STATES AS INNOVATION SYSTEM
LABORATORIES: CALIFORNIA, PATENTS, AND
STEM CELL TECHNOLOGY

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“California has a chance to set a new model for scientific research.”

Bruce Alberts, Former President, National Academy of Sciences

INTRODUCTION

In 2001, and recently reaffirmed in 2006 by presidential veto, the Bush Administration made a policy decision to limit federal funding for embryonic stem cell research—primarily for moral reasons.  

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2 See President George W. Bush, President Discusses Stem Cell Research (Aug. 9, 2001), available at http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html. There is a distinction between embryonic and adult stem cell research. The Bush Administration extended its conservative social agenda by vetoing the recent bill to allow federal funding for most types of
Embryonic stem cell research is one of the most promising areas of scientific research, and could lead to developing treatments for medical problems that affect over 128 million Americans, such as cancer, heart disease, diabetes, Alzheimer’s, Parkinson’s, HIV/AIDS, multiple sclerosis, and lung diseases. While the moral debate underlying that decision is important, the unintended consequence of that decision was to provide the impetus for states to commit large amounts of research dollars to fill the federal funding gap for embryonic stem cell research. For many years, states have attempted to provide incentives for technological innovation within their respective states; however, the dollar amounts of those incentive programs have not come close to California’s recent investment in research. In 2004, California voters passed Proposition 71, which provides three billion dollars in funding for embryonic stem cell research. California voters were persuaded to vote for Proposition 71 by arguments that the state would receive a large return on its investment in direct revenue, jobs, and lower healthcare costs through the development and commercialization of new products and services from Proposition 71 research. While Proposition 71 was clear as to the amount of public funding provided in support of embryonic stem cell research, it was unclear as to several important issues, including who would own the patentable inventions arising from that research and what rights the state would retain in those patentable inventions. See Letter from President George W. Bush to the House of Representatives (July 19, 2006), available at http://www.whitehouse.gov/news/releases/2006/07/20060719-5.html. For additional information on stem cell science, see Nat’l Insts. Health, Stem Cell Information: Stem Cell Basics, http://stemcells.nih.gov/staticresources/info/basics/StemCellBasics.pdf; Nat’l Insts. Health, Stem Cells: Scientific Progress and Future Research Directions (2001), http://stemcells.nih.gov/staticresources/info/scireport/PDFs/fullrptstem.pdf.


4 Cal. Const. art. XXX, § 1.

5 Rebuttal to Argument Against Proposition 71, http://www.ss.ca.gov/elections/bp_nov04/prop_71_argument_against_rebuttal_to_argument_against.pdf
Proposition 71’s failure to address these issues has prompted state policy makers to consider these questions. This debate includes a critical examination of the Bayh-Dole Act, the primary piece of federal legislation concerning government-funded inventions, and its purported positive and negative consequences. A public interest group, the California Council on Science and Technology (CCST), argues that states, and particularly California, should adopt the Bayh-Dole Act in slightly modified form. The Bayh-Dole Act was enacted in 1980 essentially in response to a belief that government-funded inventions were not being brought to market, and thus the public was not realizing the benefit of its investment. The Bayh-Dole Act and subsequent legislation attempt to remedy this apparent problem primarily by allowing private companies and universities to take title to inventions, which is supposed to provide an incentive for private industry to invest in the commercialization of those inventions. The Bayh-Dole Act is one of the most controversial pieces of intellectual property law related legislation. Recently, Fortune magazine published an article criticizing the Act for its unintended consequences and failure to achieve its laudable purposes. In apparent response to that article, a resolution was proposed in the United States House of Representatives that praises the Bayh-Dole Act and credits the Act with “substantial contributions to the advancement of scientific and technological knowledge, . . . strengthen[ing] the higher education system in the U.S. [and] serv[ing] as a catalyst for the development of new domestic industries.” The conflicting and very strong views of the Bayh-Dole Act and its impact perhaps best demonstrate how settled the interests are that have developed around the Act.

9 Id.
end products or services or downstream products.\textsuperscript{12} An anticommons may thwart the basic purpose of the Act, which is ensuring utilization of research results for the benefit of the public that funded the research. Second, the agendas of researchers in academia may have been diverted from projects that are directed to broadly applicable basic science to applied science.\textsuperscript{13} Because of that diversion, the public does not benefit from the spillover effects of advances in broadly applicable basic science. Third, a change to a proprietary model from an open science model based on the academic norms of science may have resulted in research not being immediately published and in research materials being unreasonably withheld.\textsuperscript{14} This can cause a delay in the advance of scientific research. Fourth, numerous conflicts of interest involving academic researchers have arisen since passage of the Bayh-Dole Act.\textsuperscript{15} These conflicts threaten to undermine the credibility of the academic enterprise as a neutral arbiter of scientific information to the public and further undermines the credibility of scientific research by prohibiting the replication of research.

Not only has the passage of the Act resulted in potentially negative unintended consequences, but the arguments in support of the Act are subject to credible criticism and the specific provisions of the Act, designed to balance the rights of the public funding the research and the funding recipient, have perhaps not been exercised as expected. First, the support for the basic argument underlying the justification for the Bayh-Dole Act is subject to question for at least two reasons. According to proponents of the Bayh-Dole Act, a large number of government-owned patents covered technology that was not being licensed and thus further commercialized, because nonprofits or private industry were unable to secure ownership of the technology and thereby justify continued investment in the commercialization of that technology.\textsuperscript{16} Professor Eisenberg states that the group of patents that were used to justify the argument, that an inability of nonprofits and private industry to own those patents was the reason why the patented technology languished with the federal government, was subject to a huge selection bias.\textsuperscript{17} A large number of those patents covered inventions that were created through Department of Defense-sponsored research, and pursuant to the sponsorship contracts, the contractors were generally allowed to obtain title to those patents.\textsuperscript{18} Thus, the patented inventions in that group of patents had already been rejected by
industry, and it should not be surprising that other industry participants would also not want to obtain title to those patents.\textsuperscript{19} Second, the provisions in the Bayh-Dole Act designed to allow access to government-funded innovation have either not been exercised or are very difficult to exercise because of the uncertain nature of biotechnology research.\textsuperscript{20} The first such provision, the “march-in” rights provided by the Act, has not been exercised to date. Second, the ability of the government to designate certain technology as subject to “exceptional circumstances,” and thus not subject to proprietary control, is not used effectively because it is very difficult to declare a case of “exceptional circumstances” before the research even takes place.\textsuperscript{21} Third, the Act has been criticized for making the public pay twice for an invention—once by funding its development and again by paying a supra-competitive price because of a patent.\textsuperscript{22} Finally, a recent, substantial study argues that the benefits of the Act may have been realized without the Act.\textsuperscript{23}

Because of the evidence, albeit somewhat conflicted and perhaps unconvincing to some, of the unintended consequences of the Act, and criticism of the Act, commentators have responded by arguing the Act should be modified.\textsuperscript{24} This Article argues that after twenty-five years of experience with the Bayh-Dole Act, the Act’s provisions should be recalibrated according to that experience at the state level. States, particularly California, are well positioned to engage in this process and inform the federal model because states are part of the general U.S. university system and are subject to the same patent laws.

