

**HOW WILL CALIFORNIA'S FUNDING OF STEM CELL
RESEARCH IMPACT INNOVATION?
RECOMMENDATIONS FOR AN INTELLECTUAL PROPERTY
POLICY**

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I. INTRODUCTION

Before 1980, all intellectual property resulting from federally funded research belonged to the federal government and was dedicated to the public domain. Congress passed the Bayh-Dole Act in 1980, permitting universities and other federally funded institutions to patent and profit from inventions arising from federally funded research.¹ Since its institution, the Bayh-Dole Act has been the subject of much commentary, both positive and negative. Proponents say it gives universities and researchers a financial incentive for useful innovation, and it induces universities to find a productive use for re-

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1. Bayh-Dole Act, Pub. L. No. 96-517 (1980) (codified as amended at 35 U.S.C. §§ 200-211 (2002)).

search that might otherwise go unused.² Critics say it promotes secrecy within academia because researchers compete to be the first to patent, creates conflicts of interest between profit and academic integrity, and allows for corporate influence over academic research.³ Some studies show that Bayh-Dole has increased useful innovation, while others show a negative impact on technology development.⁴ The controversy rages on, even after twenty-four years.

On November 2, 2004, the residents of California voted to enact Proposition 71, the California Stem Cell Research and Cures Initiative,⁵ by a large 59–41 percent margin.⁶ This initiative promises to devote \$295 million per year for the next ten years, a total of almost \$3 billion, to funding stem cell research. As funding for Proposition 71 does not come from the federal government, it is not subject to the provisions of the Bayh-Dole Act. The State of California intends to help fund this research through revenue generated from intellectual property resulting from the research. The law states that the initiative will

[p]rotect and benefit the California budget: by postponing general fund payments on the bonds for the first five years; by funding scientific and medical research that will significantly reduce state health care costs in the future; and by providing an opportunity for the state to benefit from royalties, patents, and licensing fees that result from the research.⁷

This Note will compare Proposition 71 with the Bayh-Dole Act and then will recommend some guidelines for the ownership and control of intellectual property resulting from state-funded stem cell research. Based on the lessons learned from Bayh-Dole's successes and failures, the State of California can maximize innovation and productivity without wasting taxpayers' money.

2. See, e.g., WENDY H. SCHACHT, CONG. RESEARCH SERV., PATENT OWNERSHIP AND FEDERAL RESEARCH AND DEVELOPMENT (R&D): A DISCUSSION ON THE BAYH-DOLE ACT AND THE STEVENSON-WYDLER ACT, at <http://www.ncseonline.org/nle/crsreports/science/st-66.cfm> (updated Dec. 11, 2000).

3. See Risa L. Lieberwitz, *The Marketing of Higher Education: The Price of the University's Soul*, 89 CORNELL L. REV. 763, 772 (2004).

4. See, e.g., U.S. GEN. ACCOUNTING OFFICE, TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES, at <http://www.gao.gov/archive/1998/rc98126.pdf> (May 1998) [hereinafter GAO REPORT]; Lieberwitz, *supra* note 3, at 771–73.

5. The California Stem Cell Research and Cures Initiative (Proposition 71), 2004 *Cal. Legis. Serv. Prop. 71* (West) (enacted).

6. John M. Broder, *California's New Stem-Cell Initiative Is Already Raising Concerns*, N.Y. TIMES, Nov. 27, 2004, at A10.

7. Proposition 71, *supra* note 5, § 3.

II. BACKGROUND

A patent gives its owner the right to a monopoly over her invention, for a limited time, by allowing her “to exclude others from making, using, offering for sale, or selling” her invention.⁸ While the U.S. government generally discourages monopolies because they facilitate price-fixing and other anti-competitive practices, patents are economically useful because they create incentives for inventors to innovate, disclose, and commercialize their discoveries.⁹

Without a patent system, an inventor could never recoup the costs of research and development. The inventor would put time and effort into developing an idea into a product and then would sell that product for a price that accounts for development costs. Without patent protection, an imitator could mimic the inventor’s design and sell an identical product at just above marginal cost, a much lower price that the inventor would have to meet to remain competitive. The problem is exacerbated in fields with particularly high research and development costs and low marginal costs, such as the biotechnology and pharmaceutical industries.¹⁰ By granting a monopoly for a limited time, patents allow inventors to recoup their research and development costs when they sell their product. Without patents, there would be fewer incentives to pursue useful innovations with high development and low production costs.

The patent statute requires inventors to disclose details about their inventions to receive a patent.¹¹ These details must enable readers to recreate the patented invention, as well as discern its “best mode.”¹² Incentivizing disclosure is important because, without a system that requires disclosure, information is easily kept private, preventing others from making further innovations based on previous inventions. Disclosure avoids costly duplication of previous research.¹³

Finally, patents create an important incentive to commercialize discoveries. Without a patent system, many potentially useful ideas would be lost because commercializing them would be too costly. Inventors would not bring products to market because of the great

8. 35 U.S.C. § 154 (2000).

9. See generally ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT* 37–39 (2004).

10. See Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 185, 247–49 (1999).

11. 35 U.S.C. § 112 (2000).

