patent infringement for the use of an invention it funded.[161] Another notable benefit afforded the government under Bayh-Dole is Congress's grant of march-in rights, whereby the government—as a matter of right—may require the grantee to li-

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[156] *See* Bayh-Dole Act, 35 U.S.C. § 200 (2000). Congress used language that echoes New Jersey's goals for its stem cell policy, as well as the goals contemplated in this Comment.

> 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*; . . . to ensure that inventions made by nonprofit organizations and small business firms are used in a manner *to promote free competition and enterprise without unduly encumbering future research and discovery*; . . . *to ensure that the Government obtains sufficient rights in federally supported inventions* to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions . . . .

*Id.* (emphasis added).

[157] John H. Raubitschek, *Responsibilities Under the Bayh-Dole Act*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 311, 311 (2005). Large business became subject to certain provisions of the Bayh-Dole Act when Congress amended the act in 1984. *See* Bayh-Dole Act, 35 U.S.C. § 210 (2000).

[158] *See, e.g.*, Raubitscheck, *supra* note 157, at 311. "Under the Bayh-Dole Act, universities have been very successful in commercializing their inventions. According to surveys by the Association of University Technology Managers . . . , universities earned over $1 billion in royalties annually from FY 2000[–2003]." *Id.*

[159] *See generally* 35 U.S.C. §§ 200–210; *see also* Raubitschek, *supra* note 157, at 311–18.

[160] 35 U.S.C. § 202(c)(4).

[161] Raubitschek, *supra* note 157, at 312. Further, "[t]he Government's rights may be expanded to cover other governments as are necessary to meet obligations under any treaty, international agreement or memorandum of understanding." *Id.* (citing § 202(c)(4) of the Bayh-Dole Act).

cense a patent when the grantee has not sufficiently commercialized the invention or when the grantee's conduct amounts to waste.[162]

On the other side of the balance, a major result of Bayh-Dole was the granting of absolute ownership of, and other rights regarding, their federally funded inventions to grantees.[163] President Reagan's Memorandum on Government Patent Policy of 1983, an early example of these benefits, made clear the need for "waiving some of the Government's rights and the contractor's obligations under [Bayh-Dole] to obtain a uniquely or highly-qualified contractor."[164]

Similarly, Bayh-Dole was sure to alleviate any concern that the government's enumerated rights would apply even if only a minimal amount of government funds were used in conceiving the invention.[165] That is, in order for the government to exercise its rights, "the funds must have been used in either the conception or first actual reduction of practice."[166] While superficially Bayh-Dole seems to grant more rights to the government, there are relatively minimal assurances that government funds will not be abused, as they are generally subject to the plenary interest of the Act—granting ownership to and fostering innovation within the scientific community.

To that end, the NSF revamped its own intellectual property policy in order to "better serve the purposes of [Bayh-Dole] or the interests of the United States and the general public."[167] At the very minimum—in situations where the grantee has elected not to retain title in his NSF-funded invention[168]—"[t]he grantee will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the grantee fails to disclose the subject invention within [the time specified by the

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[162] 35 U.S.C. § 203. While the necessity to exercise march-in rights has proved to be rare, *see* Raubitschek, *supra* note 157, at 312–13 (referencing, e.g., Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342 (Fed. Cir. 1998)), it nevertheless provides the government with peace of mind when issuing the grant, while simultaneously presenting a significant incentive for the grantee to make the most of his federal funding and resulting innovation.

[163] Raubitschek, *supra* note 157, at 311.

[164] Memorandum on Government Patent Policy, 1983 PUB. PAPERS 248, 252 (Feb. 18, 1983). This particular grant of flexibility was arguably weakened by the 1984 amendment to the Act, which subjected the rights of large businesses to the government's license and march-in rights. *See* Raubitschek, *supra* note 157, at 311.

[165] *See* Raubitschek, *supra* note 157, at 313.

[166] *Id.*

[167] National Science Foundation Patent Policy, 45 C.F.R. § 650.2(a) (2006).

[168] *Id.* § 650.4(e)(1).

NSF policy]."[169] Similarly, "[i]f an awardee elects not to retain rights to an invention, the Foundation will allow the inventor to retain the principal patent rights unless the awardee . . . shows that it would be harmed by that action."[170] Thus, unlike New Jersey's existing stem cell research policy, the NSF policy first sets forth a minimum level of protection for all NSF-funded innovators.[171]

Further, the NSF's adaptation of Bayh-Dole to its patent policy provides guidance regarding greater grantee rights, which could prove to be a useful starting point for New Jersey when crafting a clearer intellectual property policy:

> The grantee may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this Patents Rights clause and [Bayh-Dole]. With respect to any subject invention in which the grantee retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.[172]

Although this provision[173] and the remainder of the NSF policy[174] do not offer any specific royalty allocation guidelines, the NSF's policy, coupled with appropriate language such as that of New Jersey's Edison Fund,[175] would serve as a constructive aid to New Jersey policymakers as they develop a clear intellectual property policy for state-funded stem cell research.