The California Institute for Regenerative Medicine (CIRM), the California agency responsible for distribution of funds under Proposition 71, recently released its interim intellectual property policy (CIRM Interim Policy).\textsuperscript{25} The CIRM Interim Policy follows the general thrust of the Bayh-Dole Act by placing ownership of government-funded inventions in the grant recipient, but includes several important deviations.\textsuperscript{26} The CIRM Interim Policy includes a research exemption, price controls for therapeutics and diagnostics developed with exclusive

\textsuperscript{19} \textit{Id.} at 1703.
\textsuperscript{20} \textit{See infra} Part II.C.1.a.
\textsuperscript{21} \textit{See id.}
\textsuperscript{22} \textit{See infra} Part I.B.2.
\textsuperscript{23} \textit{See infra} Part I.B.3.
\textsuperscript{26} \textit{Id.} at 23.
licenses, retention of a royalty stream to the state, march-in provisions apparently without a cumbersome review process, and a requirement that, after publication, research materials are shared within sixty days of a request.\textsuperscript{27}

This Article makes several arguments. The first argument is that states, and particularly California, should be encouraged to create systems concerning the ownership of government-funded inventions which deviate from the provisions of the Bayh-Dole Act based on our understanding of the supposed consequences of the Act. This is beneficial because states will not contribute to the negative consequences of the Act in a meaningful way and those new versions of the Act will provide an opportunity to study the state acts and their impact on innovation. Moreover, it is unlikely that substantial modification of the Bayh-Dole Act will occur because of the reliance interests surrounding the Act\textsuperscript{28} and the supposed lack of persuasive empirical evidence concerning the impact of the Act.\textsuperscript{29} It is more likely the federal act can be modified after evidence of the success of state provisions. The second argument is that while additional transaction costs may arise because differing systems from state to state may give rise to an anticommons, that risk is outweighed by the opportunity to develop and study alternative schemes to the Bayh-Dole Act. The risk is acceptable because the question of whether an anticommons has developed or not is unclear. Moreover, participants in the biotechnology industry appear able to avoid an anticommons. Also, the anticommons impact in the stem cell research area will be mitigated by the fact that many states, in fact a substantial number, are restricting stem cell research in one form or another. Furthermore, assuming that the CIRM Interim Policy becomes final, the addition of a research exemption and march-in rights without a cumbersome review process may mitigate any additional risk of an anticommons and may actually

\textsuperscript{27} See generally id.

\textsuperscript{28} See Rochelle Dreyfuss, \textit{Biotechnology Patents Get Special Treatment: Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?}, 46 ARIZ. L. REV. 457, 470 (2004) (“At this point, it has to be assumed that many reliance interests have grown up around university patenting [and accordingly, it is unlikely that the core thrust of the [Bayh-Dole Act] could be reversed.”); cf. \textit{DANIEL A. FARBER & PHILIP P. FRICKLEY, LAW AND PUBLIC CHOICE: A CRITICAL INTRODUCTION} 1 (1991) (“Realistically, we must also consider the possibility that a statute represents private rather than public interests.”).\textsuperscript{29}

\textsuperscript{29} In a recent article, Professor Bhaven N. Sampat highlights the difficulties in assessing the causal impact of academic genomic patents and the welfare impacts of the patent system itself. Professor Sampat quotes Machlup’s authoritative Economic Review of the Patent System which suggested that, “an economic evaluation of the patent system as a whole implies an analysis of the differences between its existence and non-existence—[an effort that is] perhaps a hopeless task.” Bhaven N. Sampat, Genomic Patenting by Academic Researchers: Bad for Science? 5-6, available at \url{http://mgt.gatech.edu/news_room/news/2004/reer/files/sampat.pdf}; see also \textit{ROGER E. SCHECHTER & JOHN R. THOMAS, PRINCIPLES OF PATENT LAW} 9 (2004) (“[N]o conclusive demonstration proves the patent system achieves its laudable goals.”).
serve to prevent an anticommons from developing. Other states may adopt similar provisions which may serve to lessen the chance of the development of an anticommons.

Next, the Article argues that while there is a risk of a race to the bottom by states, the risk is limited because of the small number of states that are able to provide substantial funding for embryonic stem cell research and interjurisdictional competition may lead to the creation of a broad research exemption. Finally, the Article reviews the proposed CIRM modifications to the Bayh-Dole Act and recommends additional changes to those modifications, such as a research exemption similar to the one recently proposed by Professor Gary Pulsinelli; a broader royalty; the retention of a nonexclusive license to practice the invention or to have the invention practiced on its behalf limited to government purposes; march-in rights explicitly without a one-year period for cure; rules concerning which funder’s rules will control if there are conflicting funding sources; an exceptional circumstances provision; and an explicit provision stating that non-compliance with CIRM rules will result in a ban from receiving future grants.

Part I analyzes the purposes and provisions of the Bayh-Dole Act taking into account the interests of the participants in the technology transfer process, including the interest of the funder—the public. Part II discusses the purported consequences of the Bayh-Dole Act. Part III reviews and analyzes state promotion of innovation, focusing on the CCST reports concerning technology developed through Proposition 71 funding and the CIRM Interim Policy. Part IV argues that states should be encouraged to develop modified versions of the Bayh-Dole Act and analyzes the proposed modifications to the Bayh-Dole Act under the CIRM Interim Policy. The last Part offers some concluding thoughts.

I. THE FEDERAL MODEL: THE BAYH-DOLE ACT

The Bayh-Dole Act represents a significant change in federal policy concerning the ownership of patentable inventions created with government funding. This section will review the policies underlying the Act and its provisions.

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30 In addition to the Bayh-Dole Act, Congress also passed the Stevenson-Wydler Technology Innovation Act in 1980, which directed federal laboratories to make technology transfer a priority. See Eisenberg, supra note 8, at 1663-65. “The Bayh-Dole Act generally applies to all ‘funding agreements,’ which are defined as government contracts, grants, and cooperative agreements . . . ‘for the performance of experimental, developmental, or research work.’” ALINE C. FLOWER, INTELLECTUAL PROPERTY TECHNOLOGY TRANSFER 12 (2006) (quoting 35 U.S.C. § 201(b) (2000)).
The primary purpose of the Bayh-Dole Act is to ensure that government-funded inventions are commercialized, and thus allow the public to benefit from those inventions. Second, there was a belief that prior to passage of the Bayh-Dole Act, companies based outside the United States were benefiting from the results of research funded by the government. Finally, the drafters of the Bayh-Dole Act believed that the Act may reinvigorate U.S. industry by providing new ideas to increase productivity and create jobs.

The Act attempts to address these concerns by creating a uniform policy for the treatment of government-funded inventions by providing a presumption of ownership in the recipients of government funding.

31 See COUNCIL ON GOVERNMENTAL RELATIONS, UNIVERSITY TECHNOLOGY TRANSFER: QUESTIONS AND ANSWERS 1 (1996), available at http://206.151.87.67/docs/bayhdoleqa.htm [hereinafter COUNCIL ON GOVERNMENTAL RELATIONS] (“One major impetus for the bill was the lack of a capability on the part of the federal government to transfer technologies for which it had assumed ownership. Hundreds of valuable patents were sitting unused on the shelf because the Government, which sponsored the research that led to the discovery, lacked the resources and links with industry needed for development and marketing of the inventions. Yet the government was unwilling to grant licenses to the private sector. The few federal agencies that could grant patent title to universities, were overregulated with conflicting licensing and patenting policies. Technology transfer under those conditions was operationally prohibitive for universities and made them reluctant to enter the technology area.”).