12. *Id.*

13. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 621 (Fed. Cir. 2000) (Linn, J., concurring in part and dissenting in part) (“[D]isclosures will stimulate others to add to the sum of human knowledge through the creation of other inventions utilizing the lessons learned by the patentee.”), *vacated by* 535 U.S. 722 (2002).

uncertainty that they could ever reap economic benefits. With a patent, however, inventors can build the cost of commercialization into the price of the product, and competitors cannot undercut that price. Patentees will not over-inflate prices because an exorbitant price will drive away potential consumers, diminishing profits. By allowing patentees to profit from their inventions, the patent system rewards them for the value their inventions provide to the public.¹⁴

Of course, a patent system also has inherent drawbacks. It promotes secrecy about research before a patent is filed. Multiple parties may try to compete for a patent and thus will hesitate to collaborate and share information. It also creates impediments to cumulative innovation. An inventor who has incorporated a previously patented technology into her own invention has to cross-license with the earlier patentee in order to legally use the earlier technology. The risks and transaction costs of cross-licensing deter innovation.¹⁵ By creating the incentive to invent around existing technology to avoid cross-licensing, a patent system can lead to duplicative, wasteful research.¹⁶

Alternatives to a patent system have been proposed and implemented in limited realms. Proposed alternatives include legal reinforcement of self-help strategies, government provision of certain technological innovations, government selection and subsidization of private innovators, and government-established prizes as a reward for innovation.¹⁷ In the United States, legal protection of trade secrets allows inventors to protect their information by simply keeping it to themselves. In the cases of NASA and the National Institutes of Health (“NIH”), the government itself conducts research and development. The NIH also provides funding to non-governmental researchers to perform specific research. Finally, various types of prize

14. See JAFFE & LERNER, *supra* note 9, at 8.

15. See generally Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in 1 INNOVATION POLICY AND THE ECONOMY 119 (Adam B. Jaffe et al. eds., 2001).

16. See Simon Genevaz, *Against Immunity for Unilateral Refusals to Deal in Intellectual Property: Why Antitrust Law Should Not Distinguish Between IP and Other Property Rights*, 19 BERKELEY TECH. L.J. 741, 748 (2004).

17. See generally WILLIAM W. FISHER, PROMISES TO KEEP: TECHNOLOGY, LAW, AND THE FUTURE OF ENTERTAINMENT (2004); Steve P. Calandrillo, *An Economic Analysis of Property Rights in Information: Justifications and Problems of Exclusive Rights, Incentives to Generate Information, and the Alternative of a Government-Run Reward System*, 9 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 301 (1998); R.H. Coase, *The Lighthouse in Economics*, 17 J.L. & ECON. 357 (1974); Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, in 2 INNOVATION POLICY AND THE ECONOMY 51 (Adam B. Jaffe et al. eds., 2002); Neil Weinstock Netanel, *Impose a Non-commercial Use Levy to Allow Free Peer-to-Peer File Sharing*, 17 HARV. J.L. & TECH. 1 (2003); Michael Polanvyi, *Patent Reform*, 11 REV. ECON. STUDIES 61 (1944); Stefan A. Riesenfeld, *Patent Protection and Atomic Energy Legislation*, 46 CAL. L. REV. 40 (1958); Pamela Samuelson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 YALE L.J. 1575 (2002); David E. Van Zandt, *The Lessons of the Lighthouse: “Government” or “Private” Provision of Goods*, 22 J. LEGAL STUDIES 47 (1993).

systems have been proposed and implemented, including NASA's plan to mimic the privately funded \$10 million X Prize.¹⁸

Before the Bayh-Dole Act was passed in 1980, federal funding to universities resembled a system of government selection and subsidization of private innovators. Researchers received federal money either through allocation by the university or based on the individual research proposal. The intellectual property resulting from such federally funded research then belonged to the federal government, who usually dedicated it to the public domain, and granted nonexclusive licenses for its use.¹⁹ Because no private company could be assured that it would recover commercialization costs, much possible technology presumably never materialized.

III. THE BAYH-DOLE ACT

Concerned about the United States' failure to maximize its potential for innovation, Senators Birch Bayh and Robert Dole sought to create more incentives for federally funded researchers to commercialize their discoveries.²⁰ Passed in 1980, the Bayh-Dole Act allows universities and other federally funded institutions to patent inventions resulting from federally funded research. As stated in the law:

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and pro-

18. See Robert Roy Britt, *NASA Mulls Offering Its Own Cash Prizes*, MSNBC NEWS (June 23, 2004), at <http://www.msnbc.msn.com/id/5271859>.

19. Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1663 (1996).

