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INTELLECTUAL PROPERTY RIGHTS AND STEM CELL RESEARCH: WHO OWNS THE MEDICAL BREAKTHROUGHS?

SEAN M. O'CONNOR*

INTRODUCTION

The 2004 election year provided many focus points for those interested in stem cell research and its potential outcomes. Stem cell research became a substantial, albeit secondary, point of difference in the presidential campaigns, gubernatorial races, and congressional contests across the country. In California it was the subject of Proposition 71,² which passed by a healthy margin. At the same time, stem cell research has become one of the lightning rod issues in larger national and local bioethics debates. Some oppose it as the unjustifiable destruction of (potential) human life, while others support it, under certain restrictions, as the most promising means to finally cure a host of vexing diseases with essentially the body's own materials.

Accordingly, there is a rapidly growing wealth of literature on the science and the ethics involved in stem cell research. Some of that literature, of course, is part of this Symposium issue of the *New England Law Review*. However, this article will not address the science and ethics of stem cell research—at least as far as those topics are normally addressed in the existing literature. Instead, this article argues that an even more contentious battle is looming on the horizon, with dire practical consequences: Namely, who will own the revolutionary medical breakthroughs that are supposed to emerge from this research?

Along the way, this article will assume that stem cell research will progress in some fashion and that at least some of the purported benefits

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2. CAL. CONST., art. XXXV (as amended by Proposition 71 2004).

will materialize. But the central premise is that the 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. Further, because the 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. In this way, the ownership questions will mirror those currently faced every day by universities and their tech-transfer offices. Which funding sources were used in reaching certain patentable research inventions? Are there intellectual property (IP) ownership claims attached to these funding sources? If multiple claims exist, which one trumps the others?

But in the end, regardless of the funding sources (and concomitant ownership claims), the public's claim to reasonable access to any crucial life-saving medical breakthroughs that do arise from stem cell research may well force federal, state or local officials to circumvent the existing political opposition to compulsory licenses in the United States. The public pressure that led to the recent, highly controversial moves of some state and local governments to allow the importation of arguably cheaper prescription drugs from Canada for government employees will pale in comparison to the pressure that will be brought when the general public believes that it is being left out of revolutionary cures for cancer, diabetes, and Alzheimer's disease based on the inability to pay exorbitant private sector prices for such treatments.

This crisis, and its concomitant challenge to the social order and existing IP ownership structure, must be averted by taking pro-active 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. This initiative alone would go a long way to prevent the kind of post hoc ownership battles that are the most difficult to unwind. In addition, this article establishes that a few de facto compulsory license schemes already exist in the current IP environment. The availability of any of these avenues is conditioned on the need for governmental provision of the technology/products/services to serve a compelling public health interest that is of "vital importance" to the government. But, this article concludes that this may be exactly the right test of when the extraordinary step of a compulsory license should be taken.

Part I of this article begins by parsing the funding sources and environment for stem cell research. Part II then lays out the pros and cons of using federal funds for such research. Part III argues that stem cell research will be a victim of its own success because the more successful it is, the more contested the ownership rights to, and distribution mechanisms of resultant therapies will become. Part III also uses the examples of two

recent similar controversies to speculate as to how the conflicts over ownership and use of stem cell therapies will play out. Finally, Part IV offers perspectives on the hyperbole and rhetoric surrounding recent life sciences IP ownership debates, and asserts that pro-active, thoughtful allocation of IP rights in advance could do much to mitigate the coming crisis of ownership. Further, Part IV argues that even absent such effective planning, the government does have a few de facto compulsory license tools at its disposal that can be acted on, provided there is a public health solution that can be deemed to be of vital importance to the government.

I. DO WE NEED PUBLIC FUNDING FOR STEM CELL RESEARCH?

A. Background on the Connection Among Funding, Control, and Ownership of Patents Arising from Research Efforts.

Many of the most vexing ownership questions that arise from research funding sources involve multiple funding sources. If a private company fully funds its own internal research, then there is a single funding source and ownership of any resulting patentable inventions is generally pretty clear: Title resides with the company. This is true because the employees who invented the subject matter of the patent either: (1) contractually assigned any ownership rights to patents arising from their research through an express provision in an employment agreement;³ (2) implicitly or indirectly assigned their ownership rights by agreeing to abide by employer policies, which often include IP assignment rules, at the time of hire; or (3) must assign any ownership rights to patents to their employer under common law case precedent in the event that there is no employment agreement or IP ownership agreement.⁴

3. Such contracts are generally upheld so long as they do not violate specific state statutory restrictions on the extent to which employers may demand assignment of existing or later arising patentable inventions. ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 102-03 (2d ed. 2000). For example, both Washington State and California prohibit employers from requiring employees to assign inventions that did not arise from activities using employer facilities or on "company time," but rather only because they arose during the term of employment. *Id.* at 102; WASH. REV. CODE ANN. § 49.44.140 (West 2002); CAL. LABOR CODE § 2870 (West 2003).

4. This common law assignment occurs only where the employee is hired to invent. MERGES, *supra* note 3, at 102. Where the employee is not hired to invent, but still uses employer resources or time to invent, then the employee owns the patentable invention but must give the employer a non-exclusive "shop right" to practice the invention. *Id.* Where the employee is neither hired to invent, nor uses employer resources or time, then the employee retains all title to the patentable invention and the employer has no right or license to practice the invention. *Id.*

But the foregoing example demonstrates that even in what should be the most intuitive and straightforward case—a company’s internal research and development (R&D) process—the means for determining ownership of resultant IP are never simple. Thus private employers need to establish why they are entitled to the IP arising from the efforts of their employees, and they generally do so by explicit contractual arrangements, which head off disputes about the exact scope of employment and happenstance of the invention. In part, this derives from the mandate of U.S. patent law that the true individual inventor be named as the inventor on the patent application.⁵ Thus, even when an employee has pre-assigned ownership of inventions arising out of the scope of her employment to her employer, the patent application must still name her as the inventor.⁶ This is different from U.S. copyright law wherein employees’ creations—when the employee is hired to create—will generally be deemed a “work-for-hire,” and not only ownership but also authorship will reside with the employer.⁷ In this manner, there can be “corporate authors”—corporations listed as the actual author of a work—but not corporate inventors—corporations listed as the actual inventors of a new device or method. But this mandatory traceable lineage to the individual inventor can lead to some confusion, real or otherwise, on the part of inventors as to their ownership of the final issued patent.

Thus, in patent law the question of who funded the inventor’s efforts can have a profound impact on the question of who owns or controls the resultant patent. If we consider the development of patentable inventions outside of the privately funded and controlled labs, the picture becomes even murkier. Take a standard public university researcher and his lab: (1) the university may be using state funds and tuition dollars to pay for the basic lab and its upkeep; (2) the researcher may have received a grant from a federal agency to conduct specific research and/or from a non-profit source for closely-related research; and (3) the lab and its staff may be conducting other related work under funding through a sponsored research agreement with a private corporation. Under scenario (1), and considering the customary claim to patentable inventions included in most academic appointments,⁸ any patentable inventions that the researcher invents in the course and scope of his employment with the university must be assigned to the university. But under situation (2), when the researcher receives a grant from a federal agency, the university will only get title to an

5. 35 U.S.C. §§ 102(f), 256 (2000).

6. DONALD S. CHISUM ET AL., *PRINCIPLES OF PATENT LAW: CASES AND MATERIALS* 72 n.3 (3d ed. 2004).

7. Copyright Ownership and Transfer Works Made for Hire, 17 U.S.C. § 201(b) (2000).

8. But, interestingly, not for copyrightable works.

invention funded, even just in part, by federal agencies, in the event that the university formally elects to take such title under the provisions of the Bayh-Dole University and Small Business Patent Procedures Act of 1980 (Bayh-Dole Act).⁹ Alternatively, non-profit funding sources in situation (2) may require assignment of any IP arising from the research, or may require certain uses or limitations on what the university can do with the IP, even where the university retains title to it. Finally, under situation (3), private for-profit commercial firms rarely sponsor research without requiring assignment of any resultant IP, and further, generally institute strict confidentiality provisions on lab staff.

Clearly these claims to and possible restrictions on the uses of IP generated by the lab can be in conflict. Many university tech-transfer offices have anecdotal—and of course anonymous—stories of patentable inventions that turned out to have been assigned to two or three different funding sources. Because these are often written, legally binding pre-assignments of the patentable inventions arising from the same specific research, each claim is generally valid and enforceable, and yet impossible to fulfill. At this point, the tech-transfer office simply has to bring the affected parties to the table and hope that they will be able to reach a negotiated compromise.

At the same time, patentable inventions arising from research even only partly funded by a federal agency trigger the right of the institution to elect to retain title.¹⁰ But where the institution fails to either disclose the patentable invention or elect to take title to it, then the funding agency has the right to take such title.¹¹ Further, where the institution does elect to retain title, it may not then assign such title to another entity (except an entity established solely to manage that institution's patent portfolio, such as an external tech-transfer office) without the approval of the government funding agency.¹² Thus, where research is to be funded by both federal and private sources, the university will not be able to assign free and clear title to resultant IP in advance to the private funding source; at best, it can promise to work with the private funding source, once specific patentable inventions have arisen (and have been claimed by the university), to petition the federal funding agency to allow it to assign title to those specific inventions to the private entity.

Given the challenges of multiple funding sources, especially involving federal agencies, why should research ever be undertaken with

9. Pub. L. No. 96-517, 94 Stat. 3015, 3019-27 (1980) (codified at 35 U.S.C. §§ 200-211).

10. 35 U.S.C. § 202(a) (2000).

11. *Id.* § 202(c)(1)-(2).

12. *Id.* § 202(c)(7).

multiple sources? The easy answer is the exigencies of particular research situations—all necessary funding may not be procurable from a single source. But the more interesting question is whether the kind of very costly facilities and staff necessary for stem cell research could be funded by a single source. Referring back to the easy IP ownership example given above, it would seem that private companies would be in the best situation to research and develop stem cell therapies without entangling themselves in multiple, and possibly conflicting, claims of IP ownership.

So why are we worrying about funding and ownership? Why not just push private companies to undertake this research in-house and then allow them to reap the fruits of exclusive control of the therapies that result? At the same time, one might ask why this is in fact not the clear trend (even as there are some examples). Looking to earlier examples of private versus public initiatives in life sciences research, one might think that the race between Celera Genomics¹³ and the Human Genome Project¹⁴ to map the human genome would provide an excellent example of the capacity of private industry to take on even a broadly funded public initiative, and win. And yet, it seems that this was the exception that proves the rule. Or, alternately, this was only one very specific project, whereas stem cell research covers a host of different research projects. Will viable private sector entities step forward to undertake each and every one of these projects? Even if they did, would universities and non-profit research centers simply fold up their tents and stop doing such research themselves? Would we want them to?

B. The Bush Order on Federal Funding of hPSC Research.

Perhaps shedding some light on these questions was one of the ways that the issue of stem cell research turned up in the 2004 election year. The issue seemed to first appear during the presidential race, in which both candidates claimed to be generally in favor of it, even as John Kerry and the Democrats argued that the Bush Administration had actually restricted stem cell research. Not surprisingly, the reality was a bit more complicated. It is unclear whether any federal funding of research leading up to formal work with stem cells occurred, but by the time human pluripotent stem cells (hPSCs) were isolated and successfully cultured in 1998 by scientists at the University of Wisconsin and Johns Hopkins University (not using federal funds), the debate over the legality and ethics of such research had

13. See CELERA GENOMICS, *Our History*, at <http://www.celera.com/celera/history> (last visited Feb. 4, 2005).

14. See HUMAN GENOME PROJECT, U.S. DEP'T OF ENERGY, OFFICE OF SCI., *About the Human Genome Project*, at http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml (last modified Oct. 27, 2004).

already begun.¹⁵ There was, however, no formal prohibition on hPSC research except for the existing regulatory prohibition on the National Institutes of Health's (NIH) use of any appropriated funds to create, destroy, discard, or jeopardize human embryos. Thus, to the extent that hPSCs were deemed to be embryos, the NIH could not fund research on them.¹⁶ Accordingly, the NIH sought and received from the General Counsel of the Department of Health and Human Services (DHHS) a legal opinion that hPSCs are not actually embryos and thus fall outside of the funding prohibition for embryo research.¹⁷

Because President Clinton had offered no formal binding guidance on the question of federal funding of hPSC research—beyond recommendations or comments offered by his National Bioethics Advisory Commission (NBAC)—the Director of NIH decided to issue a moratorium on hPSC research beginning in January of 1999 and lasting until the NIH could consider the ethical, legal, and social implications of such research.¹⁸ A working group of the Advisory Committee to the Director was created for this purpose in April of 1999 and ultimately concluded that the NIH could fund hPSC research, armed in no small part with the DHHS General Counsel opinion, as well as input from the scientific community and the NBAC.¹⁹ Subsequently, the NIH set to work on drafting guidelines for funding hPSC research, which were published in the Federal Register as proposed rulemaking on December 2, 1999.²⁰ The public comment period ended on February 22, 2000, and the final guidelines (NIH hPSC Guidelines) were published, and took effect, on August 25, 2000.²¹

Presumably, at this point the NIH was fully authorized to fund hPSC research. In fact, it actively solicited funding proposals as late as January of 2001 for this research, setting an initial deadline of March of 2001 for