The express purposes of the Bayh-Dole Act are expressed in 35 U.S.C. § 200:

It is the policy and objective of the Congress to use the patent system to [1] promote the utilization of inventions arising from federally supported research or development; [2] to encourage maximum participation of small business firms in federally supported research and development efforts; [3] to promote collaboration between commercial concerns and nonprofit organizations, including universities; [4] 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; [5] to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; [6] to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and [7] protect the public against nuisance or unreasonable use of inventions; and [8] to minimize the costs of administering policies in this area.

32 See Eisenberg, supra note 8, at 1665; see also Brett Frischmann, Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy, 24 VT. L. REV. 347, 408 (2000) (“[The domestic industry preference] implies a concern regarding foreign misappropriation that is manifested in a fear of foreign competition in applied commercial innovation markets.”).

33 See Eisenberg, supra note 8, at 1665.

34 See The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary, 96th Cong. 2 (1979) (statement of Sen. Birch Bayh); id. at 30 (statement of Sen. Robert Dole); id. at 33 (statement of Sen. Orrin G. Hatch); COUNCIL ON GOVERNMENTAL RELATIONS, supra note 31, at 2; see also Pulsinelli, supra note 24, at 397-402 (discussing legislative history of Bayh-Dole Act); Eisenberg, supra note 8, at 1634-1702 (discussing legislative history of Bayh-Dole Act). The Bayh-Dole Act also specifies the conditions under which federal agencies may apply for, obtain and maintain patents, and license government-funded innovation. 35 U.S.C. §§ 207-209; see COUNCIL ON GOVERNMENTAL RELATIONS, supra note 31, at 1 (“Enactment of Bayh-Dole Act (P.L. 96-517), the ‘Patent and
Prior to passage of the Bayh-Dole Act in 1980, each federal agency and funding group had its own policy concerning whether a funding recipient could take title to an invention developed from that funding. Moreover, most, if not all, of the funding groups either required the government to take title or make the results of federally sponsored research part of the public domain. The grant of ownership in the recipient supposedly provides an incentive for that recipient to commercialize the results of government-funded research. The focus is not on ex ante incentives, but on the ex post investment of resources to develop the results of federally funded research and bring the resulting product or service to market. The Act originally was limited to nonprofits and small companies, but since has been extended to all companies.

B. Incentives to Encourage Technology Transfer

The Act is carefully structured to provide the necessary incentives to the parties involved in the technology transfer process to get them to bring the technology from the laboratory to the market. The Act takes into account the interests of the public, the government, the inventor of the technology, the employer of the inventor of the technology, and entities involved in the commercialization of the invention. More often than not, the transfer happens between universities, recipients of

Trademark Act Amendments of 1980' on December 12, 1980, created a uniform patent policy among the many federal agencies that fund research. Bayh-Dole enables small businesses and nonprofit organizations, including universities, to retain title to materials and products they invent under federal funding. This assertion is not without theoretical support. See generally F. Scott Kieff, Property Rights and Property Rules for Commercializing Inventions, 85 MINN. L. REV. 697 (2000).

35 See Eisenberg, supra note 8, at 1663.
36 See Frischmann, supra note 32, at 397.
37 See Eisenberg, supra note 8, at 1669-70.
38 See Presidential Memorandum to the Heads of the Executive Departments and Agencies, Subject: Patent Policy, 1983 PUB. PAPERS 248 (Feb. 18); Exec. Order No. 12,591, 52 Fed. Reg. 13,414 (Apr. 10, 1987); Trademark Clarification Act of 1984, 15 U.S.C. § 1501 (2000); see Frischmann, supra note 32, at 399 n.223 (“President Reagan practically extended the reach of Bayh-Dole in an executive order in which he required agencies to allow IP to be obtained by all contractors ‘regardless of size’ but ‘to the extent permitted by law.’”) (quoting Executive Order No. 12,591).
39 Notably,
[t]he principles of the Bayh-Dole act were the result of years of intense and emotional debate, dealing with fundamental concerns. The record shows that the debate included such issues as whether exclusive licenses would lead to monopolies and higher prices; whether tax payers would get their fair share; whether foreign industry would benefit unduly; and whether ownership of inventions by a contractor is anti-competitive. Safeguards were hammered out in numerous legislative drafts. COUNCIL ON GOVERNMENTAL RELATIONS, supra note 31, at 3.
government funding, and private industry, which is often best positioned to commercialize the technology.

The Act allows the government to retain title to funded inventions only in limited circumstances. For example, the government may retain title in certain national security situations, where “exceptional circumstances” may exist wherein the policies and objectives of the Act are better served by having the government retain title, or where the contractor is not located in the United States or is subject to the control of a foreign government. Those provisions protect the interests of the government and the public generally and, specifically, the exceptional circumstances provision protects the interest of the public in ensuring broad dissemination of some types of government-funded inventions. At the same time, the Act balances the interests of the government and public by providing procedural protections for potential inventors of technology and employers of inventors by requiring the government to engage in a review process of any decision concerning a retention of title by an agency.

The Act provides a presumption of ownership in the recipient of the grant funding. In order to receive title, the funding recipient must fulfill various conditions which are described below. The Act also provides obligations on the part of the government to exercise certain rights crafted to protect the interests of the government and public. First, the Act and its implementing regulations require that the recipient have an internal process requiring potential inventors to promptly disclose any patentable inventions to responsible personnel and “to sign papers necessary to file patents and establish the government’s rights.” This obligation ensures that rights to patentable inventions are not forfeited through delay in filing. The Act also requires that the recipient “disclose a subject invention to the contracting agency ‘within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters.’” The

41 Id. § 202(a)(i-iii).
42 Id. § 202(b)(1) & (2).
43 COUNCIL ON GOVERNMENTAL RELATIONS, supra note 31, at 7 (“When a university elects title to an invention, it assumes responsibility for taking certain actions to properly manage the invention.”).
44 FLOWER, supra note 30, at 18 (citing 37 C.F.R. § 401.14(f)(2)).
45 FLOWER, supra note 30.
46 Id. at 19 (quoting 35 U.S.C. § 202(c)(1)).

The regulations and standard clause clarify that a “reasonable time” is two months and permit agencies to grant extensions at their discretion. The disclosure made must “be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention.” The disclosure must also identify any publication, public use, or sale that might trigger a statutory bar.

FLOWER, supra note 30, at 19 (quoting 37 C.F.R. § 401.14(c)(1)). Interestingly, a Government
government can choose to retain title to the invention if the contractor does not comply with the disclosure requirement. 47 Those provisions provide the government with knowledge of the invention and an incentive for the recipient to disclose that invention at the risk of losing title to that invention. Following a reasonable time after disclosure, the recipient may elect to retain title of the disclosed invention.48 The decision to retain title must be made within two years of the disclosure.49 If the recipient and government do not elect to retain title, the recipient’s employee inventor can elect title to the invention.50 The election provision allows the grant recipient to retain title and the timing of the election is structured so that the government’s and public’s interests are protected. By allowing the grant recipient to take title to the invention, the grant recipient or a licensee can extract a supra-competitive price with exclusive rights provided by the patent. The supra-competitive price can ensure that the licensee or grant recipient receives a profit and reimbursement for costs to commercialize the invention. The lure of the supra-competitive price thus provides an incentive for the licensee or grant recipient to commercialize the invention.51 Thus, while the public has funded the development of the invention and will pay the supra-competitive price, the invention may be less likely to languish on a government shelf and more likely to reach the marketplace.