20. See Scott D. Locke, *Patent Litigation over Federally Funded Inventions and the Consequences of Failing to Comply with Bayh-Dole*, 8 VA. J.L. & TECH. 3, § II.A (2003), at http://www.vjolt.net/vol8/issue1/v8i1_a03-Locke.pdf.

tect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.²¹

In order to serve the public interest, the Bayh-Dole Act contains a few notable exceptions to inventor control. First, the government is allowed to take the intellectual property under “exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter.”²² Second, the government retains “a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.”²³ Finally, the government retains “march-in rights” requiring that the owner of title or of an exclusive license “grant a nonexclusive, partially exclusive, or exclusive license” with due compensation if the invention has not been commercialized within the agreed-upon time frame or if the “action is necessary to alleviate health or safety needs.”²⁴

Bayh-Dole also contains a number of recommendations for universities patenting and licensing federally funded innovations. Universities are supposed to give priority to small businesses in granting licenses.²⁵ According to a 1998 report from the General Accounting Office (“GAO”), however, this request has not been enforced.²⁶ Universities are also expected to ensure that their inventions are “manufactured substantially” in the United States.²⁷ Finally, universities are required to share some of the royalties with the inventor, although there is no requirement as to how much should be shared.²⁸

A. Has Bayh-Dole Sparked Innovation?

Since its inception, there has been much debate over the relative merits and drawbacks of Bayh-Dole.²⁹ Proponents of the Bayh-Dole Act say it gives universities and researchers a financial incentive to

21. 35 U.S.C. § 200 (2000).

22. 35 U.S.C. § 202 (2000).

23. *Id.*

24. 35 U.S.C. § 203 (2000).

25. 35 U.S.C. § 209 (2000).

26. GAO REPORT, *supra* note 4, at 13.

27. 35 U.S.C. § 204 (2000).

28. 35 U.S.C. § 202 (2000).

29. The mechanics of Bayh-Dole have been operating successfully. According to the 1998 GAO Report, the ten universities GAO studied have successfully established invention programs to implement Bayh-Dole and have designated units and personnel to oversee the activities involving inventions. “They also had set out policies and procedures to ensure that their programs were complying with the act’s reporting requirements, that they were pursuing licensing opportunities to the extent possible, and that royalties were being shared with those responsible for the inventions.” GAO REPORT, *supra* note 4, at 9.

pursue research that translates into useful inventions.³⁰ In 1998, GAO visited ten universities that received over 28 percent of the total direct science and engineering research funding awarded to universities in fiscal year 1995.³¹ Officials at these universities “believed the Bayh-Dole Act was accomplishing its objectives.”³² University officials thought the public was benefiting from Bayh-Dole “because more government-funded technology was being brought to those who could make use of it.”³³ For instance, researchers at the University of Wisconsin developed a method to extend the time an organ can be held outside the body prior to transplant, and they believe that the Bayh-Dole Act facilitated bringing this invention to market.³⁴ Similarly, researchers at the University of Washington indicated that Bayh-Dole played a positive role in their development of a Hepatitis B vaccine.³⁵ Statistics compiled by the Association of University Technology Managers (“AUTM”) in 1998 show that the number of licenses and revenues from licenses by universities grew since the implementation of Bayh-Dole.³⁶

Patents filed by universities since 1980 have been the subject of many empirical studies.³⁷ These studies have shown that university patenting and licensing have grown significantly since the passage of Bayh-Dole,³⁸ but some commentators question the quality of these patents and their utility to society. According to one study, the overall importance of patents in the United States has gone down.³⁹ Another study, however, found no such decline.⁴⁰ In one article analyzing a number of studies of university patents, Mowery and his coauthors concluded that Bayh-Dole has not reduced the overall quality of intellectual property coming out of research universities, but also expressed uncertainty about whether “changes in the academic research culture may be occurring gradually and could eventually be revealed in declines in these measures of academic patents’ importance.”⁴¹

On a theoretical level, Shavell and van Ypersele conclude that “intellectual property rights do not possess a fundamental social ad-

30. See SCHACHT, *supra* note 2.

31. GAO REPORT, *supra* note 4, at 10.

32. *Id.* at 15.

33. *Id.*

34. *Id.* at 18.

35. *Id.*

36. *Id.* at 15.

37. Such studies include those by Henderson et al. (1998), Trajtenberg et al. (1997), Mowery et al. (2001), and Mowery & Ziedonis (2002). See David C. Mowery et al., *Learning to Patent: Institutional Experience, Learning, and the Characteristics of U.S. University Patents After the Bayh-Dole Act, 1981–1992*, 48 MGMT. SCI. 73, 73 (2002).

38. See, e.g., AUTM LICENSING SURVEY: FY 2002 § 6.0, at <http://www.ipal.de/cmsupload/2002%20Licensing%20Survey%20Summary.pdf> (last visited Apr. 11, 2005).

39. Mowery, *supra* note 37, at 73.

40. *Id.*

41. *Id.* at 88.

vantage over reward systems.”⁴² They also find that a policy “in which an innovator obtains a patent and is also given a reward . . . is superior to patent, because the problem of underinvestment is alleviated by payment of a reward.”⁴³ In a sense, university research after Bayh-Dole is such a system. While federal funding for research is generally given prior to commencement of research, a researcher’s previous findings have a strong effect on her ability to procure more funding, meaning that future funding is essentially a reward for having successfully completed past projects. According to Shavell and van Ypersele, this combination of rewards and patents fosters innovation more successfully than a pure patent system.⁴⁴

Overall, the majority of sources conclude that Bayh-Dole has sparked innovation, although many argue over whether it will have beneficial effects long-term and whether it is worth the extra cost.