### *C. The Orphan Drug Act*

A third regulatory scheme—and more of an example of what happens when proper incentives are *not* in place than a substantive policy template—that New Jersey should consider in forming its intellectual property policy for its stem cell initiative is the Orphan Drug Act, a federal law enacted over twenty years ago in order to remedy private industry's failure (due to an insufficient market) to produce drugs for rare diseases ("orphan drugs").[176] Congress enacted the Orphan Drug Act in 1983 because pharmaceutical companies could

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[169] *Id.*
[170] *Id.* § 650.2(c).
[171] *See supra* Part III.B.
[172] 45 C.F.R. § 650.4(b).
[173] *See id.*
[174] *See generally id.* § 650.
[175] *See supra* notes 128–34 and accompanying text.
[176] Orphan Drug Act, 21 U.S.C. §§ 360aa–ee (2000).

not afford to develop drugs for rare diseases due to the inherently small market for such drugs.[177] Through this Act, Congress hoped to create financial incentives to ensure that pharmaceutical companies would develop treatments for these diseases to which such little attention had been paid in the past.[178]

To that end, the Orphan Drug Act sets forth several incentives for innovators who invent cures for rare diseases. These incentives are largely financial in nature and include exclusive licensing, tax credits, federal funding for clinical trials and research, and other grants for developers of orphan drugs.[179]

The significance of an incentive program like the Orphan Drug Act is evident in its results. In the decade leading up to passage of the Orphan Drug Act the FDA approved only ten orphan drugs.[180] Conversely, since its enactment nearly 300 orphan drugs have received FDA approval.[181] "The response to the Orphan Drug Act is an example of how favorably the industry responds to increased intellectual property protection that lowers the risk of investing in research, development, and marketing of a new drug."[182]

New Jersey should consider the Orphan Drug Act not so much as an intellectual property policy template,[183] but rather as an example of the power of properly established policy incentives. That is, if innovators clearly understand any control the state would have via standard agency or work-for-hire principles, especially with an intellectual property incentive system working in their favor, then they are more likely to continue developing stem cell technologies.

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[177] *Id.* § 360ee(b)(2)(B). The benefits conferred by the Act apply to treatments for "any disease or condition [for] which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug." *Id.*

[178] *Id.* § 360ee(a) (authorizing the Secretary of the Food and Drug Administration to "make grants to and enter into contracts with public and private entities and individuals" in order to defray the costs of the testing and development of treatments for rare diseases).

[179] *Id.*; *see also* Mandy Wilson, Note, *Pharmaceutical Patent Protection: More Generic Favored Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation*, 90 KY. L.J. 495, 502–04 (2002).

[180] Wilson, *supra* note 179, at 503.

[181] Marlene E. Haffner, *Adopting Orphan Drugs—Two Dozen Years of Treating Rare Diseases*, 354 NEW ENG. J. MED. 445, 445 (2006). "In the 24 years since this law was passed, 282 such drugs and biologic products" have been approved. *Id.*

[182] *Id.* at 503.

[183] *See supra* Part IV.A–B.

## V. CONCLUSION

New Jersey certainly has a proud tradition as a worthy leader and pioneer in the frontier of biomedical research.[184] However, with such an accolade comes substantial responsibility. Indeed, a foundational principle of American law is that the optimal way "[t]o promote the Progress of Science and useful Arts, [is to secure] for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[185] Thus, there is a recognized government obligation to craft policy that ensures not only appropriate distribution of ownership rights, but also a fertile marketplace in which public and private innovation can thrive together.

In undertaking this most integral governmental obligation, New Jersey would be well-advised to consider—and in some cases, emulate—the aforementioned regulatory schemes.[186] At the very minimum, New Jersey has at its disposal the Edison Innovation R&D Fund, a regulatory scheme that provides necessary clarity in royalty distribution.[187] By adapting this concrete designation of royalty amounts to the stem cell research policy, New Jersey lawmakers would eliminate the risk of deterring potential innovators who would prefer to conduct their potentially life-saving research in a state that provides them with adequate notice of how much income they can expect to share. This would not be a particularly onerous or difficult first step considering the relatively small percentage of royalties that the Edison Fund guarantees to the state.[188]

As the various policies discussed herein demonstrate, however, the bare minimum is not sufficient. It simply is not enough that New Jersey's existing policy vests title in the intellectual property of stem cell technology to the innovators by merely requiring innovators "to share with the State of New Jersey a percentage of any income received from the intellectual property that might be developed with the State's grant support."[189] The appropriate regulatory regime would, for example, qualify this required sharing of royalties with guarantees that the government will not be able to claim its percent-

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[184] *See* N.J. STAT. ANN. § 26:2Z-1 (West 2006).