The recipient, after retention of title, has several additional obligations. First, the recipient has an obligation to timely patent the invention while keeping the government informed of any conditions impacting patentability, including any publication or public use or sale.52 If the recipient “does not file a patent application in any particular country, the government has the right to take title to the invention in that country.”53 Furthermore, once a patent is filed and

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48 Id. § 202(a).
49 Id. § 202(c)(2); see also 37 C.F.R. § 401.14(c)(2) (2006).
50 See FLOWER, supra note 30, at 31 (citing 35 U.S.C. § 202(d)).
51 See GORDON V. SMITH & RUSSELL L. PARR, INTELLECTUAL PROPERTY: LICENSING AND JOINT VENTURE PROFIT STRATEGIES 322 (3d. ed. 2004) (“The development time and costs to take a laboratory invention to commercial reality are often high.”).
52 See FLOWER, supra note 30, at 25.
53 Id. at 25-26.
even granted, the recipient “must notify the government of any decision not to continue prosecution of a patent application, pay maintenance fees, or defend a reexamination or opposition proceeding, at least 30 days before the last chance to respond.”54 This requirement protects the government’s and public’s interest in timely patent filings and preventing loss of patent rights in the United States and other countries. Second, the recipient must take steps to achieve practical application of the invention or, in other words, commercialize the invention. As discussed infra, the government retains “march-in rights” and may take title to the invention if the recipient fails to take “within a reasonable time, effective steps to achieve practical application of the subject invention.”55 This provides an incentive for recipients to either license the invention broadly, ensure an exclusive license contains clauses ensuring expedient commercialization, or locate licensees in the best position to exploit the technology.56

The Act also requires that recipients and their assignees “may not grant an exclusive license to use or sell a subject invention in the United States unless the licensee ‘agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the [United States]’”57 This provision, while it does not apply to the recipients themselves and is often waived, serves to protect the interests of the public in providing employment within the United States.58 Notably, the Act does not appear to require government-funded research to be conducted in the United States. Agencies may also “require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees.”59 The agency must keep reported information confidential.60 This provision ensures that funding agencies are kept apprised of commercialization and use efforts and protects the recipient’s or licensee’s proprietary interests by keeping that information confidential.

Nonprofit organizations, including some universities, are subject to additional requirements, such as sharing licensing royalties with inventors and “the balance of any royalties or income earned by the contractor with respect to subject inventions, . . . [must] be utilized for

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54 Id.
56 See SMITH & PARR, supra note 51, at 322 (“When granting licenses, universities sometimes desire to license more than one party.”).
57 FLOWER, supra note 30, at 28 (citing 35 U.S.C. § 204).
58 See id.
59 Id. (quoting 35 U.S.C. § 202(c)(5)).
60 See id.
The possibility of royalties accruing to the inventor provides an incentive for the inventor to invent, disclose the invention, and participate in the commercialization of the invention. This leads to the probability that more inventions will be created and brought to market, thus benefiting the employer of the inventor, subsequent licensees, and the public. Royalties reinvested in scientific research or education provides an additional source of research monies for nonprofits. Moreover, the prospect of collaborations with private industry which may lead to additional funding is attractive to researchers. Nonprofit organizations must give preference to small businesses in licensing and are “prohibit[ed] from assigning rights to a subject invention except where such assignment is made to an organization which has as one of its primary functions the management of inventions.”

Subsequent to the retention of title to the subject invention by the recipient, the government retains several rights designed to protect the interests of the government and the public. First, the government retains a non-exclusive right to practice the invention and have the invention practiced on behalf of the government. This license is non-transferable and only applies to government activities or purposes. Unfortunately, it is unclear as to what would constitute a government activity or purpose. Second, the government retains so-called “march-in rights,” which allows the government to license the technology. Third, the government retains “the right to take title from the contractor if it fails to apply for, prosecute, maintain, or defend a patent on a subject invention.” These provisions ensure that the government’s and public’s interests are protected by ensuring that the government has a right to practice the invention and also the right to take title to the invention if, for example, a recipient or licensee is failing to use an invention or engaging in conduct which may lead to a forfeiture of rights.

The recipient of the funding as holder of title may require a licensee to provide it with royalties or a lump sum payment in exchange for an exclusive or nonexclusive license. The prospect of receiving additional funds for research and development is an important incentive.

61 Id. at 29 (quoting 35 U.S.C. § 202(c)(7)(C)).
62 See SMITH & PARR, supra note 51, at 323-24 (“Researchers are encouraged by the chance that an intellectual exchange and collaboration with industrial partners may attract financial sponsorship of additional research.”).
64 Id. § 202(c)(4).
65 Id. § 202(c)(4).
68 FLOWER, supra note 30, at 21.
to nonprofits, particularly universities. This is particularly important because of the decline of research dollars provided by the U.S. government. Notably, the U.S. government does not retain a right to royalties to any invention it funds. Moreover, the Act represents a federal policy that favors the patenting of government-funded inventions and does not encourage government-funded inventions to be dedicated to the public domain except perhaps in “exceptional circumstances.”

The benefit to the public of having government-funded inventions unencumbered by patent rights is that researchers can use those inventions to further innovate without having to pay a license fee.

II. PRAISE AND CRITICISM OF THE BAYH-DOLE ACT

The Bayh-Dole Act has been subject to substantial praise and criticism. The following sections discuss the purported positive impact of the Act and critiques of the Act.

A. The Asserted Positive Impact of the Bayh-Dole Act

A recent resolution introduced in the House of Representatives commemorates the twenty-fifth anniversary of the Act as well as its supposed success. The resolution credits the Bayh-Dole Act with stimulating “the development of the biotechnology and information communications industry” and states that it “is poised to continue playing a central role in the new fields of innovative activities, including nanotechnology.”

The resolution further states that the Act “has resulted in benefiting taxpayers by generating millions of dollars in annual licensing royalties for universities and nonprofit institutions” and has created more than 4,000 new companies “to develop and market academic research.”

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69 See SMITH & PARR, supra note 51, at 319 (“It is important to keep in mind the mission and goals of universities when negotiating license agreements or presenting corporate capabilities to universities. The amount of license income that a university might receive from doing a deal is only one of many factors that universities consider when selecting a licensee.”).

70 Eisenberg, supra note 8, at 1666.

71 The author is indebted to Professors Charles McManis and Sucheol Noh for their earlier excellent work on the impact of the Bayh-Dole Act. See Charles McManis & Sucheol Noh, Impact of the Bayh-Dole Act on Genetic Research and Development: The Empirical Evidence to Date (manuscript on file with author).