B. Do the Economic Costs Outweigh the Benefits?

Of course, innovation comes at a price. The American taxpayer supports academic research through the federal government, and, since Bayh-Dole, the intellectual property arising from that research is no longer in the public domain. Many consider this system a double tax on the public — Americans pay once for research in tax dollars and then again in the form of higher prices for patented inventions.⁴⁵ On the other hand, before Bayh-Dole, government-owned intellectual property that resulted from federally funded research was rarely licensed or used productively because commercial developers could only obtain nonexclusive licenses. Without the ability to restrict others from using the same technology, developers had no financial incentive to spend money on development, knowing that any other developer could then take advantage of their investment and sell the same product at a low price. If potentially productive research would otherwise remain undeveloped because of the pitfalls of developing products in the public domain, then the double tax of the Bayh-Dole Act could be a better solution than allowing the initial research funding to go to waste. Americans may be better off seeing the benefit of innovation, even if it means having to pay a premium for it.

A second problem with Bayh-Dole is that it promotes secrecy within academia, which could ultimately hurt scientific research and result in fewer useful innovations. In order to receive a patent, a researcher must not publicly disclose the innovation more than a year

42. Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525, 525 (2001).

43. *Id.* at 541.

44. *Id.*

45. Lieberwitz, *supra* note 3, at 782.

before filing.⁴⁶ Publication even within a research community is considered public disclosure, so academics must curtail publication in order to comply with the rules of the patent system. Academics also have an incentive to keep their findings secret in order to win the race to patent. Knowing that others are doing similar research, a researcher may try to hoard findings to prevent another from patenting first.⁴⁷ Failure to share information is a loss for both society and the research community because it prevents cumulative or collaborative innovation and results in duplicative research.

Before Bayh-Dole, university researchers arguably already had a strong incentive to innovate. Within academia, the pressure to produce and publish findings in order to obtain tenure creates incentives for disclosure. Similarly, the desire for prestige and fame can often stimulate researchers to be the first in their field to publish a particular finding. The ability to patent may therefore be an unnecessary benefit for university researchers, who comprise the bulk of those receiving federal funding under Bayh-Dole.

C. Will Conflicts of Interest and Corporate Influence Harm Innovation?

The Bayh-Dole Act is also problematic in its potential for creating conflicts of interest and establishing corporate influence over academic researchers' work, which can hurt the quality of research.⁴⁸ "Conflicts of interest in science arise in situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research."⁴⁹ When a corporation gives researchers stock as part of a license agreement, the researchers then have the incentive to avoid negative findings that will hurt the corporation and its stock. Even if researchers do not change their actions as a result of owning stock, the appearance of bias can still undermine their credibility.⁵⁰

Also problematic is the potential that corporate influence may skew research toward more short-term goals, reducing the overall quantity of pure scientific research. Bayh-Dole gives researchers an incentive to invent patentable products that they can sell to corporate developers. Ensuring the future of pure scientific research has long been an important policy goal. In his 1945 report to President Roosevelt on the future of American science, presidential scientific advisor

46. See 35 U.S.C. § 102(b) (2000).

47. See DEREK BOK, *UNIVERSITIES IN THE MARKETPLACE* 64–65 (2003).

48. See *id.* at 58–59.

49. See *id.* at 66–67 (internal quotations omitted).

50. See *id.* at 67.

Vannevar Bush pointed out “how much the flow of new products and medical treatments depend[s] on a vigorous program of basic research that only universities can provide.”⁵¹ Former Harvard University President Derek Bok cites a number of situations in which corporations have used clauses in licensing contracts with university researchers to try to suppress those researchers’ findings.⁵²

On the other hand, Bok ultimately concludes that fears of perverse incentives for researchers to concede their integrity to corporations have been largely misplaced. While occasional scandals have arisen over financial conflict and corporate manipulation of research results, these incidents are few compared to the number of researchers who are productively “scouring their labs for commercially valuable innovations.”⁵³ Bayh-Dole has compelled academic researchers to try to find a use for their research that might otherwise remain in desk drawer purgatory.

While it is hard to determine the precise effect of the Bayh-Dole Act on innovation in the United States, thus far the changes have at least been neutral, and perhaps even positive. Even though the risks of economic waste, conflicts of interest, and corporate influence over academic research remain salient, the benefits of inspiring useful research and encouraging its marketing have thus far outweighed these drawbacks. As discussed below, if one applies a similar intellectual property policy to Proposition 71 funding, many of the benefits of the Bayh-Dole Act will accrue and some of the drawbacks will be mitigated.

IV. THE CALIFORNIA STEM CELL RESEARCH AND CURES ACT

On November 2, 2004, California residents voted to enact Proposition 71, giving almost \$3 billion in funding to stem cell research over the next ten years.⁵⁴ Stem cell research has generated enormous controversy over the past decade. Some believe stem cells hold promise for developing therapies and cures for spinal cord injuries and conditions such as Alzheimer’s disease, Parkinson’s disease, and diabetes.⁵⁵ For others, however, the idea of generating embryonic clones only to harvest them is troubling, evoking hot-button issues like reproductive cloning and abortion. Political pressures have prevented stem cell research from receiving federal funding for any work in which a human embryo is destroyed. The issue has featured prominently in the past two presidential elections, with candidates and ac-

51. *Id.* at 59 (citing VANNEVAR BUSH, SCIENCE: THE ENDLESS FRONTIER (1945), available at <http://www.nsf.gov/about/history/vbush1945.htm>).