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15. NAT'L INSTS. OF HEALTH, *NIH Fact Sheet on Human Pluripotent Stem Cell Research Guidelines*, at <http://stemcells.nih.gov/news/newsArchives/stemfactsheet.asp> (Jan. 2001) [hereinafter NAT'L INSTS. OF HEALTH, *Guidelines Fact Sheet*].
 16. *Id.* (citing 45 C.F.R. § 46.208(a)(2) and 42 U.S.C. § 289(g)(b) (2000) (codified from the Public Health Service Act § 498(b))).
 17. *Id.*
 18. See National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976, 51,976 (Aug. 25, 2000); see also News Advisory, National Institutes of Health, NIH Publishes Draft Guidelines for Stem Cell Research, at <http://www.nih.gov/news/pr/dec99/od-01.htm> (Dec. 1, 1999) [hereinafter National Institutes of Health, News Advisory].
 19. NAT'L INSTS. OF HEALTH, *Guidelines Fact Sheet*, *supra* note 15.
 20. Draft National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells, 64 Fed. Reg. 67,576 (Dec. 2, 1999); see also National Institutes of Health, News Advisory, *supra* note 18.
 21. National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976.

funding proposals.²² However, after President George W. Bush took office in January of 2001 he evinced an intense interest in the debate over hPSC research, and, in particular, federal funding of such research. On August 9, 2001 he gave the watershed public address that contained an order restricting federal funding of hPSC research to only that using the sixty then-existing hPSC lines.²³ The NIH issued its own supportive, yet terse, statement acknowledging the President's order that same day.²⁴

In what may be evidence of some degree of scrambling or disarray in the wake of the President's address and order, the NIH then issued a notice on August 23, 2001 indicating that it would begin a process to enable researchers to use federal funds to engage in hPSC research—now dubbed “human embryonic stem cell research”—only to supersede it with a very similar notice issued days later on August 27.²⁵ Both notices made clear that researchers were prohibited from using any federal funds for hPSC research until the NIH put into place new policies and guidelines based on the President's order. However, the main difference between the two notices seemed to be that while the first stated that only hPSC lines that existed “as of August 9, 2001” could be used, the later version clarified this to include lines whose “derivation process” began prior to 9:00 p.m. EST on August 9, 2001, meaning that so long as the destruction of the embryo to start a cell line had occurred before this precise moment in time, the resultant line could be used for research. The second notice also contained more detail about the NIH Human Embryonic Stem Cell Registry, to be created and posted on a webpage hosted by the NIH. One has to wonder, however, whether researchers were feverishly working ahead of the President's address, which commenced at 8:01 p.m. CST at his ranch in Texas, thus 9:01 p.m. EST, to establish hPSC lines in anticipation of leaked news about the content, and impact, of the address, and the NIH wanted to respect those efforts as legal, right up until the address.²⁶

22. NAT'L INSTS. OF HEALTH, *Guidelines Fact Sheet*, *supra* note 15.

23. Address to the Nation on Stem Cell Research, 2 PUB. PAPERS 953 (Aug. 9, 2001); *see also* Press Release, The White House, Fact Sheet: Embryonic Stem Cell Research, at <http://www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html> (Aug. 9, 2001).

24. *See* News Advisory, National Institutes of Health, NIH Statement on the President's Stem Cell Address, at <http://www.nih.gov/news/pr/aug2001/od-09.htm> (Aug. 9, 2001).

25. *See* NAT'L INSTS. OF HEALTH, *NIH Funding of Research Using Specified Existing Human Embryonic Stem Cells* (NOT-OD-01-0598), at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-058.html> (Aug. 23, 2001); *see also* NAT'L INSTS. OF HEALTH, *NIH Funding of Research Using Specified Existing Human Embryonic Stem Cells* (NOT-OD-01-059), at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-059.html> (Aug. 27, 2001).

26. Presumably, any researchers attempting to work right up until the last possible

Two interesting questions are raised by the President's order. First, had the NIH approved any hPSC research funding proposal, and if so, how did it unwind the funding commitment, assuming that the proposal did not happily rely only on one of the sixty enumerated hPSC lines? Second, had the Bush Administration made its own legal determination that hPSCs do not in fact constitute human embryos, in agreement with the earlier opinion of the DHHS General Counsel? If not, then no federal funding of research involving hPSCs, whether from lines existing at 9:00 p.m. EDT on August 9, 2001 or not, would be permissible under the regulations promulgated under the Public Health Service Act.²⁷ Thus, one can infer that the Administration determined that the DHHS's legal position was sound. But then why limit funding to hPSCs that emanate from cell lines existing before the Presidential order? Researchers could not use federal funds to actually destroy the embryos as the first necessary step to create an hPSC either before or after the order. Thus, researchers would always have had to begin the derivation process without federal funds.

The Administration's position is not about refusing to fund work on human embryos then, but rather that allowing federal funding for hPSC research, which is legally permissible as it does not involve research on human embryos, encourages researchers to destroy human embryos *outside* of federally funded work so that the extracted hPSCs can then be used *within* federally funded projects. But such destruction outside of federally funded projects is legally permissible, assuming that consent of the donors is obtained and developmental milestones are respected in the same way that countless fertility clinics and abortion clinics are allowed to destroy unused human embryos every year in the United States. Thus, the Administration is trading off the substantial value of a robust federally funded hPSC research agenda, as advocated by many leading science and health researchers, against a speculative, yet still legally permissible, "harm" that human embryos might be destroyed *solely* for the purpose of starting a new hPSC line (as opposed to opportunistic use of human embryos destroyed for other reasons) outside of any federal funding. Clearly other approaches were possible. At the same time, the Administration asserts that the enumerated sixty-odd cell lines are completely adequate to support just such a robust federally funded hPSC research agenda.²⁸ This, of course, has been heavily contested, with opponents of the policy asserting that many of these lines are unusable,

moment in this manner did so without the use of federal funds, which would have been unavailable due to the pre-existing prohibition on federal funds for research involving human embryos anyway. See HUMAN GENOME PROJECT, *supra* note 14.

27. *See id.*

28. *See* Address to the Nation on Stem Cell Research, *supra* note 23.

unavailable, or just unsuitable for certain research projects.²⁹

Nonetheless, the NIH dutifully withdrew its hPSC Guidelines first in part,³⁰ and then *in toto*,³¹ during November of 2001. The NIH ultimately issued new guidelines in March of 2002, finally funding hPSC projects, allowing the Bush Administration to correctly claim that it was the first to fund such research. Of course, the Clinton Administration had not prohibited or opposed funding hPSC research, but rather had worked fairly and expeditiously to establish the original guidelines that were put in place in 2000. Thus, in theory, and given mere historical happenstance, the Clinton Administration could easily have been the first to fund hPSC research. Further, it is not too speculative to say that a Gore Administration would have retained the original guidelines and a more robust federally funded hPSC research agenda would have ensued.

Some further evidence of this is that the next Democratic presidential candidate, Senator John Kerry, in fact added a pro-hPSC research plank to his ticket's platform—presumably offering funding opportunities to hPSC lines derived after the fateful August 9, 2001 deadline—playing on the strong arguments from the scientific and medical community that the Bush policy was inadequate. Of course, it is unclear whether there is solid empirical evidence that federal funding is needed to further progress in stem cell research. Further, as complete speculation, perhaps the Bush Administration views reduced or limited federal funding for science and technology as a good way to push its larger privatization initiative: The private sector will be forced to take on a greater proportion of scientific research, thus freeing up federal funds and resources to focus on other core government projects, or as a means to reduce taxes and government spending even further.

C. California's Proposition 71

While the presidential race set out some impressive rhetoric about the need for federal funding to realize the goals of hPSC research, and under what restrictions such funding could occur, it did not really present much in the way of empirical evidence that extensive federal funding is needed. It is hard to read too much into George W. Bush's victory in relation to some sort of public statement or mandate about his hPSC funding policy because

29. See Ceci Connolly & Rick Weiss, *Stem Cell Colonies' Viability Unproven*, WASH. POST, Aug. 28, 2001, at A1.

30. NAT'L INSTS. OF HEALTH, *Notice of Withdrawal of NIH Guidelines for Research Using Pluripotent Stem Cells* (NOT-OD-02-007), at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-007.html> (Nov. 7, 2001).

31. National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 66 Fed. Reg. 57,107 (Nov. 14, 2001).

there were clearly so many other factors at play in the election. But other electoral contests did give us some targeted evidence for how segments of the U.S. population perceive the question of public funding of hPSC research.

Most notable was the solid passage of Proposition 71 in California.³² In part as a response to the Bush policy for limited funding for hPSC research, Californians were presented with an initiative to fund stem cell research (using both hPSCs and adult stem cells) to the tune of \$3 billion over ten years.³³ The measure authorized California to raise these funds through general obligation bonds.³⁴ It also created the California Institute for Regenerative Medicine (the CIRM) to award grants and loans for stem cell research using the proceeds from these bond sales, and to manage subsequent research under these awards.³⁵ The CIRM is to be governed by a twenty-nine member Independent Citizen's Oversight Committee (ICOC), with members selected from University of California campuses, a public or private California university (other than the specified UC campuses), non-profit academic and medical research institutions, companies experienced in developing medical therapies, and disease research advocacy groups.³⁶ Priority for funding is to be given to hPSC and progenitor cell research that "cannot, or is unlikely to, receive timely or sufficient funding, unencumbered by limitations that would impede the research."³⁷

Because Proposition 71 passed by fifty-nine percent of the vote, and is geared towards funding stem cell research that the federal government, under the Bush Administration, is unlikely to fund, one can reasonably infer that a majority of Californians: (1) do not agree with the Bush Administration's stance; and (2) believe that stem cell research requires public funding. Of course, it is not clear how closely examined the proposition was by many voters—indeed one newspaper account called it a "cause célèbre," and suggested that the influence of celebrities such as

32. The vote was officially tallied at 59.1% for, 40.9% against, and 5.6% votes not cast. OFFICE OF THE SECRETARY OF STATE, STATE OF CALIFORNIA, *State Ballot Measures*, at http://www.ss.ca.gov/elections/sov/2004_general/formatted_ballot_measures_detail.pdf (last visited Feb. 4, 2005).

33. *See generally* CAL. HEALTH & SAFETY CODE §§ 125290.10-125290.70 (West Supp. 2005).

34. *Id.* §§ 125291.10-125291.85; *see also* Attorney General of the State of California, *Official Title and Summary: Proposition 71*, at <http://www.voterguide.ss.ca.gov/propositions/prop71-title.htm> (last visited Feb. 4, 2005).

35. CAL. CONST., art. XXXV (adopted Nov. 2, 2004); *see also* Attorney General of the State of California, *supra* note 34.

36. CAL. HEALTH & SAFETY CODE § 125290.20(a) (West Supp. 2005).

37. *Id.* § 125290.60(c)(1)(C).

Brad Pitt likely helped the measure in no small part.³⁸ At the same time, of course, other celebrities such as Mel Gibson came out against the measure.³⁹ To the extent that the voters were looking for more academically credible advocates of the initiative, they were apt to be swayed by the endorsements of twenty-odd Nobel laureates, including Paul Berg of Stanford and Roger Guillemin of the Salk Institute.⁴⁰

Many voters no doubt fell in line with the somewhat simplistic position that this was a liberal versus conservative and/or pro-choice versus pro-life issue. But in neither the official *Rebuttal to Argument in Favor of Proposition 71* nor the *Argument Against Proposition 71* presented in the election materials was there an opposition to stem cell research, embryonic or otherwise.⁴¹ Instead, the former argued that an increase in human embryo cloning through somatic cell nuclear transfer, as might be the case under an aggressive stem cell research program, could endanger the lives and well being of the thousands of women needed to provide the initial eggs through the use of high dose hormones and egg extraction procedures.⁴² Further, it questioned the wisdom of prioritizing the funding of this type of research over other types of research with more proven track records.⁴³ Perhaps most interesting, these arguments were advanced by Judy Norsigian, Executive Director of Our Bodies Ourselves, and others who are most decidedly pro-choice.⁴⁴

The *Argument Against Proposition 71*, on the other hand, 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 to “corporate research” that would ultimately result in windfall profits to private corporations.⁴⁵ These criticisms are echoed in a

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

39. See Kathryn Jean Lopez, *Braveheart Stands Athwart a Brave New World*, NAT'L REV. ONLINE (Nov. 1, 2004), at <http://www.nationalreview.com/interrogatory/gibson200411010950.asp>.

40. See Leon Thal et al., *Rebuttal to Argument Against Proposition 71*, at http://www.ss.ca.gov/elections/bp_nov04/prop_71_argument_against_rebuttal_to_argument_against.pdf (last visited Feb. 18, 2005).

41. See SEC'Y OF STATE, STATE OF CAL., *Arguments and Rebuttals: Proposition 71*, at <http://www.voterguide.ss.ca.gov/propositions/prop71-arguments.htm> (last visited Feb. 18, 2005).

42. See Judy Norsigian et al., *Rebuttal to Argument in Favor of Proposition 71*, at http://www.ss.ca.gov/elections/bp_nov04/prop_71_argument_in_favor_rebuttal_to_argument_in_favor.pdf (last visited Feb. 13, 2005).