73 Id.

74 Id.
about the Act from The Economist, the former counsel to the Wisconsin Alumni Research Fund, the director of the Technology Transfer Office at the Massachusetts Institute for Technology, and the President’s Council of Advisors on Science and Technology. The resolution concludes with the following statements, including a commitment to the Act:

Resolved by the House of Representatives (the Senate concurring), That it is the sense of the Congress that—

(1) the Bayh-Dole Act (Public Law 96-517) has made substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in public health and safety, strengthened the higher education system in the United States, served as a catalyst for the development of new domestic industries that have created tens of thousands of new jobs for American citizens, strengthened States and local communities across the country, and benefited the economic and trade policies of the United States; and

(2) it is appropriate that the Congress reaffirm its commitment to the policies and objectives of the Bayh-Dole Act by acknowledging its contributions and commemorating the silver anniversary of its enactment.

The President of the Association of University Technology Transfer Managers (AUTM) recently made the following arguments in defense of academic technology transfer, based upon AUTM Licensing Surveys and government reports. First, more than 3,800 U.S. patents were issued in 2004 to universities and less than 250 were issued to universities in 1980. Second, over 3,100 new products have been brought to market based on university or nonprofit research since 1998. Third, 4,543 companies have been created based on licenses from universities and nonprofits since passage of Bayh-Dole. Finally, according to the Biotechnology Industry Organization, almost 200,000 U.S. residents are employed in the biotechnology field. Other commentators have noted that, “in 1965, a mere 28 universities received just 96 patents, and by 1980, 25 universities received just 150 patents, by 1992, 150 universities received nearly 1,500 patents—an increase of over 1500% for a period when overall U.S. patenting rose less than

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75 Id.
76 Id.
78 Id. at 1.
79 Id.
80 Id.
81 Id.
Moreover, in 2004 alone, “[l]icense income received from licenses/options in fiscal year 2004 . . . was $1.385 billion reported by 196 institutions, up 6 percent from $1.306 billion in fiscal year 2003 reported by 194 institutions.”83 Additionally, “[r]unning royalties on product sales in fiscal year 2004 were $1.122 billion reported by 187 institutions, up slightly from $1.119 billion in fiscal year 2003 reported by 189 institutions.”84 There has been an 800% increase since 1980 of universities that have transferred technology to industry.85 The increased licensing, patenting, start up activity and the generation of licensing revenue since passage of the Bayh-Dole Act is impressive. The question of whether some or all of the economic activity is the direct result of passage of the Act is a much more difficult question to answer,86 although Congress seems very willing to make that assumption.87

Despite the praise and the statistics purportedly demonstrating the positive impact of the Bayh-Dole Act, the very basis and purpose of the Act have been criticized as have the unintended consequences of the Act. The following sections discuss that criticism.

**B. Challenging the Need for the Bayh-Dole Act**

Criticism of the Bayh-Dole Act includes challenges to the empirical data used to support the Act, and arguments against double-paying for inventions by the public. Finally, a recent study argues that the benefits of the Act may have occurred without passage of the Act.

1. **Selection Bias**

The empirical evidence used in support of the basic argument

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82 McManis & Noh, supra note 71, at 12.
83 See AUTM SURVEY, supra note 77, at 3.
84 Id. at 3.
86 See Jerry G. Thursby & Marie C. Thursby, University Licensing Under Bayh-Dole: What are the Issues and Evidence? 8 (May 2003), available at http://opensource.mit.edu/papers/Thursby.pdf (“Does university licensing under Bayh-Dole satisfy the Act’s intent? While it is unclear what might have transpired in the absence of the Bayh-Dole Act, it is clear that the Act has at least facilitated technology transfer from universities.”); see also Rebecca Henderson, Adam B. Jaffe & Manuel Trajtenberg, Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965-1988, 80 REV. OF ECON. & STAT. 119, 126 (1998) (“Clearly, the Bayh-Dole Act has been a success with respect to the second of these incentive effects. Both the rate of patenting and the extent of licensing have increased dramatically.”).
underlying the justification for the Bayh-Dole Act is subject to question for at least two reasons. According to proponents for the Bayh-Dole Act, a large number of government owned patents covering technology that was not being licensed, and thus further commercialized, because nonprofits or private industry were unable to secure ownership of the technology to justify continued investment in the commercialization of that technology.88 According to Professor Eisenberg, the group of patents that was used to justify the argument that an inability of nonprofits and private industry to own those patents was the reason why the patented technology languished with the federal government was subject to a huge selection bias.89 A large number of those patents covered inventions that were created through Department of Defense-sponsored research, and pursuant to the sponsorship contracts, the contractors were generally allowed to obtain title to those patents.90 Thus, the patented inventions in that group of patents had already been rejected by industry, and it should not be surprising that other industry participants would also not want to obtain title to those patents.91 “Rather than attributing the low licensing rate to government ownership or to the unavailability of exclusive licenses, one might ask why such commercially irrelevant inventions were patented at all.”92 Indeed, two commentators admit that the oft repeated assertion that of the 28,000 to 30,000 patents that the federal government held in 1978, less than 4 to 5 percent were ever successfully licensed, was apparently based on flawed data, and thus never should have been cited as evidence that the results of government-sponsored research was languishing in federal archives.93

Finally, using the number of government owned patents that were not licensed to industry is misleading.94 It is unclear how much of the technology covered by government owned patents was actually being commercialized and how much of the technology not covered by government-owned patents but developed through the use of government funding was being commercialized.95 It apparently was “common knowledge” that prior to the enactment of the Bayh-Dole

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89 See Eisenberg, supra note 8, at 1702.
90 Id.
91 Id. at 1703.
92 Id.
93 McManis & Noh, supra note 71, at 11.
94 See Eisenberg, supra note 8, at 1703-04.
95 Id. at 1704.
Act government owned inventions could be used without a formal license. Moreover, there is no “data on the utilization of unpatented government-sponsored discoveries by industry.”

2. Double Payment

A fundamental problem with the Bayh-Dole Act is that the public arguably pays twice for the same invention. The public funds the research. The grant recipient is allowed to take title to the patentable inventions created through the research. The grant recipient obtains a patent for the patentable inventions and then may extract a supra-competitive price from the public. This results in double paying.

In general, the grant of patent rights attempts principally to cure one problem: the problem of underproduction. Because information goods, which are intangible, are public goods, it is believed that information goods will be produced below the socially optimal level because there are insufficient incentives to produce those goods. Patent rights attempt to solve that problem by providing exclusive rights in those goods to provide an ex ante incentive for inventors or authors to create those goods. The grant of exclusive rights ensures inventors or authors that they will be able to recoup some of their development costs. Practically, this is not true in all situations; for example, there may be a substitute for the patented invention or the inventor may need to secure regulatory approval to practice the invention. The U.S. Constitution provides the source of Congress’ authority to create exclusive rights for inventors for limited times to provide an incentive for the creation of information goods: to promote the progress of the useful arts. The question of whether the patent system actually achieves this goal is open to debate and some argue that the desire to be first to market may be a sufficient incentive to invent for some types of inventions.

The Bayh-Dole Act is directed to a different problem than the grant of intellectual property rights and the purpose of that grant: providing an ex ante incentive to create information goods. The Bayh-Dole Act is principally concerned with underuse of information goods not underproduction. The Bayh-Dole Act addresses this problem by shifting ownership from the party that funded the innovation, the government, to a party who may be able to effectively commercialize

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96 Id.
97 Id.
98 There are costs associated with a grant of exclusive rights in information goods. For example, the owner of patent rights will raise the price of the information goods above the competitive level and extract a supra-competitive price. The difference between the competitive price and the price secured by the owner is considered a deadweight loss.
the invention or license it to an entity that can commercialize the invention. Thus, the Bayh-Dole Act is concerned with ex post incentives.