52. *Id.* at 71–76.

53. *Id.* at 77.

54. Proposition 71, *supra* note 5, § 5.

55. Broder, *supra* note 6.

tivists causing political uproar by applying pro-life rhetoric to the stem cell debate.⁵⁶

Much of the debate over Proposition 71 has therefore centered on the morality of stem cell research and the urgency of funding it, rather than logistical questions,⁵⁷ such as who will profit from the fruits of the research. Proposition 71 sets forth the State's intention to profit from patents resulting from the research funding.⁵⁸ The Independent Citizens' Oversight Committee ("ICOC"), a group comprised of twenty-nine individuals from various universities, medical schools, and research groups throughout the State, will allocate funding.⁵⁹ Proposition 71 provides:

The ICOC shall establish 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.⁶⁰

While the ICOC is in charge of "[e]stablish[ing] policies regarding intellectual property rights arising from research funded by the Institute," the chairperson "lead[s] negotiations for intellectual property agreements," and the president "manage[s] and execute[s] all intellectual property agreements."⁶¹

The funding for Proposition 71 will come from tax-free state bonds. "These bonds will be self-financing during the first five years, so there [is] no cost to the State's general fund during this period of economic recovery."⁶² The State expects the funding to generate thousands of jobs, \$185 million in tax revenue over the next ten years, and a share of the royalties resulting from the research.⁶³ Many, however,

56. Glenn McGee, Lecture at Harvard Law School, What This Year's Election Means for Stem Cell Research (Nov. 4, 2004).

57. See Broder, *supra* note 6; Bobby Brooke, Letter to the Editor, *Stem Cell Funds a Polarizing Issue*, L.A. TIMES, Oct. 31, 2004, at C3.

58. Proposition 71, *supra* note 5, § 3.

59. *Id.* § 5.

60. *Id.*

61. *Id.*

62. OFFICIAL BALLOT SUMMARY, ARGUMENT FOR PROPOSITION 71, available at <http://www.healthvote2004.org/71/foragainst.php?pid=71&sid=2> (last visited Apr. 11, 2005).

63. *Id.*

have expressed concerns over how the money will be allocated and overseen.⁶⁴

First, critics worry that there will not be public oversight sufficient to ensure that the public will benefit from the spending.⁶⁵ Unlike federal research, over which Congress can exercise budgetary authority, research funded by Proposition 71 is not subject to state lawmakers' budgetary control.⁶⁶ Although no member of the ICOC may vote on funding for his own institution,⁶⁷ the fact that the ICOC is comprised of "representatives from most of the State's major medical schools, members of nonprofit research institutes, executives of commercial biotechnology firms and public members who are advocates for research in a range of diseases" means that vested interests have complete oversight over the stem cell research funding.⁶⁸

Second, critics believe that the research money allocation is too narrowly focused. The extent of stem cell research's practical application is not yet known, so the funding might be better directed to more mature medical technologies.⁶⁹ While the research funding is almost guaranteed to bring stem cell researchers to California, it may also spark a gold rush in which people claiming to be interested in stem cell research apply for the funding only to pursue useless projects.⁷⁰ Because the funding is earmarked specifically for a narrow field of research, there is a heightened probability that the worthwhile uses of that research will not justify the amount of money committed to it.

Third, the University of Wisconsin and the Geron Corporation of Menlo Park, California, hold the patents to twenty fundamental stem cell discoveries arising from early research, which has led to concerns that the royalty fees paid to these organizations might overwhelm the productive uses of the funding.⁷¹ Critics also worry that any new patents will go to pharmaceutical and biotechnology giants, leaving the

64. See, e.g., Broder, *supra* note 6; OFFICIAL BALLOT SUMMARY, ARGUMENT AGAINST PROPOSITION 71, available at <http://www.healthvote2004.org/71/foragainst.php?pid=71&sid=2> (last visited Apr. 11, 2005).

65. See Broder, *supra* note 6; Justin Hibbard, *Divvying up the Stem Cell Bonanza*, BUS. WK., Nov. 22, 2004, at 50; *California's Largest Nurses Group Warns Flaws in Stem Cell Research Measure Will Set Poor National Standard*, PR NEWSWIRE, Oct. 26, 2004, at <http://sev.prnewswire.com/health-care-hospitals/20041026/SFTU14926102004-1.html> [hereinafter *California Nurses Group*]. Robert Klein, the wealthy housing developer who put up \$3 million to finance the Proposition 71 campaign, is a favorite candidate for chairperson of the ICOC. Editorial, *Stem-Cell Project on Fast Track*, S.F. CHRON, Nov. 22, 2004, at B8. This appointment would be controversial, as Klein is a generous campaign contributor to at least three of the four people charged with nominating the chairperson. See *id.*

66. Hibbard, *supra* note 65.

67. Broder, *supra* note 6.

68. See *id.*; Hibbard, *supra* note 65.

69. See Broder, *supra* note 6.

70. See *id.*

71. See Denise Gellene, *Election 2004: Stem Cell Firms Bet on Big Payoff*, L.A. TIMES, Nov. 7, 2004, at C1; Broder, *supra* note 6.

public with almost no benefits.⁷² Finally, the California Nurses Association has expressed concerns that “private industry patents will result in prohibitively expensive treatments” that only the wealthy can afford.⁷³

V. WHAT CAN CALIFORNIA LEARN FROM BAYH-DOLE?

The lessons from twenty-four years under the Bayh-Dole Act should inform the intellectual property policies of California's stem cell research funding. For California's purposes, many of Bayh-Dole's successes should prove instructive, especially because Bayh-Dole's inherent drawbacks are mitigated in the context of Proposition 71. Because Proposition 71 mandates very little patent policy,⁷⁴ the ICOC will soon need to determine what incentives inventors need to develop useful intellectual property, as well as which rights the State of California should retain in order to promote productive use of inventions and secure income from its investment in stem cell research.