43. *Id.*

44. *Id.*

45. Tom McClintock et al., *Argument Against Proposition 71*, at <http://www.voterguide.ss.ca.gov/propositions/prop71-arguments.htm> (last visited Mar. 3, 2005).

widely-distributed letter written by Mitch Kapor, the famed software innovator and current Chair and President of the Open Source Applications Foundation.⁴⁶ Kapor argues that Proposition 71 is “the wrong way to do the right thing” on three issues: (1) the conflict of interest created by the fact that many of the members of the ICOC will control the flow of money that will likely wind up back at their home institutions; (2) the Institute is authorized to act outside of the normal federal and state rules regarding such things as informed consent and protection of human research subjects (because these regulations are generally tied to funding agreements); and (3) the IP rights and mechanisms for state recoupment of its investment are murky which will likely lead to protracted legal battles and diminished returns to California.⁴⁷ This last point will be considered further below.

Regardless of whether you believe the pro and con arguments presented in the Proposition 71 debates, it is again interesting that neither of the official opponent groups opposed stem cell research. Instead, they both seemed to go out of their way to make it clear that they supported it. Further, neither group argued that stem cell research did not need public funding or that it could adequately proceed under private and/or corporate funding. Rather, they argued that there is other research that is more immediately deserving of state funding and/or that this particular initiative was not the best way to go about channeling public funds to the research.

At the same time, opposition groups seemed slow to pick up on what might be the most important flaw of the initiative: the absence of a strong mechanism to recoup the state’s investment and the failure to allocate IP (and other) ownership rights in the resultant medical breakthroughs. Indeed, Kapor’s letter—the clearest statement of this issue in advance of the election—is dated October 25, 2004, only a little more than a week before election day.⁴⁸ Outside of presumed loan repayment revenues, Proposition 71 merely provides for a direct return on state investment through the authorization of the ICOC to:

[E]stablish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements.⁴⁹

46. Mitch Kapor, *For Stem Cell Research, Against Proposition 71 (California)*, at <http://www.ofbyandfor.org/node/view/830> (last visited Jan. 22, 2005).

47. *Id.*

48. *Id.*

49. CAL. HEALTH & SAFETY CODE § 125290.30(h) (West Supp. 2005).

In the abstract this 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 ICOC. In contrast, as discussed below, the federal Bayh-Dole Act that governs the allocation of IP rights arising from federally funded research, articulates such allocation in detail, including requirements for specific contractual clauses that must be part of funding agreements. Proposition 71 instead grants enormous discretionary power to an untested body that will determine the success (or failure) of a \$3 billion venture with taxpayers' money. Legislative grants of discretionary power can, of course, be a necessary and positive means of preventing legislative paralysis based on the extreme difficulty of working out the fine details of a new program's implementation. Further, the grant of discretionary power to an agency can allow the program's implementation to be flexible in response to new data and insights that arise as such implementation plays out. But sometimes the grant appears to be so big and vague as to suggest that the legislature is simply punting on the hard questions. The price for such avoidance tactics can be an implemented program that seems to have strayed quite far from the form advertised in the political battles leading to passage of the enabling statute.

Because Proposition 71 is an independent measure taken directly to the voters at large in California, it is hard to know what intentions to ascribe to such a vague grant of discretionary authority to a quasi-government agency. But the result is the same—Californians can have no idea what form these IP and recoupment contract provisions will take until after the ICOC finally establishes the standards. By contrast, as was briefly discussed above, the federal Bayh-Dole Act is far more specific in allocation of IP rights whenever federal funds are used in research that leads to a patentable invention. The Act also provides some safety valves for situations where funding recipients and/or their exclusive licensees appear to be improperly using these federally funded inventions. As discussed below, these have been quite controversial. Proposition 71 is troubling particularly because it means 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. A similar concern was raised recently in an article on Proposition 71 in the *Sacramento Bee*:

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.⁵⁰

Admittedly, the measure does suggest that the state will receive an indirect return on its investment in other ways, such as:

[B]y funding scientific and medical research that will significantly reduce state health care costs in the future....

... by creating projects, jobs, and therapies that will generate millions of dollars in new tax revenues in our state....

... [and by] [a]dvanc[ing] the biotech industry in California to world leadership, as an economic engine for California's future.⁵¹

And there is some evidence that at least the last part of this justification might work too, with early media accounts documenting what, to paraphrase former presidential candidate Ross Perot, might be described as a giant sucking sound as star talent researchers, life sciences management, and venture capitalists are drawn into a state that is committed to fund stem cell research in a way that neither the federal government nor other states are currently able to do.⁵² Further, the voter material for Proposition 71 asserts that "to the extent that the UC system receives a share of the grants awarded by the institute, it could attract additional federal or private research funding for this same purpose."⁵³ This sounds like a benefit, but it also represents the heart of the problem raised by this article: multiple funding sources will lead to nasty battles over ownership and control of whatever medical breakthroughs arise from hPSC research.

D. Other State and Local Stem Cell and Life Sciences Research Funding Initiatives

Outside of what appears to be a strong message from California voters that they both perceive the Bush policy to be inadequate and believe that there is a need for enhanced public funding of stem cell research, there are suggestions that citizens and leaders of other parts of the country were,

50. Leavenworth, *supra* note 38.

51. Attorney General of the State of California, *Text of Proposed Laws: Proposition 71*, available at <http://www.voterguide.ss.ca.gov/propositions/prop71text.pdf> (last visited Mar. 3, 2005).

52. See Jonathan Knight, *Joys Match Fears as California Agrees to Stem-Cell Proposal*, NATURE, Nov. 10, 2004, available at http://www.nature.com/news/2004/041108/pf/432135a_pf.html; Ceci Connolly, *Calif. Stem Cell Initiative Could Backfire Nationally*, WASH. POST, Nov. 14, 2004, at A15.

53. SEC'Y OF STATE, STATE OF CAL., *Analysis by the Legislative Analyst*, at <http://www.voterguide.ss.ca.gov/propositions/prop71-analysis.htm> (last visited Feb. 18, 2005).

or are now, thinking along similar lines. In Washington State, then candidate, now Governor, Christine Gregoire proposed a “Washington Institute of Stem Cell Research,” possibly as a result of the Kerry campaign’s espousal of its support for enhanced federal funding of such research.⁵⁴ It is not clear yet whether Gregoire will follow through on this campaign plank. In Boston, Mayor Thomas Menino announced a proposal to create a city venture fund to invest in biotechnology companies that promise to establish facilities within city limits.⁵⁵ Meanwhile, Governor Jim Doyle of Wisconsin has announced a stem cell research funding initiative that will invest \$750 million of public and private money to build two research centers and support hPSC research.⁵⁶ Part of this funding must still be approved by the Wisconsin legislature, but other parts appear to be fully under Doyle’s discretionary control.⁵⁷ New Jersey’s Acting Governor, Richard J. Codey, also recently announced a major stem cell research funding push to the tune of \$1 billion over the next ten years primarily for the already existing Stem Cell Institute of New Jersey.⁵⁸ The New Jersey initiative seeks to distinguish itself from Proposition 71 both because it will locate all the funding and research at the Stem Cell Institute of New Jersey, rather than dispersing funds and research across the state as California plans to do, and because it will encourage its researchers to collaborate with researchers in other states.⁵⁹ Rounding out this new gold rush, various officials in Connecticut,⁶⁰ New York,⁶¹ Minnesota,⁶² and Illinois,⁶³ have all announced some sort of plan to dramatically increase state funding for stem cell research, in no small part as a defensive measure against the

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54. Elizabeth M. Gillespie, *Gore Plugs Stem-Cell Research at N.J. Event*, USA TODAY, Oct. 10, 2004, at http://www.usatoday.com/news/health/2004-10-10-gore-stems_x.htm.
 55. Ross Kerber, *For Job Stimulus, Boston Mulls Direct Investments*, BOSTON GLOBE, Oct. 18, 2004, at C1.
 56. Associated Press, *Wisconsin Announces Stem Cell Funding*, MSNBC, Nov. 18, 2004, at <http://www.msnbc.msn.com/id/6515491/>.
 57. *Id.*
 58. See Associated Press, *NJ Stem Cell Research Leader with Funding?*, KYW-TV PHILA., Jan. 10, 2005, at http://kyw.com/Local%20News/local_story_010145006.html.
 59. *Id.*
 60. Alison McCook, *An Eastern U.S. Stem Cell Hub?*, THE SCIENTIST, at <http://www.biomedcentral.com/news/20050120/02/> (Jan. 20, 2005).
 61. *Id.*
 62. Chad Hamblin, *Funding Proposed For Stem Cell Research*, MINN. DAILY, available at <http://www.mndaily.com/articles/2004/12/13/11714/> (Dec. 13, 2004).
 63. Press Release, Office of the Comptroller of the State of Illinois, Hynes Proposes Creation of Stem Cell Research Institute, available at <http://www.ioc.state.il.us/office/IOCNews/ViewNewsRelease.cfm?ID=2070837170> (Nov. 23, 2004).

anticipated “brain drain” that will result from Proposition 71. And these recent initiatives are all on top of previous impressive state funding commitments to the life sciences, such as Pennsylvania’s pledge of \$250 million, which the state expects to receive in settlements from litigation against the tobacco companies, to life sciences research and commercialization centers across the Commonwealth.⁶⁴

The sum of all of these initiatives seems to be that there is at least a compelling perception in many parts of the country that some level of public funding for stem cell research will be needed if this promising area of inquiry is to have any reasonable chance of success. There remain questions about whether the research will in fact lead to any cures or therapies in even the next couple of decades. Further, the moral and ethical concerns over this research will continue to ebb and flow, with possible political ramifications for the continuance of the research. But, as will be discussed below, early stage basic scientific research, such as the current state of stem cell research, has historically been funded primarily by public dollars in the United States. At the same time, some argue that public funding is desirable precisely because it will result in more accountability, careful regulation, and public scrutiny of controversial research.⁶⁵ A participant in this Symposium even went so far as to claim that public funding means that the results wind up in the public domain.⁶⁶ However, neither of these assertions is exactly true. Once again, the devil is in the details, and the most relevant details for the stem cell research and its funding initiatives lie in the IP rights allocation clauses of the funding agreements that pay for any particular work.

II. THE GOOD NEWS AND BAD NEWS FOR FEDERALLY FUNDED RESEARCH

As mentioned above, federal funding has supported an enormous amount of basic scientific research in this country throughout the twentieth century.⁶⁷ Private money is not as interested in basic research because such research is almost by definition at the very early stage of exploration and is not yet directed towards a commercializable technology. This means that any calculation of a return on investment—both in amount and

64. David Wenner, *Biotechnology Gets Big Shot in Arm*, HARRISBURG PATRIOT, Apr. 4, 2002, at B5.

65. Gillespie, *supra* note 54.

66. Suzanne Kadereit, *An Overview of Stem Cell Research*, 39 NEW ENG. L. REV. ____ (2005).

67. *See, e.g.*, Organisation for Economic Co-operation and Development, *Reviews of National Science Policy: United States* (Paris, 1968) (showing an annual growth rate for federal government spending on R&D of 24.9% between 1940 and 1965, culminating in the federal government’s financing of 64% of all U.S. R&D at the end of that period).

timeframe—is so speculative as to be nearly useless. Accordingly, private funding of basic research is often more of an altruistic gesture than an investment venture. At the same time, many educated citizens and leaders buy into the view that basic research is important because it leads, serendipitously and indirectly, to the most revolutionary breakthroughs. Stories of the accidental discovery of penicillin, for example, resound in many of these individuals' thinking and makes the rationale for the funding of basic research nearly an axiomatic principle. But, with private money largely out of the picture, the only other solution is public funding.

Accordingly, following in the path of the noble civic investment that led to the great state land grant universities of the late 1800s, the 1900s became the century of unprecedented public investment in basic scientific research. In particular, World War II and the race for the atomic bomb showed the essential nature of scientific and technological primacy for national security in the modern world, as well as the link between the most advanced theoretical science—physics in this case—and the very survival of the nation. As World War II gave way to the Cold War, the need for accelerated scientific and technological progress did not diminish as it had in the wake of previous wars. Cementing the permanent status of the science and technology race, the Soviet launch of the Sputnik satellite in the 1950s was perhaps the final push that opened the floodgates of federal spending on all sorts of R&D, basic and applied, in public institutions and even in private contractor labs.