A defense of the Bayh-Dole Act is based upon the premise that “the public was paying for the research and deriving no benefit from it . . . , thus wasting public funds.”

However, instead of the public choosing between paying once and getting nothing, or paying twice and getting something, the public may have only had to pay once to get something. Moreover, the argument that patent rights are necessary for commercialization may not be true for most research tools. A research tool is generally used to aid further research, but it is unnecessary for there to be further research on the tool itself. There may already exist a market for some of those tools and thus, additional commercialization is unnecessary. Thus, for the supposed basic research that is funded by Proposition 71 or other states, it may be unnecessary to allocate patent rights at the outset, and the funder should make a considered decision as to whether a recipient should receive title for its innovation. Or, research tools should always be non-exclusively licensed. Moreover, an exclusive license should be reserved only for those situations when it is necessary that private capital is used for further commercialization.

3. Benefits of Technology Transfer Absent the Bayh-Dole Act

As discussed supra, since the passage of the Bayh-Dole Act in 1980, there has been a substantial increase in the number of government-funded inventions that have been patented and licensed by universities. Often the upswing in patenting and licensing and the economic impact from that patenting and licensing has been directly attributed to the Bayh-Dole Act. In a recent major study, a group of researchers examined the question of whether the Bayh-Dole Act is the cause of the increase in patenting and licensing by universities. The researchers found that, “[e]ven without the Bayh-Dole Act . . . university patenting would have grown significantly during the 1980s and 1990s [and] that the Bayh-Dole Act was one of several factors that contributed to the growth of patenting and licensing by U.S. universities

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99 Pulsinelli, supra note 24, at 411.
100 This is likely not true for all research tools. Some research tools are part of the end product that is sold to the public. For an extensive discussion of the commercialization theory and the Bayh-Dole Act, see McManis & Noh, supra note 71, at 9-11.
101 See Rai & Eisenberg, supra note 24, at 289, 294.
during the 1980s and 1990s.” \(^{104}\) The researchers asserted that many U.S. universities engaged in patenting and licensing before 1980 and “expanded these activities during the 1970s and early 1980s in response to advances in biomedical research and changes in the legal treatment of patents on life forms.” \(^{105}\) Thus, in addition to the development of biomedical research, legal changes also likely caused increased patenting and licensing, which included the creation of the U.S. Court of Appeals for the Federal Circuit, \(^{106}\) a clarification of patent eligible subject matter to include living organisms in \textit{Diamond v. Chakrabarty} \(^{107}\) and a change in the utility requirement allowing patenting closer to the laboratory bench in \textit{In re Brana}. \(^{108}\) The researchers further found that:

[[the contributions of U.S. universities to economic growth and innovation during the 1980s and 1990s assuredly were important, but no evidence suggests that these contributions were more important than they were during the 1930s and 1950s. Nor does any evidence “prove” that Bayh-Dole substantially increased these contributions or that any such expansion would not have occurred in the absence of this Act. \(^{109}\)

Moreover, U.S. universities, through publications, conference presentations, faculty consulting and personnel movement between industry and universities, have been a critical source of knowledge and research inputs for industry for the last 100 years. \(^{110}\) And, the “evidence’ of low rates of commercialization before Bayh-Dole is weak.” \(^{111}\) The authors conclude that, “much of the current discussion of the economic role of U.S. research universities and the contributions of U.S. universities to the economic boom of the 1990s exaggerates the

\(^{104}\) \textit{Id.}

\(^{105}\) \textit{Id.} at 2. “Since the trend toward increased academic patenting and licensing (including patenting of government-funded research) predates the passage of Bayh-Dole, the Act’s most important effect arguably was its provision of a congressional endorsement of patenting and licensing (including exclusive licensing) as appropriate activity for universities and public laboratories.” \textit{Id.} at 181.

\(^{106}\) See \textit{ADAM B. JAFFEE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS} 10 (2004).

\(^{107}\) \textit{See} \textit{Diamond v. Chakrabarty}, 447 U.S. 303 (1980); \textit{see also} \textit{MOWERY ET AL., supra} note 103, at 3.

\(^{108}\) 51 F.3d 1560 (Fed. Cir. 1995).

\(^{109}\) \textit{MOWERY ET AL., supra} note 103, at 183.

\(^{110}\) \textit{Id.} at 2, 179; \textit{see} David C. Mowery, The Bayh-Dole Act and High-Technology Entrepreneurship in U.S. Universities: Chicken, Egg, or Something Else? 25 (2005), \textit{available at} http://entrepreneurship.eller.arizona.edu (“A substantial body of research suggests that industry and academic researchers interact and exchange knowledge through a diverse array of channels, among which patenting and licensing is but one and in most sectors far from the most important one.”); \textit{see also} Thursby & Thursby, \textit{supra} note 86, at 10. (“Prior to the passage of Bayh-Dole, universities had a long tradition of working with industry. Moreover, there is clear evidence from patent citations that industrial labs picked up university inventions from publications, so it is difficult to determine if licensing displaced or enhanced this activity.”).

\(^{111}\) \textit{MOWERY ET AL., supra} note 103, at 184.
Based on the authors’ research it is unclear whether passage of the Bayh-Dole Act was necessary to achieve its purported benefits. Thus, society may be able to enjoy the economic benefits of the Bayh-Dole Act resulting from the commercialization of government-funded inventions without some of the Act’s unintended consequences. Or, at least, the development of the evidence of the unintended consequences caused by increased patenting and licensing would have occurred at a slower rate. Accordingly, some of the purported unintended consequences of the Act, such as the creation of conflicts of interest with academic researchers, diversion of research agendas and withholding of material may have occurred absent passage of the Act, but, at least, at a slower, incremental pace. The Bayh-Dole Act, thus, may have just provided a catalyst to increase the rate of patenting and licensing higher than without the Act. The benefit of moving at a slower pace may have provided the institutions additional time to react to changes before reliance interests developed.

The authors, however, are “asserting a counterfactual—namely that ‘much’ of the post-1980 upsurge in university patent and licensing would have occurred even if the Bayh-Dole Act had not been enacted.” Professors Charles McManis and Sucheol Noh argue that the researchers bear the burden of proof to prove the counterfactual and fail to do so. However, Professors McManis and Noh admit that the researchers present “persuasive evidence” that some universities were engaged in patenting before passage of the Act and that there were additional causes to the upswing in patenting after passage of the Act.

Whether the full purported benefits of the Act would have occurred in the absence of the Act may be debatable. However, the question remains whether the Act as it stands is worth the difference between the amount of benefits that would have accrued with the Act and without it. This question is particularly important because of the apparent failure of the provisions designed to provide access to government-funded inventions and the potential negative consequences of the Bayh-Dole Act.