There are some key differences in funding under Bayh-Dole and Proposition 71. In some ways, Proposition 71 is the reverse of Bayh-Dole. When Congress passed Bayh-Dole, research institutions already received federal funding for their research, and the added incentive became the right to patent whatever innovations came out of the research. Conversely, twenty-four years later, universities and research institutions are accustomed to obtaining intellectual property based on their discoveries, but they have never been able to receive federal funding for stem cell research. This will be stem cell researchers' first chance to receive government money. A second key distinction is that Proposition 71 funding is already earmarked for a specific cause, while federal funding for research institutions tends not to be earmarked until after a recipient has been designated.

In other ways, however, federal funding under Bayh-Dole and state funding under Proposition 71 are similar, and critics have voiced similar concerns. Both acts allow the government to give money for research, and, based on the wording of Proposition 71,⁷⁵ intend for the

72. See *California Nurses Group*, *supra* note 65.

73. *Id.*

74. As of the writing of this paper, no one has been selected for any of the top ICOC positions, although Proposition 71 includes procedures for these selections. For instance, the act provides that “[t]he Chancellors of the University of California at San Francisco, Davis, San Diego, Los Angeles and Irvine, shall each appoint an executive officer from his or her campus.” Proposition 71, *supra* note 5, § 5. Also, “[t]he Governor, the Lieutenant Governor, the Treasurer, and the Controller shall each appoint an executive officer.” *Id.*

75. While the intellectual property policy has not yet been set, the ICOC has been instructed to “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.” Proposition 71, *supra* note 5, at § 5.

inventor to retain at least some of the rights to intellectual property resulting from that research. Bayh-Dole and Proposition 71 apply to the same institutions: universities, small private research companies, and nonprofit research institutes. And both acts have raised concerns about whether it is the taxpayer or the pharmaceutical industry whose interests are served by the allocation of funding.⁷⁶

*A. A Proposal for an Intellectual Property Policy
under Proposition 71*

Based on the similarities and differences between Bayh-Dole and California's stem cell research funding, the following proposal takes advantage of the benefits of Bayh-Dole while mitigating some of its negative effects. The State of California should allow an institutional funding recipient to retain complete ownership of its patents when funded by the State's grant in whole or in part, subject to the payment of a ten percent "exceptional research royalty" to the State. This royalty should be imposed on any gross income derived from the intellectual property generated by state funding, including income from exclusive or nonexclusive licensing or sale of the patent. Gross income is totaled before accounting for patent filing fees. The exceptional research royalty should include ten percent of any stock as well as cash paid for the license or ownership of the patent. Like the Bayh-Dole Act, California should be able to take the patent only when extenuating circumstances implicating the public interest so require.⁷⁷ California should also retain a license to practice the invention for its own use and similar "march-in rights," which allow it to license the patent for reasonable compensation if necessary for public health or because the inventor has not commercialized the invention within a previously agreed upon time frame.⁷⁸ Like Bayh-Dole funding recipients, universities and other entities receiving state funding should

76. In fact, proponents of Proposition 71 raised over \$25 million just to promote the stem cell initiative to voters. The primary backers were venture capitalists, wealthy individuals, and disease advocacy groups. Charles Krauthammer, a member of the President's Council on Bioethics, criticized the measure:

This is an unbelievable rip-off by people with an interest in the business of stem cells This is a huge grant from the people of California to a very specific biotech business, and it's only because of stem cells' notoriety that it's this and not something else. If taxpayers were to spend \$3 billion, the logical thing would be to devote the money to the most promising areas of research, but that was never discussed because of the sexiness of stem cells. The oversight provisions are abysmal and it's basically a slush fund.

Broder, *supra* note 6. Critics also think that the venture capitalists would get too good a deal out of Proposition 71's success. According to Mitchell Kapor, a software entrepreneur in San Francisco, "If it doesn't work, VCs don't lose anything But if it does work, they get all these fundable companies." Hibbard, *supra* note 65.

77. See SCHACHT, *supra* note 2, at 5.

78. See *id.*

have to give priority in granting licenses to small businesses,⁷⁹ share royalties with the inventor, and attempt to ensure that the invention is manufactured substantially in the United States,⁸⁰ preferably in the State of California.

B. The Rationale Behind the Proposal

One purpose of Proposition 71 is to help find cures using stem cells by supporting stem cell research.⁸¹ Taking into account this goal, California should incentivize pure research but also create additional incentives to perform *useful* research by allowing inventors to patent and sell any resulting cures.