But the growing wealth of government funded research also led to questions of its ownership and use. Private contractors wanted to retain any resulting patent rights, especially where they might cover commercial, civilian applications, but certain factions in the federal government did not want research funding to turn into a windfall for private corporations. At the same time, the mounting inventory of patentable inventions developed in government and university or non-profit institution labs was not benefiting anyone, as the private commercial sector that was needed to turn these inventions into saleable products distributed to retail outlets was often unwilling to do so on anything less than exclusive license rights. Thus a long-simmering debate commenced shortly after World War II over whether the government funding agency should grant the title or merely a license to patentable inventions arising from funded research. In time, this would be largely resolved by first the Statement of Government Patent Policy issued by President John F. Kennedy in 1963 (Kennedy Patent Policy),⁶⁸ and then later by the passage of Bayh-Dole itself in 1980.⁶⁹

68. The Kennedy order is actually set out in two parts. The first part, the Memorandum for the Heads of Executive Departments and Agencies, 3 C.F.R. 861 (1959-1963), sets out the policy and objectives and directs the agencies to follow the rules and

In many important ways, Bayh-Dole simply codified the Kennedy Patent Policy, particularly in its definitions of key terms and focus on balancing the competing values of free public access to federally funded inventions, on the one hand, and the need for exclusive rights as an incentive for private sector commercialization of otherwise unused patented inventions.⁷⁰ Further, Bayh-Dole adopted nearly wholesale the crucial concept, mechanisms, and language of the “march-in rights,” as discussed in more detail below, set out first in the Kennedy Patent Policy.⁷¹ But in one equally critical way, the two sets of rules were very different: Whereas the Kennedy Patent Policy explicitly rejected a “one-size fits all” approach to the title vs. license question,⁷² Bayh-Dole comes down firmly on the side of granting title to the patentable invention to the researcher/contractor, provided that the contractor reports the invention in a timely fashion and then affirmatively elects to retain such title.⁷³

But even while Bayh-Dole appears to side with the contractor—at least insofar as the contractor is a non-profit or small business because Bayh-Dole does not speak to situations where larger businesses are the contractor⁷⁴—it does retain and expand many of the encumbrances on the title grant, where the contractor elects to retain title in the subject invention, that were first established by the Kennedy Patent Policy. First, the federal funding agency must 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....”⁷⁵ Second, the

guidelines, set out in the second part, which contains the actual “Statement of Government Patent Policy,” 3 C.F.R. 862 (1959-1963).

69. The history of U.S. government patent policy is an extensive and fascinating topic, but outside the scope of this Symposium article. The cursory version presented here is based on another manuscript I am currently drafting. See Sean M. O’Connor, *The Evolution of Government Research Patent Policy: Putting Bayh-Dole Into the Proper Context* (working paper on file with author). A somewhat different version can be found in Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996).
70. Compare the “Policy and objective” section of Bayh-Dole, 35 U.S.C. § 200 (2000), to the policy objective set out in the Memorandum for the Heads of Executive Departments and Agencies part of the Kennedy Patent Policy, *supra* note 68.
71. Compare 35 U.S.C. § 203 (1988) with 28 Fed. Reg. 10,943 (1963).
72. See 3 C.F.R. 861.
73. See 35 U.S.C. § 202 (1988).
74. However, a subsequent order by President Ronald Reagan in 1983 adopted the rules of Bayh-Dole as the official executive branch policy across all funding agencies for large businesses as well. See Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, PUB. PAPERS 248 (Feb. 18, 1983).
75. 35 U.S.C. § 202(c)(4). The funding agency is authorized to request even further

contractor must give notice of the federal funding, and the concomitant rights of the federal funding agency in the subject invention, in both the patent application and any resultant issued patent.⁷⁶ Third, non-profit contractors may not assign their rights to the subject invention to any other party without the approval of the funding agency, unless the assignment is to an external technology transfer or patent portfolio management entity, in which case that entity is prohibited from any further assignments of the subject invention without the approval of the funding agency.⁷⁷

The fourth title encumbrance, march-in rights, is actually a set of conditions for when the funding agency can exercise a type of compulsory license. The set of conditions that constitute march-in rights is also a continuation from the Kennedy Patent Policy, and is perhaps the most well-known—and most contested—of the provisions. The march-in rights provide the funding agency with the authority to:

[R]equire the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—

(a) 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;

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

(c) 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

(d) action is necessary because the agreement required by section 204 [that any exclusive licensee must substantially manufacture the products embodying the subject invention in the United States] 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 [and therefore no exclusive license is

license grants over this statutory minimum license grant.

76. *Id.* § 202(c)(6).

77. *Id.* § 202(c)(7)(A).

permitted or valid].⁷⁸

As will be seen below, the proper scope of march-in rights has been hotly contested – even as they apparently have never been formally exercised by the government. This is true despite at least two formal proceedings involving petitions requesting that the relevant funding agency exercise its march-in rights.⁷⁹ One important dimension of this debate centers on the question of whether march-in rights impart a pricing control or regulation authority on the funding agency or only a more limited authority to ensure that the subject invention is actually commercialized and brought to market.

The technology transfer system codified by Bayh-Dole is also subject to two further criticisms. One is based on a claim that the law as implemented effectively forces the public to “pay twice” for products arising out of federally funded inventions.⁸⁰ We pay first through our tax dollars that are used to fund the federal agency grants to contractors for their research. Then we pay again through the high retail prices enabled by the allowance of exclusive control of the patents ensuing from that research. But this argument is more persuasive in situations where the patent arising from the federal funding effectively covers the eventual product that will be brought to market. Even then, the costs associated with ramping up a manufacturing, distribution, marketing, and sales operation for the product means that the final retail price may be quite expensive. Further, it is not as if the commercializing entity gets the exclusive license for free—universities and non-profits are increasingly striking savvy bargains requiring substantial upfront payments, patent prosecution and maintenance fees, and minimum royalties. Thus, one might equally question what is happening with the money that universities are making from patenting and licensing federally funded inventions.

The real test would be whether a comparably situated product that was developed from a patent arising from privately financed research was placed on the market at a far higher price. This would effectively demonstrate the discount the public receives because the first company did not incur the same patent R&D expenses. Of course, the first company would then be foolish not to raise its prices to capture the extra profit margin since the public may be willing to pay the higher price, assuming that its product is in fact a viable market substitute for the other company's

78. *Id.* § 203(1).

79. *See infra* Part III.

80. *See Eisenberg, supra* note 69, at 1666; Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part From Federally Funded Research*, 75 TUL. L. REV. 631, 658 (2001).

product. But at the same time, the second company may not be able to enter the market at such a higher price, as it would be unable to capture market shares as against the first company's (federally subsidized) lower price. In this way, the Bayh-Dole system could theoretically work to keep prices down overall in markets with products that embody federally funded research results. This seems to fly in the face of an economic reality in which prices seem to spiral ever higher—especially in the science and technology-heavy markets—and few would believe that the grant of exclusive patent rights leads anywhere but to higher retail prices.

The problem with all of this armchair theorizing is that quite a number of largely untestable scenarios can be spun out: What if the company with the federally funded patent tries to enter the market after the company with a self-funded patent? Will it deploy a cut rate to steal market share quickly from its competitor, or will it come in just under the competitor's price so as to maximize the profit margin on each unit sold? Yet, precisely because patented technologies are at the core of these scenarios the reality check of comparing acceptable market substitutes is particularly difficult. In fact, relatively few products embody only the patent that arises from federally funded university or non-profit research. In no small part this is because much of the research that is funded is early stage, basic science that often has no commercial product in sight, or that at least will require substantial translational R&D to bring it to the level of commercialization. This translational R&D, combined with the standard commercialization costs of scaling a production and sales operation, lends some support to industry arguments that it is not improperly leveraging off of or profiting from its exclusive, albeit paid, licenses, but rather simply charging fair market value for what it has invested to bring the product to market—which may, again, include upfront payments, patent fees, and royalties to one or more universities/non-profits.

But as the U.S. Patent and Trademark Office (USPTO) has shown an increasing willingness to issue patents on early stage, pre-commercializable research results, a more trenchant concern has been raised: this second main criticism of the technology transfer system created by Bayh-Dole focuses on the USPTO's current "easy patenting" stance in combination with Bayh-Dole's strong incentives for universities and non-profits to patent research results, and argues that too many patents are being issued, particularly on so-called "up-stream" research results and research tools/platforms.⁸¹ This, in turn, leads to "patent thickets," especially in the life sciences, that make it prohibitively difficult and/or expensive to either conduct new R&D or to commercialize important new technologies. It is

81. See Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 290 (2003).

prohibitively difficult because the researcher and her company must carefully set a course of R&D through a dense maze of sometimes overlapping patent claims to avoid infringement. And it is prohibitively expensive because ultimately the researcher and her company wind up paying multiple royalties to different patent holders—sometimes called “royalty stacking”—just to engage in the necessary R&D and bring a product to market.

Despite the pros and cons of federal research funding under the Bayh-Dole technology transfer system, at least this system is reasonably well fleshed out in the statute and the rules promulgated under it. Further, a fair bit of received wisdom has accumulated within the segments of the technology transfer system—universities, non-profits, start-ups, established technology companies, and venture capitalists—that arguably has achieved the level of settled expectations around things like the allocation and use of IP rights when federal funding is involved. This is all in marked contrast to the status of IP rights under state, local, or private funding. But, because federal funding is at least partly behind so much university and non-profit patentable research, the Bayh-Dole system's set of rules and settled expectations tends to be the standard. The next Part of this Article will consider what happens when federal funding becomes a minor or limited player as it has in hPSC research because of the Bush Administration policy.

III. STEM CELL RESEARCH WILL BE A VICTIM OF ITS OWN SUCCESS

At this point no one really seems to know whether any type of stem cell research—adult or hPSC—will live up to the hype that has surrounded the whole area. We do know that some therapies involving adult stem cells have been demonstrated and deployed with a fair degree of success.⁸² But these therapies are not the home runs that are usually associated with the most wide-eyed prognostications for stem cell research overall. This is because adult stem cells are generally only multipotent, meaning that they can differentiate into only a few specific types of human body cells.⁸³ In particular, adult stem cells generally exist in certain parts of the human body such as bone marrow and muscle, and organs such as the liver and

82. NAT'L INSTS. OF HEALTH, *Stem Cell Information: FAQs*, at <http://stemcells.nih.gov/info/faqs.asp#classes> (last visited Feb. 4, 2005) [hereinafter NAT'L INSTS. OF HEALTH, *FAQs*]. One type of adult stem cells in particular—hematopoietic stem cells (HSCs)—that exist in the bone marrow and create blood cells have been used successfully to treat leukemia, lymphoma, and other blood disorders, either through bone marrow transplants or advanced harvesting or collecting techniques. *Id.* Other adult human stem cells have been demonstrated in therapies for diabetes and advanced kidney cancer. *Id.*

83. *Id.*

skin, and then are limited to differentiation into only the component cells of that tissue or organ.⁸⁴ However, there is evidence that some adult stem cells may have extended “plasticity” such that they can in fact be directed to develop into the cells of a different tissue or organ.⁸⁵

At the other end of the scale, a fertilized human egg is deemed totipotent as it can develop into any and all types of cells of the human body, and, of course, into an embryo, a fetus, and then a self-sustaining human being.⁸⁶ But, in between the totipotent egg and the generally multipotent adult stem cells, in terms of their ability to develop into different types of cells, are the pluripotent human embryonic stem cells, or what we have been referring to as “hPSCs.” Pluripotent stem cells can develop into nearly any type of cell in the adult human body, save those needed to develop the human fetus in the first place.⁸⁷ HPSCs have generated most of the strongest excitement inside and outside of the scientific community because they, at least theoretically, have the potential to be directed into regenerating entire tissues and organs of the adult body, such that many terminal diseases could be completely cured.⁸⁸ But such applications are usually considered to be a decade or so away, and in fact may never come to fruition.⁸⁹ A somewhat less spectacular sounding goal for hPSCs—and adult stem cells for that matter—is as a means for studying normal cell development that would shed light on why that process sometimes goes astray, leading to debilitating medical problems such as cancer and birth defects.⁹⁰ Therapies, cures, or perhaps even preventive measures might be developed from this knowledge and controlled experimentation with the cell differentiation process.⁹¹

The point of this Article is not to debate when, whether, or how stem cell research will be translated into revolutionary therapies for “Parkinson’s and Alzheimer’s diseases, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, and rheumatoid arthritis.”⁹² Instead, this Article merely relies on the premise that at least some of these therapies will be demonstrated and ultimately made available commercially. So long as this happens, then the nightmare tussles over ownership and control will begin.

84. See NAT’L INSTS. OF HEALTH, *Stem Cell Information: Stem Cell Basics*, at § IV, at <http://stemcells.nih.gov/info/basics/basics2.asp> (last modified June 10, 2004) [hereinafter NAT’L INSTS. OF HEALTH, *Stem Cell Basics*].

85. *Id.*

86. NAT’L INSTS. OF HEALTH, *FAQs*, *supra* note 82.

87. *Id.*

88. *Id.*

89. NAT’L INSTS. OF HEALTH, *Stem Cell Basics*, *supra* note 84, at § 6.

90. *Id.*

91. *Id.*

92. *Id.*

First up would be the private sector corporations jockeying to control—or at least tap into—the mammoth revenue streams that flow from a blockbuster, life-saving therapy. But next would be the slowly developing murmur and then roar from the public as to why only the wealthy can afford the likely exorbitant prices that will be charged. Further, to the extent that any federal, state or local public funds were used in the research leading up to commercialization of the therapy, the question may well be why it is not available for free, or at least at a serious discount, to the public. This clamor will increase proportionally to the success of the therapies, such that if anything near the expected revolutionary life saving advances come out of the research, then the public may well find themselves in their own revolutionary mode when their access to these crucial regimes is effectively denied.

The rest of this Part will sketch the likely funding scenarios for stem cell research and then assess their implications for the ownership, control, and public response issues in the event of a “home run” in the research. It will also look at two recent controversies regarding the patentable results of federally funded life sciences research as an indication of what is in store for any successful commercialization of stem cell research.