112 Id. at 179.
113 McManis & Noh, supra note 71, at 15 n.69.
114 Id. (“[T]heir evidence falls short of proving the counterfactual being asserted, as even they concede that ‘the Bayh-Dole Act accelerated growth of university patenting and resulted in the entry into patenting and licensing by many universities during the 1980s’; that ‘aggregate university ‘patent propensity’ does increase after 1981’; that an important factor that ‘affected growth in patenting by universities during the 1970s was the negotiation of [Institutional Patent Agreements] with federal research funding agencies’; and that ‘prior to 1980, federal policy remained ambivalent toward university licensing, [as] evidenced in the debates over the appropriateness of exclusive licensing under IPAs.”) (citations omitted).
115 Id.
C. The Unintended Consequences of the Bayh-Dole Act

The Act may have resulted in numerous unintended consequences not considered at the time it was passed. For example, provisions designed to ensure access to government-funded inventions have not been exercised or utilized frequently, an anticommons may develop, there may be a shift in research agendas, a delay in publication or dissemination of research results and materials may exist and conflicts of interest may be created.

1. Failure of Provisions of the Bayh-Dole Act Designed to Ensure Access

The Bayh-Dole Act contains two provisions which are supposed to protect the interests of the public and ensure that technology is either available to the public or will be commercialized. The two provisions are the “exceptional circumstances” provision and the “march-in” provision.

a. March-In Rights

The Bayh-Dole Act provides for government “march-in rights,” which allow the government to compel an owner of a patent covering a federally funded invention to license its rights to a third party for several stated reasons, including:

- action is necessary because the [grantee] 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; (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensee . . . .

To date “march-in” rights have not been exercised. The ability to exercise “march-in” rights is encumbered by a complex set of regulations, including provisions allowing for appeal of any decision to exercise such rights, and could serve as a disincentive to use those rights. Apparently, only three petitions requesting the Government to

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116 The Bayh-Dole Act also provides that the government retains a nonexclusive license to practice the invention or have the invention practiced on its behalf. Pulsinelli, supra note 24, at 408.
118 FLOWER, supra note 30, at 22.
exercise “march-in” rights have ever been filed.119 In the three cases, the Government determined that the use of “march-in” rights was not warranted.120

In the first matter, Cell Pro, Inc. petitioned the Government to exercise march-in rights because the owners of the patents concerning a stem cell purification and suspension technology, John Hopkins University (Hopkins) and Baxter Healthcare Corporation (Baxter), had failed to take reasonable steps to commercialize the technology and because such action was necessary to alleviate health and safety needs.121 The filing of the march-in petition arose out of litigation and failed license negotiations between CellPro and Hopkins and Baxter.122 In the march-in rights determination, the NIH first examined whether Hopkins and Baxter had taken or were expected to take within a reasonable time, effective steps to achieve practical application of the subject invention.123 First, the NIH noted that Hopkins had exclusively licensed the technology to Becton-Dickenson & Co., who began marketing the anti-CD34 antibody in 1985 and has since sold the anti-CD34 antibodies worldwide.124 Becton-Dickenson & Co. then exclusively sublicensed therapeutic rights to Baxter which subsequently began development of a therapeutic system and sublicensed rights to Applied Immune Sciences.125 By late 1991, Baxter developed a prototype stem cell selection device and began clinical trials with the device the next year.126 In 1995, Baxter’s Isolex 300 System received regulatory approval in Europe and “[i]n the U.S., Baxter’s systems have been installed in numerous transplant centers over the past three years.”127 “[T]he Baxter device has been used in clinical trials to process peripheral blood and bone marrow for hematopoietic reconstitution in patients.”128 “On February 24, 1997, Baxter filed for Pre-market approval” of its Isolex 300SA System with the Food & Drug

120 Id.
122 Id. at 1100.
123 Nat’l Insts. of Health, Determination in the Case of Petition of CellPro, Inc., at 1.
124 Id. at 5.
125 Id. at 5.
126 Id.
127 Id.
128 Id.
The NIH determined that this activity along with, notably, aggressive defense of the patents in court, constituted “effective steps to achieve practical application.”

The NIH also determined that Hopkins and Baxter took appropriate steps to reasonably satisfy the health and safety need for the patented technology. First, the NIH stated that, “[Hopkins and Baxter] have refrained from enforcing patent rights to the full extent of the law in order to allow the continuing sale of [CellPro’s device] until the Baxter product is approved for sale by the FDA.”

Second, Hopkins and Baxter “have pledged to ensure that the Baxter product is as widely available as possible through clinical trials, and to ensure patient access to the fullest extent possible.” CellPro argued that if it is made to pay Baxter for sales of the CellPro device under the terms proposed by Baxter, CellPro would be forced out of business and the public would not have the benefit of its device. Notably, the NIH stated:

> we believe it is inappropriate for the NIH to intercede in this matter to ensure CellPro’s commercial future. Viability and success in the private sector is appropriately governed by the marketplace, and significantly influenced by management practices and decisions. CellPro had the opportunity to license the invention from Baxter but decided against doing so, and instead risked patent infringement litigation. It would be inappropriate for the NIH, a public health agency, to exercise its authorities under the Bayh-Dole Act to procure for CellPro more favorable terms than it can otherwise obtain from the Court or from the patent owners. CellPro’s commercial viability is best left to CellPro’s management and the marketplace.

Finally, the NIH relied upon Baxter’s commitment that it would install “its device free of charge at any site from which CellPro might withdraw, and to provide that site with the same level of support on the same terms as CellPro” to ensure that “there would be no gap in patient access to stem cell separation technology.” The NIH stated that it would “continue to monitor the situation and will retain jurisdiction to initial march-in without the filing of a new request, in the event that health needs are not being reasonably satisfied.”

In the case of Norvir, the NIH again refused to exercise march-in rights pursuant to the Bayh-Dole Act. Norvir is a pharmaceutical

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129 Id.
130 Id.
131 Id. at 6.
132 Id.
133 Id. at 7.
134 Id. at 8.
135 Id.
136 Id.
137 Nat’l Insts. of Health, Office of the Director, Opinion in the Case of Norvir 1 (July 29,
used in treating HIV/AIDS. The NIH determined that Norvir has reached practical application and achieved wide dissemination because Norvir has been on the market and available for the treatment of HIV/AIDS for at least eight years. The NIH also found that there was no evidence that there was a health and safety need to be alleviated as Norvir has been approved by the FDA as safe and effective, and is widely prescribed and used. The NIH also rejected the argument that Norvir should be available at a lower price. The NIH stated:

Finally, the issue of the cost or pricing of drugs that include inventive technologies made using Federal funds is one that has attracted the attention of Congress in several contexts that are much broader than the one at hand. In addition, because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus is appropriately left for Congress to address legislatively.

In the case of Xalatan, the NIH again refused to exercise march-in rights. Xalatan is a pharmaceutical used in treating glaucoma. The NIH found that the invention reached practical application and achieved wide dissemination because it has been on the market and available for use for eight years. The NIH further found that Xalatan has been approved by the FDA and is widely prescribed and used and thus, there is no evidence of any health and safety need that warranted alleviation. The NIH also made the same arguments made in the Determination in Norvir in rejecting petitioner’s arguments that the government should exercise march-in rights because Xalatan is offered for a much lower price in Canada and Europe than in the United States.

Notably, in the CellPro, Norvir, and Xalatan matters, the NIH refused to exercise march-in rights to address issues related to pricing. Clearly, the NIH did not believe that it had within its authority to grant licenses to ensure that a technology is disseminated at a certain price.