Inventors should have some incentive to innovate beyond the promise of funding grants. If all of the intellectual property from the funding goes to the State of California, researchers are less likely to try to develop useful inventions, and those who do will be less intent on ensuring the inventions are patented. While there should be no shortage of researchers seeking a portion of the \$3 billion fund dedicated to stem cell research,⁸² the promise of royalties will prevent the researchers from squandering it on either useless inventions or duplicative research.

Inventors should also have a measure of control over licensing their inventions. The pre-Bayh-Dole era demonstrates that without the ability to grant exclusive licenses, biotechnology corporations and developers have very little economic incentive to license an invention. A competitor who has also obtained a non-exclusive license can free ride on any progress a developer makes, forcing developers to sell at just above marginal cost. While, ideally, government money would go toward research that would end up in the public domain, pre-Bayh-Dole problems warn that such a scheme often causes productive developments to go to waste. Allowing university patentees to grant exclusive licenses, however, may make products prohibitively expensive, justifying some fears about passing Proposition 71.⁸³ A provision allowing the State to license a patent for reasonable compensation if the public interest so required would somewhat mitigate the damaging effect, but much of the resulting stem cell-related technology will probably be expensive, at least initially. Also, like the Bayh-Dole Act, if Proposition 71 allows inventors to file and maintain their own patents, it will promote unfortunate secrecy within academic institutions. These drawbacks, however, are outweighed by the

79. 35 U.S.C. § 209 (2000).

80. 35 U.S.C. § 204 (2000).

81. Proposition 71, *supra* note 5, § 3.

82. *See* Broder, *supra* note 6.

83. *California Nurses Group*, *supra* note 65.

benefits of giving researchers control over their own intellectual property.

The ten percent figure for the exceptional research royalty derives from several different considerations. The exceptional research royalty is a percentage of the licensing fees and royalties that universities receive from their patents, so yet another entity is taking a slice of the pie. The State, however, has promised its taxpayers that it will receive revenue from the intellectual property generated from Proposition 71. Because the royalty is a gross fee, taken before accounting for patent filing costs, the State has no stake in the patentee's business skills. While a ten percent exceptional research royalty on income from an invention is a significant amount of money, the seed money comes from the State, and the State deserves some return if the innovation is successful.⁸⁴ Additionally, since so few patented inventions ever make money, universities avoid economic risks because they have to give money back to the State only if patents actually generate income. The author of this Note chose ten percent as the value for the exceptional research royalty so as to minimally impact the inventor's financial rewards while assuring California voters that Proposition 71's promise of generating royalty income is appreciably realized. While the number is somewhat arbitrary, the State could start with ten percent and shift the number down if it seems to deter inventors or up if it seems that inventors would not be deterred by having to give up more of their patent licensing fees.⁸⁵ The university will obviously lose ten

84. According to AUTM, in 2002, U.S. universities spent a total of \$31.7 billion on sponsored research and received \$959 million in adjusted gross license income (adjusted for licensing fees that a university then had to pay to a research partner). This means U.S. universities received a 3.03% return on their research investments. In 2003, U.S. universities spent \$34.8 billion and received \$964 million in adjusted gross license income, a 2.77% return. In 2002, the University of California ("UC") System spent \$2.42 billion and received \$82.0 million in adjusted gross license income, a 3.39% return. In 2003, the UC system spent \$2.62 billion and received \$61.1 million in adjusted gross license income, a 2.33% return. Because the UC System constitutes such a large portion of all California research institutions, the percentage return on California's investment should approximate the UC System's previous return rates. The average of the UC System's 2002 and 2003 rates of return is 2.86%, so a rough estimate of California's return rate on \$3 billion of stem cell research funding is approximately \$85.8 million. This means that, if the state takes a 10% exceptional research royalty, it can expect to receive approximately \$8.6 million in "stem money" for its \$3 billion seed investment. See AUTM LICENSING SURVEY: FY 2002, at <http://www.ipal.de/cmsupload/2002%20Licensing%20Survey%20Summary.pdf> (last visited Apr. 11, 2005); AUTM LICENSING SURVEY: FY 2003, at http://www.cmos.ca/PrivateSector/TechTransfer/03AUTMSurvey_interim.pdf (last visited Apr. 11, 2005).

85. The UC System's patent policy states that of the net royalties and fees accruing from its patents, the inventor receives 35% of the revenue, the inventor's lab or campus receives 15% for research purposes, and the UC System receives 50%. UNIV. OF CAL. OFFICE OF TECH. TRANSFER, UNIVERSITY OF CALIFORNIA PATENT POLICY (Oct. 1, 1997), at <http://www.ucop.edu/ott/patentpolicy/patentpo.html#pol>. Apportioning a 10% cut of the gross revenue among these interests would mean that the inventor would receive 31.5% of the university's negotiated license fee, the lab would receive 13.5%, and the UC System would receive 45%.

percent of the gross revenue it would have received if it retained all of its intellectual property rights. In order to make up for the exceptional research royalty losses, the university can try to negotiate a higher royalty with developers to whom it licenses intellectual property. The university will likely have some sway with the developers because all California stem cell technology will incorporate this additional ten percent markup, but the university may still have to take a slightly smaller share than is its custom. Conversely, although ten percent of a small fraction of the revenue is a relatively small amount of money compared to the annual state budget, the State of California never expected to receive a large profit off of royalties.⁸⁶ Instead, the State hopes stem cell research will result in technology that will lower state health care expenses.⁸⁷

Fixing a rate at which researchers share their profits with the State benefits all concerned. In particular, transaction costs are reduced when the terms of the royalty are uniform for every research institution. The State will not have to negotiate a new licensing contract each time it allocates money to an institution, which is important considering how rarely funding allocations will result in royalty-generating patents.