A. Funding for hPSC Research

1. Federal Funding

As discussed in Part I above, current federal funding for hPSC research is limited to research that uses only hPSCs from the cell lines existing at the time President Bush made his address to the nation. Original estimates put the number of such cell lines at sixty to seventy, but currently available cell line listings in the NIH Human Embryonic Stem Cell Registry (the Registry) number only twenty-two.⁹³ At least in part due to this small number of available approved hPSC lines, the total funding of hPSC research by NIH currently stands at approximately \$25 million annually.⁹⁴ It is unclear whether this funding level will increase over the years. But wherever such funding is applied, the full set of rights and obligations under Bayh-Dole—as sketched out above in Part II—will govern the use of any patentable inventions that result. Further, it is likely that any and all mainstream research performed in non-profit and/or university labs using hPSC lines listed in the Registry will be done under at least some federal funding: the NIH, under the Bush Administration, probably wants to grant as much federal funding for eligible hPSC research

93. NAT'L INSTS. OF HEALTH, *FAQs*, *supra* note 82.

94. Ivan Oransky, *California OKs Stem Cell Measure*, THE SCIENTIST, at <http://www.biomedcentral.com/news/20041103/02> (Nov. 3, 2004).

as possible to show its commitment to stem cell research in particular, and science in general, to counter criticisms that it is anti-science; and the labs would be foolish for not taking advantage of this largesse where it exists, so as to be better able to cover the funding gap for the greater portion of hPSC research that will be ineligible for federal funding under the Bush Administration policies.

The trickier question is whether Bayh-Dole will wind up applying to patentable inventions arising from an overall research program that includes work with both eligible and ineligible hPSC lines. At first blush, it would seem that such a research program is prohibited. The NIH is clear that, under the Bush Administration:

No federal funds may be used, either directly or indirectly, to support research on human embryonic stem cell lines that do not meet the criteria established by President Bush on August 9, 2001. Cell lines not listed on the NIH Human Embryonic Stem Cell Registry do not meet these criteria. Thus, research on lines (or their derivatives) not listed on the NIH Human Embryonic Stem Cell Registry may not be supported by federal funds.

...

Scientists who receive federal funds and study both federally fundable and non-federally fundable human embryonic stem cells must charge research costs for study of non-federal lines only to non-federal sources of funding. With respect to indirect costs, such as facilities and administrative (F&A) costs, scientists should adhere to the guidelines in applicable federal cost principles such as OMB Circular A-21 (Colleges and Universities). These documents describe how to keep budget and accounting records so as to prevent federal funds from improperly subsidizing non-federally supported research. These cost principles are also applicable to work on non-federally fundable activities using human embryonic stem cells not included in the Stem Cell Registry.⁹⁵

This emphasis on both direct and indirect costs would seem to push researchers (and their institutions) to rigidly separate research projects using eligible hPSC lines from those that do not. The potency of the “indirect costs” language is that it forces funding recipients to consider parts of funding that may have been used for F&A costs—such as institutional allocation of costs to the specific lab, such as a rent equivalent, and for phones, networks, and maintenance—as now constituting partial funding for other research projects that may happen to occur in the same lab during the same time period. In other words, labs are not supposed to

95. NAT'L INSTS. OF HEALTH, *FAQs*, *supra* note 82.

use federal funds to pay general lab F&A costs unless the lab is willing to allow research projects being performed in that lab space during the funding period to essentially be partly federally funded projects, even if the lab and the particular project PI did not directly seek federal funding for that project or consider it to be a federally funded project.

In many lab environments this might not be a problem, because there may be little consequence to having non-directly funded research “tainted” in this way by application of funding for another project to lab F&A costs. But, in the context of hPSC research such indirect cost allocation can have dramatic effects, because a lab that wants to pursue both federally funded research on eligible hPSC lines and non-federally funded research on ineligible hPSC lines may miss the prohibition on indirect costs and wind up violating the terms of their federal funding agreement. Another way of looking at it is that by specifically prohibiting the use of federal funds not just for direct costs of ineligible hPSC research, but also for indirect costs of that research, the Bush Administration policy is arguably attempting to push ineligible hPSC research out of non-profit and university labs altogether. Ultimately, President Bush has leveraged his limited authority to shape the contours of federal spending on hPSC research into an effective tool to reduce the amount of hPSC research overall—whether aided by federal dollars or not—in funding dependent non-profit and university labs.

This change, of course, plays right along with the bootstrapping method mentioned in Part I above to try to reduce the total number of human blastocysts (or embryos, depending upon which scientist you are talking to) that will be destroyed to access the hPSCs within. The prohibition on federal funding for hPSC lines derived from any source other than the Registry means that the value of newly derived hPSC lines is diminished because the primary source for non-profit and university life sciences research remains the federal government. And yet, until and unless Congress acts to ban the derivation of new hPSC lines from any or all source blastocysts/embryos, such derivation, and any subsequent research, on the resultant hPSC line is perfectly legitimate. Clearly, Congress itself exercises its “power of the purse” on many occasions to try to achieve policy goals indirectly that it either is not authorized to address under the Constitution, or that it is politically unwilling to address directly. But for a presidential administration that opposes social activism by the judiciary, on the grounds that these activities represent overreaching by the judges, the Bush stem cell policy seems awfully activist itself: It seeks to reach beyond a limited grant of discretionary power over agency spending to achieve far larger and consequential social policy goals, which arguably should be left

to Congress.⁹⁶

At the same time, this attempt to reduce the number of new hPSC lines developed and used even outside of federally funded projects may not be entirely successful. Once again, the devil is in the details. A further look at the NIH FAQs page for stem cell research and researchers shows a surprising amount of minutiae devoted to this issue of cost allocation, considering the very basic language used to define and answer questions about stem cells themselves:

Technical guidance provided by the DHHS Division of Cost Allocation states that the cost principles and Cost Accounting Standards contained in OMB Circular A-21, particularly with regard to the treatment of activities sponsored by industry and foreign governments, are equally applicable to unallowable stem cell research. The regulations strictly forbid the shifting of costs from these activities to federally sponsored activities. Strict adherence to the principles contained in the circular requires the allocation of indirect costs, also known as facilities and administrative (F&A) costs, to both federally sponsored and other activities, which would include unallowable stem cell research. Federal policy is clear that no federal funding may be used, either directly or indirectly, to support human embryonic stem cell research outside the criteria established by the President on August 9, 2001. Therefore, the direct costs of such unallowable activity must be charged only to non-federal sources of funding. With respect to indirect costs, or F&A costs, institutions engaged in unallowable stem cell research must strictly adhere to guidance contained in OMB Circular A-21. Strict compliance with cost allocation methodologies described in the circular, including the Cost Accounting Standards, will prevent the shifting of unallowable stem cell research costs to federally sponsored programs. The F&A costs, which are allocable to stem cell research falling outside the criteria established on August 9, 2001, will not be charged to federally sponsored activities because the direct costs of such research must be directly charged to non-federal sources of funding. A properly documented F&A proposal utilized in the establishment of F&A rates should demonstrate that none of the costs of

⁹⁶ Of course, a distinction can, and should, be made that the president is an elected official, whereas federal judges are appointed. Thus, one could argue that the Executive branch, like the Legislative, *is* the appropriate place for social policy decisions to be made. However, the Executive branch is also like the Judiciary in that it is supposed to be implementing the law created by the Legislative branch, not making that law.

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unallowable stem cell research or other unallowable activities have been shifted to federally sponsored activities.⁹⁷

The FAQs page then goes on to give even more specific guidance from OMB Circular A-21 and OMB Circular A-122:

Accounting for unallowable costs is discussed in Circular A-21, Section C.12.e:

All unallowable costs covered by subsections a through d shall be subject to the same cost accounting principles governing cost allocability as unallowable costs. In circumstances where these unallowable costs normally would be part of a regular F&A cost allocation base or bases, they shall remain in such base or bases. Where a directly associated cost is part of a category of costs normally included in a F&A cost pool that shall be allocated over a base containing the unallowable cost with which it is associated, such a directly associated cost shall be retained in the F&A cost pool and be allocated through the regular allocation process.

In Circular A-122, see Section B.3 for unallowable costs and activities:

The cost of certain activities are not allowable as charges to Federal awards (see, for example, fundraising costs in paragraph 17 of Attachment B). However, even though these costs are unallowable for purposes of computing charges to Federal awards, they nonetheless must be treated as direct costs for purposes of determining indirect cost rates and be allocated their share of the organization's indirect costs if they represent activities which (1) include the salaries of personnel, (2) occupy space, and (3) benefit from the organization's indirect costs.⁹⁸

The final paragraph on the FAQs page may be one its most illuminating, however:

Each organization that receives federal funds on NIH grants and contracts must have in place adequate policies, procedures, and internal controls to provide reasonable assurance that federal funds are not used to support non-federally supported or unallowable costs. These policies are appropriate for work on stem cells lines not included in the NIH Human Embryonic Stem

97. *Id.*

98. *Id.* (citing OMB Circular A-21 and OMB Circular A-122).

Cell Registry. Organizations will be well served by providing training to staff working with non-registered lines to reinforce these policies and procedures and the need to carefully document the assignment and allocation of costs between federally supported and non-federal projects.⁹⁹

As all lawyers know, terms like “reasonable” can dramatically qualify an otherwise strict or unqualified obligation or duty. Thus, the draconian prohibition of federal funds for both direct and indirect costs of ineligible hPSC research is softened, under the NIH’s implementation, by a requirement only that the recipient’s policies to prevent improper use of federal funds “provide reasonable assurance that federal funds are not used to support non-federally supported or unallowable costs.”¹⁰⁰ This “softening” is further enhanced by the extra language that such organization policies “are appropriate for work on stem cells lines not included in the NIH Human Embryonic Stem Cell Registry.”¹⁰¹

Combined with the specific language from (and hyperlinks to) the OMB Circulars regarding how organizations can use careful accounting to narrowly slice and dice cost allocation even within a lab—or even within a specific research project?—so that even indirect costs such as F&A can be divvied up among multiple projects, this final section of the FAQs page seems to give researchers and their organizations the play book for how to prevent the Bush hPSC policy from in fact squelching their ability to engage in non-federally funded, ineligible hPSC research right alongside federally funded, eligible hPSC projects. But, if so, it is quite possible that a patentable invention could arise from both the federally funded eligible hPSC work *and* the non-federally funded ineligible hPSC work done in a single lab—or for that matter, multiple labs in a larger collaborative research effort.

But would this patentable invention then fall under the provisions of Bayh-Dole? The usual test of this is whether federal funding was at least partly used for the research in which the patentable invention, or now “subject invention” under the parlance of Bayh-Dole, was first conceived.¹⁰² On one level, then, only “subject inventions” conceived in the performance of the federally funded eligible hPSC research should lead to patents governed by Bayh-Dole. But researchers are not always able to say with precision exactly how and when a particular invention was conceived. This is especially true when one considers that “conceived” here is intended as a specific term of art in patent law. Any number of priority of

99. *Id.*

100. *Id.*

101. *Id.*

102. 35 U.S.C. § 201 (2000).

invention battles have turned on small details evidencing a party's claim of the date of conception of the idea. It will be no more clear here, in many cases, as to the actual date and exact circumstances of conception in research projects with multiple federally funded and non-federally funded components. The upshot of all this is that Bayh-Dole may indeed wind up covering patentable inventions arising only in part from federally funded hPSC research.

Before turning to other sources of funding for hPSC research, it is worth pausing over some of the inferences and speculations made above. Certainly, there is a fair bit of reading tea leaves in those inferences and speculations, most of which are based primarily only on language from NIH web pages. But, I cannot help believing that these inferences are at least plausible, given the fact that NIH is largely staffed by serious scientists—most of whose non-governmental counterparts support nearly unfettered hPSC research—who are not direct political appointees and indeed will remain through the administrations of both political parties. Thus, a change at the top does not necessarily change the core convictions of the vast rank and file who must implement the latest boss's edicts. And, without asserting any charges of disloyalty on this quasi-permanent bureaucracy, it is not unimaginable that they might exercise to the fullest their own discretionary authority in how to implement an executive directive, just as the President seems to have exercised his discretionary authority to decide agency spending policy to the fullest. Further evidence supporting this speculation is perhaps provided by the NIH's decision to also include the following on the FAQs page:

Who is responsible for setting the policy to allow federal money to be used for human embryonic stem cell research?

As the head of the executive branch of the federal government, which includes the National Institutes of Health, the President of the United States has the final responsibility and authority to set federal government policy for funding human embryonic stem cell research. But Congress has appropriations authority and can possibly override the President's decision.¹⁰³

A reminder from within the bowels of the NIH as to the impermanence of presidential directives perhaps?

2. Other Sources of Funding for hPSC Research

Prior to the 2004 elections, the only real viable alternative to federal funding for hPSC research was private money. However, as mentioned in Part I above, a substantial portion of private funding comes in under the

103. NAT'L INSTS. OF HEALTH, *FAQs*, *supra* note 82.

guise of sponsored research. This usually means that the research will be effectively owned by the paying sponsor, subject to strict confidentiality provisions, and any resultant IP will be assigned to the sponsor. In many ways, then, these sorts of research projects might best be viewed as simply extensions of private corporate in-house research. But this will, of course, put virtually all of the control and ownership of the research results out of the public's grasp. Further, given past trends, this source of funding—even coupled with philanthropic private funding—will be inadequate to fund the types of hPSC research needed to advanced the science to a commercializable stage.

But, as also set out in Part I above, in the wake of the 2004 elections some major new public sources of hPSC funding have emerged. Proposition 71 alone will generate twenty-four times the annual spending on hPSC research than the NIH currently provides.¹⁰⁴ This will be matched, or nearly matched, by any number of other states who are desperate to prevent the feared “brain drain” to California.¹⁰⁵ Thus, state and local funding of hPSC should easily dwarf federal spending within a year or so.