[185] U.S. CONST. art. I, § 8, cl. 8.

[186] *See supra* Part IV; *see also* Entrepreneur Assistance, *supra* note 124.

[187] Entrepreneur Assistance, *supra* note 124.

[188] STATE OF N.J. COMM'N ON SCI. & TECH., EDISON INNOVATION R&D FUND APPLICATION GUIDELINES, *supra* note 133, at 6. "1% of net sales resulting from IP developed under the grant—up to the original amount of the grant. 1% of royalty payments received by the company for licensing IP developed under the grant—up to 10 times the original amount of the grant." *Id.*

[189] Stem Cell Research Grant Program, *supra* note 124.

age merely because it provided some fraction of the funding that may have led to a major, perhaps even unforeseen, advance several years later. As such, the NSF Grant Policy, governed by the Bayh-Dole Act,[190] provides particularly useful guidance through a clause requiring that the conception or first application of the technological advance be at least partially attributable to the state's funds before the government can claim its due percentage of royalties.[191]

At the same time, of course, an ideal policy would recognize the importance of the government interests as well. For instance, CIRM's Intellectual Property Policy for Non-Profit Organizations[192] reflects such interests by guaranteeing free availability of state-funded advances to other California research institutions, despite the fact that the owner-inventors will maintain ownership of all intellectual property.[193] New Jersey's intellectual property policy on stem cell research should include a march-in rights provision similar to that provided by CIRM.[194] That is, if the private innovator—who maintains ownership of the intellectual property—wastes such ownership by underutilizing his licensing rights, then the Stem Cell Institute of New Jersey can step in to ensure public benefit from the medical breakthrough. Thus, while New Jersey's policy seems to provide such intellectual property ownership to innovators,[195] a more thorough policy would protect the public and governmental interests while balancing these interests with those of the private innovator.

Therefore, a thorough intellectual property policy scheme that takes into account the interests of all involved parties is an absolutely essential element to adequate government regulation of state-funded scientific research. As the Orphan Drug Act illustrated, government failure to establish the proper environment to develop innovation can have dire consequences.[196] Thankfully, New Jersey lawmakers have taken an important first step by recognizing the immeasurable potential of stem cell research.[197] To tap into that potential in the most productive and responsible manner, however, New Jersey must learn from the past, as well as the present treatment of such tech-

[190] *See supra* Part IV.B.
[191] *See supra* note 165–66 and accompanying text.
[192] *See supra* Part IV.A.
[193] *See supra* note 147 and accompanying text.
[194] *See supra* note 149 and accompanying text.
[195] *See supra* Part II.D.
[196] *See supra* Part IV.C.
[197] N.J. STAT. ANN. § 26:2Z-1(c) (West 2006).

nologies by its contemporaries, such as California and the federal government.

By proclaiming that New Jersey's status as a biomedical leader "would be significantly diminished by limitations imposed on stem cell research,"[198] and creating the first state-funded stem cell research facility in the United States, New Jersey has undoubtedly obligated itself to provide a suitable market for the development of this technology. New Jersey has thus far taken positive steps toward encouraging and funding this groundbreaking research.[199] However, the state must recognize the potentially devastating effects of an unsatisfactory intellectual property policy. Upon making this recognition, New Jersey should take account of existing legislative and regulatory regimes that are instructive to a government that must adapt its intellectual property policies to cutting-edge technology.[200]

> [T]he pitch of the ownership battle will rise proportionally to the success rate of the research. Thus, the more we achieve the vaunted promises of stem cell research, the more a crisis will be precipitated over the ownership of its results. . . . [B]ecause greater certainty in the investment environment almost always draws more investment because the risks are more easily calculated . . . we could then get back to the truly important mission at hand—creating an environment in which the miracles latent in stem cell research can be realized for the benefit of humankind.[201]

Presumably, Thomas Jefferson would not have commissioned Lewis and Clark without first assuring them that it would be their names, along with his, that would be remembered for revealing the bounty of the Louisiana Territory. Likewise, New Jersey cannot afford to withhold such crucial assurances from the scientists on whom the state will rely to maintain its coveted status as a leader in this burgeoning scientific frontier.

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198 *Id.* § 26:2Z-1(e).

199 *See supra* Part II.D.

200 *See supra* Part IV.

201 O'Connor, *supra* note 96, at 666, 714.