While Bayh-Dole has sparked concerns about conflicts of interest and corporate influence over researchers' work, the effect of corporate influence under Proposition 71 will be much less than its effect on federally funded science research. Because the California funding is earmarked for stem cell research, the research performed with this funding is already purpose-driven. Allowing researchers a stake in the profits from their research will not affect their desire for a specific outcome. Although researchers may desire a specific positive outcome to please their corporate sponsors, they would also have the same incentive to please the State of California and receive more Proposition 71 funding, with or without the availability of patents.

Also mitigated by Proposition 71 is the problem of public double taxation. Under Bayh-Dole, the public has to pay twice for developments, first in taxes and again in royalties to the inventor. Under Proposition 71, if the State kept the intellectual property it funded and placed it in the public domain, it would be available for the entire country to use. This would mean that California residents would pay for information from which the entire country would benefit. Instead, if researchers get to keep the intellectual property, the State of California benefits from its royalty payment, whether the buyer is in California or not. California residents therefore benefit from the tax dollars that they put into research.

86. See Broder, *supra* note 6.

87. See *id.*

Allowing inventors to retain a significant stake in the intellectual property they develop will also help alleviate concerns over public oversight of Proposition 71 funding. Proposition 71 may provide for less public oversight than Bayh-Dole because the ICOC's budget is fixed for the next decade and not subject to lawmakers' control. Under the proposed allocation of intellectual property, however, researchers will have an incentive to develop useful inventions rather than wasting public money since only patents that are useful to the public will be financially successful. Allowing researchers to keep their intellectual property will not resolve the gold rush problem wherein people seek to obtain funding for useless proposals, but neither will it exacerbate this problem since useless proposals will not result in income from a patent.⁸⁸

The existence of a number of patents in stem cell technology, held by the University of Wisconsin and the Geron Corp., will probably not be affected by whatever intellectual property system is implemented. While the already existing patents will probably cause blocking⁸⁹ and force the owners to cross-license, the identity of the owner of the new intellectual property will not impact this problem. It is likely that fewer of the forthcoming patents on stem cell technology will be as useful as the average patent; if stem cell research should hit a dead end in the next ten years, researchers will still apply for funding and will probably continue to patent, regardless of the utility of these patents.⁹⁰ But a system that allows the inventor to control her own intellectual property will force the inventor to weigh the utility of the invention before filing for a patent, creating an incentive to do more useful research and reducing the strain on the system resulting from useless patents.

Finally, as Shavell and van Ypersele demonstrated, a system of both prize and patent is superior to a pure patent system.⁹¹ Although the authors did not determine whether prize and patent is superior to a pure prize system, they did find that both were superior to a pure patent system. Stem cell researchers have always been able to patent their research, regardless of Bayh-Dole, because they received no federal funding for it. Since researchers are accustomed to the extra incentive of receiving a patent, California might deter these researchers if it retained all intellectual property rights under Proposition 71 funding and offered a pure prize system. Although Shavell and van

88. *See id.*

89. Patent blocking occurs when a new patent consists of an improvement on old, patented technology. The new technology cannot be used without the consent of the old patentee, but the old patentee is likewise constrained from using the new technology without the new patentee's consent. If patentees do not cross-license in this situation, no one can take advantage of the new technology.

90. *See Broder, supra* note 6.

91. *See Shavell & van Ypersele, supra* note 42, at 541.

Ypersele's theoretical analysis does not demonstrate whether stem cell research money, without any corresponding intellectual property rights, would be a better or worse incentive than the research money plus intellectual property rights, it does demonstrate that either system would be better than the pure patent system in place before the advent of Proposition 71. Given that stem cell researchers are accustomed to patenting their inventions, the combination of Proposition 71 funding with intellectual property rights as proposed here seems the most natural choice.

VI. CONCLUSION

After the Bayh-Dole Act was passed in 1980, it took a long time to generate information regarding its effects. Many still question it twenty-four years later, although most empirical studies have shown that it has improved the connection between academic research and the public's access to products derived from universities' research.

Now that California has passed Proposition 71, allotting \$295 million per year for the next ten years to stem cell research, the State can benefit greatly from the lessons of the Bayh-Dole Act in choosing a policy for the intellectual property resulting from Proposition 71 funding. This Note recommends a policy in which inventors, as under Bayh-Dole, own their intellectual property but owe the State of California a ten percent exceptional research royalty on any income they receive from such intellectual property. Such a policy will retain the incentives that Bayh-Dole created to innovate, disclose, and market inventions. Many of the drawbacks of Bayh-Dole are inherent in Proposition 71, whether or not inventors can patent their inventions, so California and the public at large will only benefit from a system that allows researchers to keep their intellectual property resulting from state-funded research.