This good news is also the bad news though. As seen above, Proposition 71 is incredibly vague as to how IP rights will be allocated when state funded hPSC research leads to patentable results. Talk about a discretionary grant: the ICOC is given essentially complete discretion to structure IP rights allocation in funding agreements with researchers, including on an ad hoc basis. This means that there may be a myriad of different types of IP rights allocation under the various ICOC/CIRM funding grants.

Further, even though Proposition 71 clearly prioritizes funding for hPSC research that is unlikely to receive federal funding, it does not flat out prohibit such funding. Thus, where the CIRM funds hPSC that NIH also funds, Bayh-Dole should trump any IP rights allocation that the CIRM negotiates for in its funding agreement. And even in cases where the CIRM funds the ineligible hPSC research of a particular lab, while NIH funds the eligible research, any resultant IP may wind up being captured as partly funded by NIH, and thus covered under Bayh-Dole in supremacy over whatever rights allocation is set out in the CIRM funding agreement.

All of the foregoing will be even further complicated once other state and local governments get into the picture too. Perhaps they will do a better job setting firmer guidelines or rules for IP rights allocation under their respective funding agreements. But, what of the case where local, state,

104. This statistic is based on the estimates of \$300 million in annual funding under Proposition 71 for ten years and \$25 million in annual funding by the NIH. *See supra* Part I.C. and *infra* note 112 and accompanying text.

105. *See supra* Part I.

federal, *and* private funds are used for different parts or phases along a long-term research project—such as often occurs in life sciences research—and patents arise that are nearly impossible to allocate precisely to one set of funding? None of this, of course, is different from the same sorts of ownership snafus that play out in tech transfer offices across the country currently. But, with the reduction of the role of federal funding, and dramatic increase in the role of state and local funding, even more confusion is likely to ensue.

B. Adult Stem Cell Research.

Outside of hPSC research, the situation is almost guaranteed to be worse. Because embryos are not involved, the Bush Administration clearly favors adult stem cell research. Thus, federal funds will flow much more readily to these sorts of projects than to hPSC projects. At the same time, even though some opponents of Proposition 71 claimed the opposite,¹⁰⁶ Proposition 71 very much allows the CIRM to fund adult stem cell research.¹⁰⁷ Certainly, the law prioritizes hPSC research, but it does so only to the extent that the same “cannot, or is unlikely” to receive federal funding—if other types of stem cell research later become off limits to federal funding agencies such as the NIH, then the CIRM is fully able to prioritize funding that research too.¹⁰⁸ Admittedly, this prioritization scheme is intended “to ensure that [CIRM] funding does not duplicate or supplant existing funding....”¹⁰⁹ But, despite the use of the term “ensure,” the entire text of the prioritization clause of Proposition 71 does not seem to entirely preclude the possibility that CIRM funds will mix with federal funds in the financing of a research project.

Furthermore, outside of this negative partial requirement regarding federal funding possibilities, Proposition 71 only limits CIRM funding to “pluripotent stem cell and progenitor cell research.”¹¹⁰ The term “pluripotent cells” is defined in Proposition 71 essentially the same way as the term “hPSC” has been used in this Article:

“Pluripotent cells” means cells that are capable of self-renewal, and have broad potential to differentiate into multiple adult cell types. Pluripotent stem cells may be derived from somatic cell nuclear transfer or from surplus products of in vitro fertilization treatments when such products are donated under appropriate

106. See Tom McClintock et al., *Argument Against Proposition 71*, at <http://www.voterguide.ss.ca.gov/propositions/prop71-arguments.htm>.

107. CAL. HEALTH & SAFETY CODE § 125290.60(c)(1)(C) (West Supp. 2005).

108. *Id.*

109. *Id.*

110. *Id.*

informed consent procedures. These excess cells from in vitro fertilization treatments would otherwise be intended to be discarded if not utilized for medical research.¹¹¹

But, “progenitor cells” are defined by Proposition 71 as “multipotent or precursor cells that are partially differentiated but retain the ability to divide and give rise to differentiated cells.”¹¹² This clearly includes adult stem cells.

Thus the key limitation for CIRM funding is that “a high priority shall be placed on funding” hPSC and adult stem cell research that “cannot, or is unlikely to,” receive adequate, timely, unencumbered federal funding. Yet, with \$300 million to dispose of annually, the CIRM might well fully fund all “priority” projects and still have money to distribute. Further, a subsequent provision of Proposition 71 gives the CIRM the authority to not only fund non-priority projects, but also to fund “other scientific and medical research and technologies and/or any stem cell research proposal” not already funded by it, provided only that “two-thirds of a quorum of the members of the Scientific and Medical Research Funding Working Group recommend to the ICOC that such a research proposal is a vital research opportunity.”¹¹³ What constitutes a vital research opportunity? Proposition 71 gives us the very model of an exercise in circularity:

“Vital research opportunity” means scientific and medical research and technologies and/or any stem cell research not actually funded by [CIRM] under [the high priority clause] which provides a substantially superior research opportunity vital to advance medical science *as determined by at least two-thirds vote of a quorum of the members of the Scientific and Medical Research Funding Working Group and recommended as such by that working group to the ICOC*. Human reproductive cloning

111. *Id.* § 125292.10(q). Note that the definition is actually for “pluripotent cells” not “pluripotent stem cells,” or even “human pluripotent stem cells.” However, in the regular provisions of the law, the term “pluripotent stem cells” is used. This is likely simply a drafting oversight, although in theory it could have consequences. More interesting is the explanatory or possibly argumentative flourish provided by the last sentence of the definition: it is not a definition *per se*, such as if it said “cells ... *must* otherwise be intended to be discarded.” Instead it seems to be an extra argument for hPSC research, such as is often employed anyway—these embryos would be discarded otherwise. *See, e.g.,* Bill Press, *Jesus Votes for Stem-Cell Research*, WORLDNETDAILY, Dec. 31, 2004, at http://worldnetdaily.com/news/article.asp?ARTICLE_ID=42191 (arguing that it would be better to use discarded embryos “to save perhaps millions of lives” than to “[t]oss them in the dumpster along with the coffee grinds, orange peels and empty beer bottles”).

112. CAL. HEALTH & SAFETY CODE § 125292.10(r).

113. *Id.* § 125290.60(c)(1)(D).

shall not be a vital research opportunity.¹¹⁴

At least we know that “vital research opportunity” cannot include human reproductive cloning.

While it is too early to know what other post-Proposition 71 state funding proposals will look like, there is a good chance that they will be at least as flexible as the California law. Further, state life sciences funding proposals that predate Proposition 71—such as Pennsylvania’s dedication of its tobacco litigation settlement money—already are directed to a wide variety of research. Because adult stem cell research is well established as the less controversial path for stem cell funding, the myriad state and local funding initiatives may well flow to that, even as the point of Proposition 71 was to essentially do an end run around the Bush Administration funding limitation on hPSC research.

But with the increasingly complex nature of life sciences research projects in general, it is not uncommon for funding and subsequent ownership and control issues to stretch across multiple institutions, researchers, and a fairly long time period. Thus, even in the area of adult stem cell research, where federal dollars should still flow fairly freely, states and local municipalities may still find themselves competing to keep stem cell researchers, institutes, and companies. This will likely result in attractive (for the recipient) financing and tax packages such as the kind that have pursued the dwindling manufacturing opportunities in this country. But a crucial card that would-be funders can play in these races to the bottom is the waiver of any and all IP rights that come out of the stem cell research. At the same time, IP revenues may well be the only viable recoupment or return on investment avenue open to these suitor governments. This may explain Proposition 71’s coyness on the subject—it needs to preserve the flexibility of the CIRM to negotiate with differently situated research entities as the background environment for such entities changes over time. Other states and localities may decide that their funding agencies need the same flexibility to wage an all-out battle for brain power and high employment opportunities for their locality.

C. Two Recent High Profile Public Funding Controversies

One argument of this Article is that the ownership and control of the medical breakthroughs that may arise from stem cell research have a strong possibility of being mired down in hopelessly conflicting IP claims. The case for that was made above. But another fundamental argument of the Article is that where revolutionary medical breakthroughs arise from stem cell research that was at least partly publicly funded, and the

114. *Id.* § 125292.10(y) (emphasis added).

commercializing entity charges exorbitant monopolistic prices for the resultant life saving therapies, the public will demand that the government step in to reduce these retail prices. In part, this is due to the recent publicity given to arguments in scholarly articles and the popular media that the public is already “paying twice” for many medications and therapies that arose in part from federally funded research. The resultant attention has focused on the need for the government to issue compulsory licenses or exercise march-in rights under Bayh-Dole.

While the scholarly and factual bases for these arguments may be flawed, the pull they exert on a public weary of astronomical health care prices—excruciatingly and prohibitively so for those without adequate health insurance—is substantial. Thus, the following two cases that appear to constitute the only formal march-in rights petitions lodged since Bayh-Dole was passed are instructive.

1. *Johns Hopkins University v. CellPro, Inc.*¹¹⁵

The first major march-in rights petition involved, appropriately enough, stem cell research. Dr. Curt Civin, a researcher at Johns Hopkins University (Hopkins), received NIH funding that led to the publication of a paper in 1984 on his discovery of certain antibodies that would bind to certain antigens appearing on hematopoietic stem cells.¹¹⁶ These antibodies, which he dubbed “anti-My-10,” could allow a technician to separate out the hematopoietic stem cells, because only these cells have the stage specific antigen “My-10” on their surface.¹¹⁷ The anti-My-10 monoclonal antibodies bind only to the My-10 antigens, and hence only to hematopoietic stem cells. Over time, the anti-My-10 and similar antibodies came to be referred to as “CD34 antibodies.” The name shift has been explained as arising from the practice of panels of scientists reviewing research data and then designating clusters of antibodies that have similar binding characteristics. Anti-My-10 was in a group of antibodies that was the thirty-fourth cluster to be designated, hence Cluster Designate 34 (CD34).¹¹⁸ Accordingly, the hematopoietic stem cells’ distinctive, stage specific,¹¹⁹ antigen is referred to as the “CD34 antigen,” while the binding antibodies are dubbed “CD34 antibodies”¹²⁰ or “anti-CD34 antibodies.”¹²¹

115. 152 F.3d 1342 (Fed. Cir. 1998).

116. See NAT’L INSTS. OF HEALTH, *Determination in the Case of Petition of CellPro, Inc.*, at http://www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf (Aug. 1, 1997).

117. *Johns Hopkins Univ.*, 152 F.3d at 1347.

118. *Id.* at 1350 n.13.

119. *Id.*

120. *Id.*

121. NAT’L INSTS. OF HEALTH, *supra* note 116.

Civin and Hopkins filed patent application serial number 670,740 ('740 application), around this same time.¹²² This application led to the issuance of U.S. Patent No. 4,714,680 ('680 patent), as well as divisional applications that led to U.S. Patent Nos. 4,965,204 ('204 patent), 5,035,994 ('994 patent), and 5,130,144 ('144 patent).¹²³ All four of these patents (collectively, the Civin Patents) were the basis for a hematopoietic stem cell purification and suspension technology that Hopkins exclusively licensed to Becton-Dickinson & Co. (BD) around 1984 or 1985, although the first of the patents did not issue until 1987.¹²⁴ "BD ... market[ed] the first [CD34 antibody in 1985 and has sold [CD34 antibodies worldwide" since then.¹²⁵ Because BD focused on the diagnostic applications of CD34 antibodies, it exclusively sublicensed therapeutic application rights to Baxter Healthcare Corporation (Baxter); Baxter then further sublicensed its rights to Applied Immune Sciences (later RPR Gencell) and Systemix (later acquired by Novartis).¹²⁶

Hopkins formally notified the NIH, as required under Bayh-Dole, on October 4, 1984 that it was electing to take title to the invention covered by the '680 patent. In the later march-in rights petition proceeding, NIH determined that it had jurisdiction over the technology as covered by the '204, '994, and '144 patents as well because they all stemmed from the same original disclosure in the '740 application, which disclosure itself could be traced to utilization reports filed by Hopkins from the 1980s through the early 1990s with the NIH.¹²⁷ Hopkins also sent a license to NIH regarding this technology, as required under Bayh-Dole.¹²⁸ In sum, NIH argued that conception of the inventions contained in all of the Civin Patents occurred in Civin's performance of a NIH funded project, and hence all resultant patents were subject to Bayh-Dole. This, of course, is exactly the sort of long range, complicated research project that frequently occurs in the life sciences and around which a truism of sorts has arisen in the university community that Bayh-Dole reaches essentially everything that university labs develop.

Four years after Hopkins filed the '740 application, Dr. Ronald Berenson, a researcher at the Fred Hutchinson Research Center in Seattle (Hutchinson), developed a similar method for targeting and separating hematopoietic stem cells by means of an antigen binding monoclonal

122. *Id.* at 4 n.6.

123. *Id.*

124. *Id.* at 1, 5.

125. *Id.* at 5.

126. *Id.*

127. NAT'L INSTS. OF HEALTH, *supra* note 116, at 3-4.

128. *Id.* at 4.

antibody that he dubbed the 12.8 antibody.¹²⁹ In 1989 CellPro, Inc. (CellPro) was founded by Berenson, some colleagues at Hutchinson,¹³⁰ and some venture capitalists.¹³¹ CellPro turned the 12.8 technology into the hematopoietic stem cell separation machines named Ceprate LC and Ceprate SC, began selling the units on a limited basis to clinics,¹³² and then received FDA approval to commercially market the units to the public.¹³³

Hopkins, Baxter, and BD approached CellPro about taking a license for the Ceprate machines because the 12.8 technology appeared to infringe the Civin Patents.¹³⁴ CellPro declined and instead instituted an apparently unsuccessful action in federal court for the Western District of Washington in 1992 for a declaratory judgment that it was not in fact infringing the Civin Patents.¹³⁵ Hopkins, Baxter, and BD (Hopkins) later sued CellPro in 1994 in federal court for the District of Delaware.¹³⁶ After a complicated proceeding, Hopkins won a judgment on June 28, 1996 for infringement.¹³⁷ The damages phase concluded on July 24, 1997, with a finding of willfulness and an award for treble damages, to the tune of approximately \$7 million.¹³⁸

But after the initial infringement finding, CellPro petitioned the NIH to exercise march-in rights based on an argument that Hopkins *et al* had either failed to bring the Civin Patents inventions to the point of practical application, or that they failed to reasonably satisfy health or safety needs.¹³⁹ Despite the scathing opinion of the district court judge that documented extremely bad faith behavior on the part of CellPro both inside and outside the courtroom—wining and dining a court deputy and flying her for a vacation to California, for example—the CellPro march-in rights petition has been used in some quarters as the shining example of a noble small company just trying to save lives while being repressed by an evil coalition of big corporations and a major university obsessed with enforcing patent rights.¹⁴⁰

129. Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1347-48 (Fed. Cir. 1998).

130. *Id.* at 1348.

131. Johns Hopkins Univ. v. CellPro, 978 F. Supp. 184, 187 (D. Del. 1997).

132. *Johns Hopkins Univ.*, 152 F.3d at 1348.

133. *Johns Hopkins Univ.*, 978 F. Supp. at 189.

134. *See* NAT'L INSTS. OF HEALTH, *supra* note 116.

135. *Johns Hopkins Univ.*, 978 F. Supp. at 195.

136. *Id.* at 184.

137. Johns Hopkins Univ. v. CellPro, 931 F. Supp. 303, 303, 328 (D. Del. 1996).

138. *Johns Hopkins Univ.*, 978 F. Supp. at 184, 193, 196.

139. *See* NAT'L INSTS. OF HEALTH, *supra* note 116. The first argument was based on section 1(a) of the Bayh-Dole march-in rights, 35 U.S.C. § 203(1)(a), while the second was based on 35 U.S.C. § 203(1)(b).

140. *See, e.g.,* CONSUMER PROJECT ON TECH., *CellPro and Bayh-Dole March-in Rights, at*

Despite an enormous amount of publicity generally favoring this “David” against the “Goliath” of Hopkins the NIH was unimpressed and found that: (1) Hopkins *et al.* was proceeding diligently with commercializing the Civin patents and (2) health and safety needs were being filled by CellPro’s current sales of the Ceprate machines. Hopkins allowed it to continue selling in a limited and monitored way under a revised injunctive order from the patent infringement proceedings, and Baxter was likely to have a suitable alternative product commercially available shortly anyway.¹⁴¹ In the end, some saw this as confirmation that the federal government, through the NIH, will never exercise march-in rights.¹⁴² But perhaps the more important message is that the NIH will seriously consider the speed of commercialization efforts, as it should, in determining whether to exercise march-in rights. Had Hopkins demonstrated no compelling story about their diligence in commercializing, and had Baxter not been able to show a near ready commercial market substitute for CellPro’s Ceprate machines and technology, then the NIH may well have required Hopkins to grant a license to CellPro, or stepped in and granted it itself if Hopkins did not comply.¹⁴³

2. Essential Inventions, Inc. and Abbott Laboratories

If the CellPro march-in petition was a test of commercialization diligence, then the next formal petition, involving the patents behind Abbott Laboratories’ (Abbott) Norvir AIDS drug, was a test of Bayh-Dole and march-in rights as price or profit regulation. It is interesting to note that while the NIH addressed the CellPro petition as just that (“In the Case of Petition of CellPro, Inc.”), it did not even mention the prime movant of the Abbott petition by name anywhere in its official determination report. That report is simply titled “In the Case of Norvir Manufactured by Abbott Laboratories, Inc.”¹⁴⁴ But Essential Inventions, Inc., an affiliate of the

<http://www.cptech.org/p/cellpro> (last visited Feb. 7, 2005). The Consumer Project on Technology was created by Ralph Nader in 1995 and was the prime force behind the later Essential Inventions petition for march-in rights against Abbott Laboratories discussed below.

141. See NAT’L INSTS. OF HEALTH, *supra* note 116.

142. See, e.g., David Halperin, *The Bayh-Dole Act and March-In Rights* (May 2001), available at <http://ott.od.nih.gov/meeting/david-halperin-attorney-counselor.pdf>.

¹⁴³ Of course, Hopkins had already offered a license to CellPro, for which it was rewarded with a declaratory judgment action. Thus, a second question, picked up in the Essential Inventions petition described below, is whether a potential licensee can use march-in rights to obtain more favorable licensing terms that it would otherwise get in the marketplace from the patent owner.

144. NAT’L INSTS. OF HEALTH, *In the Case of Norvir, Manufactured by Abbot Laboratories, Inc.*, at <http://ott.od.nih.gov/Reports/March-in-norvir.pdf> (July 29,

Consumer Project on Technology that was created by Ralph Nader, was the formal petitioner that requested that NIH exercise march-in rights on the Norvir patents based solely on a dramatic price increase by Abbott midway through the patent term.¹⁴⁵ In response, NIH solicited public comments and held a day of hearings on May 25, 2004.¹⁴⁶ Essential Inventions, Inc. also prompted legislators such as Senator Clinton of New York to submit letters requesting that NIH exercise march-in rights on the Abbott patents.¹⁴⁷

The crux of the Essential Inventions, Inc. arguments, as espoused by James Love, that organization's leader, is that the march-in rights of Bayh-Dole are as much about price regulation and the prevention of "unreasonable use" of Bayh-Dole covered patents, as about simple non-use or failure to commercialize the patent.¹⁴⁸ But the origin of Love's argument is actually a controversial article in the *Tulane Law Review* by Professors Arno and Davis entitled *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*.¹⁴⁹ This piece purports to exhaustively research the legislative history of Bayh-Dole, only to "discover" that the law's drafters wisely incorporated price control provisions—through the march-in rights provisions—that somehow the entire tech transfer community forgot about or never realized were in there. The authors then followed the article up with an op-ed in the *Washington Post* entitled *Paying Twice for the Same Drugs*¹⁵⁰ that successfully brought their arguments to a wider audience.

That broader audience included Senators Birch Bayh and Bob Dole, who were incensed by what they saw as an attempt to "rewrite history."¹⁵¹ They quickly responded with their own piece in the *Washington Post*

2004).

145. ESSENTIAL INVENTIONS, INC., *Petition to use Authority Under Bayh-Dole Act to Promote Access to Ritonavir, Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220*, at <http://www.essentialinventions.org/legal/norvir/norvir-29Jan04petition.pdf> (Jan. 29, 2004).

146. Notice of Public Meeting, 69 Fed. Reg. 23,210 (Apr. 28, 2004).

147. Letter from Eight U.S. Senators, to Elias A. Zerhouni, Director, National Institutes of Health (May 11, 2004), available at <http://www.essentialinventions.org/legal/norvir/8senators2nih.pdf>.

148. ESSENTIAL INVENTIONS, INC., *supra* note 145.

149. *Id.*; see also Arno & Davis, *supra* note 80.

150. Peter S. Arno & Michael Davis, *Paying Twice for the Same Drugs*, WASH. POST, Mar. 27, 2002, at A21.

151. Statement of Senator Birch Bayh to the National Institutes of Health (May 25, 2004), available at <http://ott.od.nih.gov/meeting/senator-birch-bayh.pdf>.

directly contradicting Arno and Davis' claims as to the former's intentions in sponsoring Bayh-Dole.¹⁵² Senator Bayh later described the series of events—and the mistakes at the root of them—in his testimony at the NIH march-in hearings for Abbott's Norvir patents (where he was confronted by more of the same revisionist history):

It was first brought to my attention that attempts were underway to rewrite history when I saw an article in the Washington Post on March 27, 2002, entitled *Paying Twice for the Same Drugs*. The crux of the article was that:

Bayh-Dole ... states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price. If it is not, then the government can insist that the drug be licensed to more reasonable manufacturers, and if refused, license it to third parties that will make the drug available at a reasonable cost.

This view mistakes how our law works. Bob Dole and I responded in a letter to the editor of the Washington Post on April 11, 2002 setting the record straight.

You can imagine my surprise when I see the same arguments were being formally presented in a petition to NIH in an attempt to control drug prices. The quotations in the petition flagrantly misrepresent the legislative history supporting Bayh-Dole. The petition shows complete lack of understanding of how the legislative process works. The current petition says: "The clear language of the Bayh-Dole act requires reasonable pricing of government supported inventions." It later adds: "The legislative history evidences an intent to require that government supported inventions be priced reasonably."

All but one of the citations in the petition used to conclude that march-in rights were intended to control prices actually refer to hearings on bills other than Bayh-Dole. While perhaps interesting, these are not pertinent legislative history.¹⁵³

Senator Bayh is correct. Computerized legal research tools such as LEXIS generate a long and broad list of "legislative history" for Bayh-Dole, but do not clearly delineate that much of the list's contents are either much earlier bills that were never passed, or competing bills in the

152. Birch Bayh & Robert Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASH. POST, Apr. 11, 2002, at A28.

153. Senator Birch Bayh, *supra* note 151.

Congress at the same time as Bayh-Dole.¹⁵⁴ Professor Rebecca Eisenberg accurately documents a bit of this history in an article in the *Virginia Law Review* when she contrasts the proposed tech transfer bill submitted to Congress by the Carter Administration with that of Senators Birch Bayh and Bob Dole.¹⁵⁵ Interestingly, Arno and Davis cite some of the early parts of Professor Eisenberg's article, but then ignore the bulk of it that clearly undercuts many of their historical arguments.

Senator Bayh further documents examples in which the Essential Inventions, Inc. petition, again based on the Arno and Davis article, actually takes snippets of statements being made in testimony for entirely different bills and then splices them together, with the claim that such statements were made at the hearings for Bayh-Dole itself.¹⁵⁶ It is hard to deny Senator Bayh's claims—particularly if you look to the legislative history that he cites—and yet, if true, these are very disturbing allegations. Additional support for Senator Bayh's statements as to the true intent and meaning of his own bill is given by direct testimony from Norman Latker, one of the actual drafters of Bayh-Dole,¹⁵⁷ and indirect endorsement of the Bayh/Dole/Latker position by Howard Bremer, another key player in the development of Bayh-Dole, through the statement submitted by Mr. Bremer's longtime employer, the Wisconsin Alumni Research Foundation (WARF).¹⁵⁸

In the end, while few people are pleased with Abbott's decision to dramatically increase the price of Norvir, the NIH was persuaded that Abbott has indeed fulfilled its commercialization requirements under Bayh-Dole and so an exercise of march-in rights is not warranted.¹⁵⁹ But, as Bayh-Dole supporters such as Norman Latker point out, there are other avenues, such as antitrust law, that should be, and are being, pursued with relation to Abbott's actions in the marketplace.¹⁶⁰ What is instructive, however, is how far Essential Inventions, Inc. was able to take its campaign, including the successful corralling of influential legislators such

154. See Sean M. O'Connor, *The Evolution of Government Research Patent Policy: Putting Bayh-Dole into the Proper Context* (working paper on file with author).

155. Eisenberg, *supra* note 80, at 1695-96.

156. Statement of Senator Birch Bayh, *supra* note 151.

157. See Statement of Norman J. Latker, Before NIH On Essential Inventions Petition Regarding Norvir, National Institutes of Health, Hearings on Ritonavir (May 25, 2004), at <http://www.ott.od.nih.gov/meeting/norman-j-latker.pdf>.

158. See Letter from Carl E. Gulbrandsen, Managing Director, Wisconsin Alumni Research Foundation, to Dr. Mark Rohrbaugh, Director of the Office of Technology Transfer, Office of Intramural Research, National Institutes of Health (April 15, 2004), at <http://ott.od.nih.gov/meeting/carl-e-gulbrandsen.pdf>.

159. See NAT'L INSTS. OF HEALTH, *supra* note 144.

160. See Statement of Norman J. Latker, *supra* note 157.

as Senator Clinton who may not really have understood what was going on. But when positioned as a battle between a greedy corporation and a charitable non-profit simply trying to look out for indigent individuals who are dying from AIDS, the issue seems to become quite clear cut for those who want to show that they are fighting for the little guy and against Big Pharma.

D. The Need for a Comprehensive Framework for IP Rights Allocation in Stem Cell Funding Agreements.

The foregoing sections amply demonstrate the conflicting ownership and control issues involved when valuable research results arise from projects with multiple funding sources. No less important today than the claims of the normally recognized parties – the research institution, government funding agency, and commercializing entity – is the newly empowered claim of the public itself to free or sharply discounted access to final commercialized products that trace their IP lineage back to publicly funded research. The question now is how to allocate the IP rights in relation to those claims.

One way *not* to do it is through *ex post* negotiations, agency proceedings, or litigation. These methods are unpredictable, expensive, time consuming and, worst of all, often deeply unsatisfying for the parties involved. Instead, funding parties, researchers, and their institutions need to begin—or strengthen as appropriate—efforts to carefully allocate IP rights in advance of the funding and performance of any research. Further, the tradition of largely relying on the framework of Bayh-Dole may prove less effective, and perhaps be downright dangerous, in the new world of hPSC research that will likely derive the majority of its funding from non-federal sources.

But this suggests a partial solution: state and local initiatives like Proposition 71 should explicitly incorporate the Bayh-Dole rights allocation framework, including inter-governmental coordinating mechanisms for patents arising from research that relied on combinations of federal, state, and local funding. Of course, this would remove the ability of state and local governments to directly recoup their funding “investments” through royalty streams, such as California is apparently relying on. But I am skeptical as to how much California should be counting on these revenue streams under the actual Proposition 71 anyway. The foregoing proposal also does nothing to remove potential conflicts over IP rights with private funding arrangements. However, the provisions of Bayh-Dole already seem to contemplate their supremacy over private

arrangements.¹⁶¹ State and local funding legislation could take a similar tack. This could have the potential to chill private funding, but, at the same time, the existence of Bayh-Dole itself does not seem to have had a substantial negative impact on such funding.

Finally, a central premise of this Article is that the problems sketched in the foregoing sections will be exacerbated proportional to the urgency and vitality of the hPSC therapy that results from any research program. Given the astounding claims for hPSC work, one can expect astounding conflicts and claims for any such research that actually bears fruit. But at the same time, contractual agreements that are put into place, and settled expectations of both the research and investment communities, need to be respected so as not to create an upheaval that might destroy the highly productive pipeline of American life sciences innovation. Thus, the final Part of this Article will suggest that federal and state governments should defer to such contractual IP rights allocation, provided that it complies with the inter-governmental framework proposed above, unless a compelling public health crisis threatens the general population.

IV. REQUIRING A PUBLIC HEALTH CRISIS TO TRIGGER GOVERNMENT DISTRIBUTION OF PROPRIETARY THERAPIES

As outlined above, and discussed in more detail in another paper of mine, the notion that Bayh-Dole establishes a pricing or profit regulation mechanism is simply false. Thus, in the normal course of events, the marketplace should be allowed to take care of the exact commercialization, distribution and pricing mechanisms for life sciences products, including hPSC derived therapies. But what about broad public health crises that affect the general population? For example, what if anthrax or other bioterror attacks were unleashed again in the United States, but this time on a wider scale?

Clearly, many citizens would quickly look to the government to supply the necessary vaccines or antidotes, or at least guarantee that such medicines were made available. But would this require the exercise of march-in rights or a straightforward, but totally disfavored, compulsory license? Actually, it would not necessarily require any of these. Instead, the federal and state governments already have some *de facto* compulsory license powers available to them, even without relying on Bayh-Dole march-in rights.

First, where any part of the invention that led to the vaccine or

¹⁶¹ For example, any patent arising from a (partially) federally funded subject invention must contain “a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.” 35 U.S.C. § 202(c)(6).

antidote was federally funded, the government has a non-exclusive license to practice, or have practiced on its behalf, the technology for government purposes.¹⁶² This is not a march-in right, because it is not about granting a license to a private contractor/licensee's competitor to compete with the contractor/licensee in the marketplace. Thus, it is not like taking a pioneer drug that is still on patent and suddenly licensing generic drug manufacturers to take a competing generic version to market. Instead, the government non-exclusive license under Bayh-Dole simply means that if the government needs to provide the product developed under the patented technology to government employees or presumably even the public as a government service, then it can do so with no further notice to, or requests on, the patent owner.

Second, the federal government has long had an ability to authorize private contractors to practice patented technology owned by other private parties, so long as such use is on behalf of the government as it provides government services.¹⁶³ Under 28 U.S.C. § 1498(a):

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.¹⁶⁴

This clause originated from the early twentieth century when the federal government was facing a shortage of private sector military contractors because they feared being sued by other patent owners for work done even under military contracts.¹⁶⁵ Essentially, this provision removed that potential liability—even though contractors may still be required to raise it as an affirmative defense in patent infringement litigation.¹⁶⁶ In this way, it does not completely remove the burden from the contractor of

162. See *supra* Part II.

163. See Carly M.M. Chan, 28 U.S.C. § 1498(a) as an Affirmative Defense to Patent Infringement by Universities: Why *Duke v. Madey* May Be a University Researcher's Best Friend (working paper on file with author); DONALD S. CHISUM, 5 CHISUM ON PATENTS § 16.03[3][f] (2004). Of course, the government can practice any patented technology directly under an eminent domain theory. See *Crozier v. Fried. Krupp Aktiengesellschaft*, 224 U.S. 290, 308 (1912). But it may not be in the position to manufacture and distribute a good or service normally provided by the private sector. Thus, it will need to authorize private sector entities to perform these functions under contract on behalf of the government.

164. 28 U.S.C. § 1498(a) (2000).

165. See Chan, *supra* note 163.

166. *Id.*

threatened or filed infringement suits. But the practice of issuing so-called “authorization or consent” letters or other documentation to contractors has its roots in the definition of “use or manufacture [by or] for the United States”:

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.¹⁶⁷

Essentially, § 1498(a) is a type of formalized takings provision. The federal government can exercise its power of eminent domain to take a license for government purposes where none was granted. But, again, like the mandatory nonexclusive license that encumbers Bayh-Dole governed patents, the government may only authorize use by or on its behalf—in other words, for use of the patented good or service in the government’s performance of its governmental functions.

The original focus of this provision, as mentioned above, was to facilitate the government’s core function of national defense. But the clause does not seem to be limited solely to military related patent infringements. Rather, the test seems to be whether the use is in “work of vital importance to the government.”¹⁶⁸ Such work has included federally funded university basic science research, albeit where such work was still of “special interest to the United States Navy.”¹⁶⁹ Nonetheless, major treatises and casebooks on patent law appear to treat the clause as operating generally, and not as restricted to military functions of the government.¹⁷⁰

Third, state governments enjoy sovereign immunity under the Eleventh Amendment, which has been claimed to extend to state immunity from patent infringement suits.¹⁷¹ In 1992, Congress attempted to abrogate this right through the Patent and Plant Variety Protection Remedy Clarification Act, but the Supreme Court ultimately found this law unconstitutional.¹⁷² There have been other bills introduced to reduce state immunity from patent infringement, including one that would have required states to waive such immunity before pursuing their own patent

¹⁶⁷ 28 U.S.C. § 1498(a).

¹⁶⁸ *John J. McMullen Associates, Inc. v. State Board of Higher Education*, 406 F.2d 497, 498 (9th Cir., 1969), *cert. denied*, 89 S.Ct. 2016 (1969).

¹⁶⁹ *Id.*

¹⁷⁰ *See, e.g., CHISUM, supra* Note 166.

¹⁷¹ *See Florida Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 635, 647 (1999).

¹⁷² *See id.* at 627.

infringement claims against any private party. But to date, no such legislation has been successful. Accordingly, states are relatively free to practice the patented technology of private parties for state purposes. It is less clear whether they have anything like the authorization and consent power of the federal government under 28 U.S.C. § 1498(a).

The common thread in all three of these scenarios is that the particular government entity has to provide the patented goods or services as a public service or benefit. Accordingly, without exercising march-in rights under Bayh-Dole—and thus being limited to federally-funded inventions in the first place—the federal government may not authorize a new competitor in the commercial marketplace vis á vis forcibly granting license rights. State governments appear to be similarly restricted. Further, at present, even the exercise of march-in rights is seen as a draconian measure with uncertain market ramifications. Thus, it may continue to be limited to its *in terrorem* power. But, if the governmental entity instead views the infringement of private patent rights as a necessary component in its performance of governmental functions, then different immediately-actionable avenues open up.

So what justifies a governmental entity to provide a good or service that is—or can be—supplied by the private sector? One test would be that the work is of “vital importance to the government” at described above. But, this may be a more restrictive test than is required for purposes of the Bayh-Dole non-exclusive government license or state sovereign immunity. However, even if we used the more stringent “vital importance” test, then one could imagine various scenarios that might satisfy it. For example, federal or state public health officials could determine that it is vitally important to the government that crucial threshold health services be provided by the government at low or no cost to low-income or impoverished citizens. It could also mean that it is of vital importance to the government to confront a widespread health crisis or epidemic in a comprehensive and rapid manner.

In contrast, the Abbott march-in rights petition was based largely on price; however the remedy available under the exercise of march-in rights would not have been government provision of Norvir at low or no cost, but rather simply a license to another private sector entity, “upon terms that are reasonable under the circumstances”,¹⁷³ so that the latter could then bring the Norvir to market. Some evidence was then brought to bear that a competitor acting under a march-in rights compulsory license would provide Norvir to the market at a cheaper price; and certainly our experience with generic drug manufacturers tells us that enabling competing, nonproprietary players will keep prices down. But will the

¹⁷³ 35 U.S.C. § 203(1).

prices decrease enough to really address the problems of, say, indigent AIDS victims without health insurance, who may not be able to pay much if anything for medications? One could argue that we are just trying to get the price down low enough so that some patients could afford it, while the rest would hopefully be supplied by non-profits or foundations that could afford to cover the reduced-cost medicines.

But why not instead avoid all of the uncertainties of a march-in process, not the least of which is that, again, it does not appear that march-in rights can be exercised simply for price control reasons. Rather, if the public health need is of vital importance to the government, as it may well be in the AIDS context, then federal and state governments could provide the medicines as a public health service. Further, the more dire the public health threat, measured either by the intensity of victims' suffering, the breadth across the general population such as a pandemic, or the degree to which the therapy is crucial or life saving, such as is predicted for hPSC therapies, then the easier it is to make the argument that it is of vital importance to the government to provide these services.

Would the "vital importance" test be subject to abuse, such that any number of patent infringing activities be authorized by the government even to the extent of undermining the effectiveness of the patent system? Possibly, but there are other limiting factors that would balance any liberal trend in this regard. First, under the authorization and consent government services model, the government is restricted by both its own limited manufacturing and distribution capabilities as well as its ability to pay private contractors to perform these services on its behalf. In other words, just because the government may be able to have the patent practiced for "free"¹⁷⁴, it must still pay the substantial manufacturing and distribution costs to deliver the services. Second, state governments would have similar limitations, even under sovereign immunity patent infringement powers. Third, any drastic expansion of government services at either the federal or state level will require political authorization that may be hard to come by.

In conclusion, the current patchwork, hit-or-miss IP rights allocation system in stem cell research will lead to a nightmare of litigation proportional to the very success of the most ambitious projections for stem cell therapies. Further, until a future presidential administration relaxes the current limitations on federal funding of hPSC research, the stem cell therapy environment will suffer a reduced ability of the standard Bayh-Dole IP rights allocation framework to govern, as it will formally apply to a smaller subset of patents arising in the field. At the same time, non-

¹⁷⁴ This may be a mischaracterization because at least for the federal government under 28 U.S.C. § 1498 it may be liable to pay reasonable royalties for it unauthorized "taking" of the patent license.

traditional funding and IP rights allocation systems, such as Proposition 71 may come to dominate the field, creating a tangle of ownership claims.

Thus, the first step is to demand that any state or local stem cell funding legislation approximate the model of the inter-governmental coordination framework sketched in Part III(D) above. The second step is to largely abandon the notion that the solution to the severe lack of availability or access problems lies in march-in rights, or any corollary that might be created in state or local funding agreements. Instead, the Bayh-Dole type mandatory non-exclusive license for government use incorporated in the inter-governmental coordination framework legislation would be the primary vehicle for government provision of patent infringing services. However, where such legislation is not forthcoming, then an alternative proposal is for state and local funding entities to incorporate analogous provisions directly into any and all stem cell funding agreements. Essentially, this would call on state and local government agencies to self-regulate their funding activities such that an inter-governmental coordination framework could still be substantially achieved.

Two provisions would then be added under either alternative. First, guidelines would be created as to what constitutes work or services of "vital importance" to the relevant government in which proprietary stem cell therapy could or should be provided directly to the public as a government health service. Creating such guidelines would also have the virtue of preventing the destruction of the private sector life sciences innovation market, as it would act as a limiter or governor on the otherwise unchecked temptation to commandeer all valuable proprietary life sciences research. Second, a recoupment clause, such as was originally included in Bayh-Dole before being dropped prior to final enactment, would be required. This clause would operate as a minimal royalty, payable on revenues (or perhaps only profits) only until the governmental entity had recouped its original funding investment. It could possibly include an interest component such that even the most concerned citizen could be comfortable that no one would receive a free ride.

If all of these could be accomplished in a coordinated framework, the result would be a system largely free of the specter that the public is "paying twice" for publicly-funded inventions, even while greater certainty for all market participants would be achieved. These two benefits would lead to further benefits. The former could lead to even greater public financing of research projects because the taxpaying public could more clearly see where its money is going and how it will be returned. The latter benefit should lead to increased private sector investment, both because the primary concern of having to give a license to your arch competitor, as under Bayh-Dole march-in rights, would be largely eliminated, and because greater certainty in the investment environment almost always draws more

investment because the risks are more easily calculated. Hopefully, 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.