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138 Id. at 5.
139 Id. at 5.
140 Id.
141 Id. at 5-6.
142 Id. at 5-6.
143 Id.
144 Id. at 5.
145 Id.
146 Id. at 5-6.
even if a “high” price may result in less use of the government-funded technology.\textsuperscript{147}

b. Exceptional Circumstances

The “exceptional circumstances” provision in 35 U.S.C. § 202 allows the funding agency to restrict or eliminate the right to retain title; however, the nonprofit organization or small business firm is entitled to appeal that determination. Subsection (a) of section 202 provides:

Each nonprofit organization or small business firm may . . . elect to retain title to any subject invention: \textit{Provided, however,} That a funding agreement may provide otherwise (ii) in 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.\textsuperscript{148}

The exceptional circumstances provision has been rarely applied.\textsuperscript{149} The question becomes why this provision has been rarely applied. One problem is that it is only applied in exceptional circumstances and thus is not to be applied routinely.\textsuperscript{150} It may be also very difficult to draw the line between what is exceptional and what is not, especially since the decision to find a situation exceptional is subject to extensive review by the Department of Commerce and the courts. Notably, this is an \textit{ex ante} decision to allow a recipient to grant title in the results of government-funded research.\textsuperscript{151} The research has not been completed. Because of the uncertain nature of biotechnology research in particular, it may be unclear at the time of the award of funds whether this particular research proposal justifies a determination of “exceptional circumstances.”\textsuperscript{152}

\begin{footnotesize}
\begin{enumerate}
\item[147] See John H. Raubitschek & Norman J. Latker, \textit{Reasonable Pricing—A New Twist for March-in Rights Under the Bayh-Dole Act}, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 149, 167 (2005) (“There is no reasonable pricing requirement under 35 U.S.C. § 203(1)(a)(1), considering the language of this section, the legislative history, and the prior history and practice of march-in rights. Rather, this provision is to assure that the contractor utilizes or commercializes the funded invention. However, that does not mean that the price charged for a drug invented with Government funding is never of concern to the funding agency. There are other mechanisms to address this concern, including the health march-in authority of 35 U.S.C. § 203(1)(a)(2), the Government license in 35 U.S.C. 202(c)(4), and eminent domain in 28 U.S.C. § 1498(a).”); Amy R. Schofield, \textit{Currents in Contemporary Ethics: The Demise of Bayh-Dole Protections Against the Pharmaceutical Industry’s Abuses of Government-Funded Inventions}, 32 J.L. MED. & ETHICS 777 (2004) (criticizing NIH’s statements in Determination in Norvir that Bayh-Dole does not provide the authority for NIH to control pricing of products).
\item[149] Rai & Eisenberg, \textit{ supra} note 24, at 289, 294.
\item[150] \textit{Id.} at 294.
\item[151] Pulsinelli, \textit{ supra} note 24, at 396.
\item[152] \textit{Id.}
\end{enumerate}
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Several commentators have offered proposals for the modification of the Bayh-Dole Act. Professors Arti Rai and Rebecca Eisenberg argue that the “march-in” and “exceptional circumstances” provisions should be modified, while Professor Gary Pulsinelli critiques their proposal and offers his own proposal.

Professors Rai and Eisenberg’s proposals particularly concern the “challenge . . . in distinguishing discoveries that are better developed and disseminated through open access from discoveries that are better developed and disseminated under the protection of intellectual property rights.” Their arguments for legislative change are directed to the “exceptional circumstances” and the “march-in” provisions and propose to provide funding agencies with more discretion to determine which government-funded inventions should be placed in the public domain. First, the authors argue that the word “exceptional” should be removed from the statute, thus resulting in a liberalization of the situations in which funding agencies can deny the grant of title to inventions developed from federally-funded research. The substantive standard would then be “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 objects of this chapter.” Accordingly, the provision could be invoked more frequently to ensure the widespread dissemination of research results.

Second, the authors assert that the march-in rights should be modified so that those rights are not held in abeyance during the exhaustion of court appeals. The authors argue that the delays associated with the appellate process contradict the asserted standard of the provision, which is practical application of the invention in a reasonable time and “alleviating health or safety needs.” According to the authors, “[u]nlike a prospective agency determination to restrict patenting at the grant stage before any invention has been made, a subsequent exercise of march-in rights disturbs settled expectations of grantees and licensees that may underlie investments.” The authors’ two proposals will provide the parties with the knowledge and incentives, the funding agencies, the power to make the determination of whether title should be withheld or march-in rights should be exercised.

Professor Pulsinelli argues that Professors Rai and Eisenberg’s proposal to require the NIH to determine in advance which funding

153 Rai and Eisenberg, supra note 24, at 310.
154 Id. at 291-93.
155 Id.
156 Id.
157 Id. at 311.
158 Id.
159 Id.
160 Id. at 291.
agreements will result in research that should be patented or not patented is unworkable. In challenging Professors Rai and Eisenberg’s proposal to eliminate the “exceptional” language in the statute, Professor Pulsinelli asserts that unfettered discretion with the funding agency to determine whether a funding recipient should receive a patent or exclusive license is exactly the situation that existed prior to the passage of the Bayh-Dole Act—a situation that arguably resulted in fewer results from federally funded research being brought to market. Professor Pulsinelli also argues that the funding agencies, such as the NIH, do not have the institutional competence to make the decision of whether a particular invention will need further development and a patent vis-à-vis those inventions that do not need additional development and do not require a patent. According to Professor Pulsinelli, the NIH’s mission is to advance scientific knowledge by engaging in research and funding the research of others, but not to determine whether a discovery needs a patent to be developed. Further, according to the former president of the University of Tennessee Research Corporation, the NIH would have to hire over 1,000 new employees to do this job properly. Finally, Professor Pulsinelli argues that, in fact, no one could make the determination that Professors Rai and Eisenberg desire. Professor Pulsinelli asserts that the proposed reform would require a two step ex ante determination at the time of drafting the funding agreement: “(1) Predict what invention or inventions will be created under the funding agreement, and then (2) predict whether any such postulated invention(s) will be better developed with a patent or without one.” The first prediction is difficult to make because the actual direction of research often is different from the planned direction. The second prediction is almost impossible to make, except for obvious determinations, because of “the wide range of viewpoints on the process of development and the lack of consensus of what will and will not lead to optimum development of inventions.” Professor Pulsinelli finally argues that the determination of whether a patent impedes or encourages development of an invention is difficult in hindsight let alone in advance.

Professor Pulsinelli offers an alternative proposal to Professors Rai and Eisenberg’s proposal. Professor Pulsinelli argues that “[a]ll

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161 Pulsinelli, supra note 24, at 436.
162 Id.
163 Id. at 437-40.
164 Id. at 437-38.
165 Id. at 438.
166 Id. at 441.
167 Id.
168 Id.
169 Id.
researchers whose work is supported by federal funds should have a limited, royalty free license to make and use for research purposes all inventions developed with federal funds.\textsuperscript{170} Professor Pulsinelli argues that this proposal puts fundamental research in the hands of academic researchers and does not require any review of a funding agreement or litigation concerning “whether an invention should be patented or dedicated to the public domain.”\textsuperscript{171} Private researchers would likely have to take a license under this approach. Professor Pulsinelli’s approach is likely much broader than the Rai and Eisenberg approach and would impact more government-funded inventions.

Another approach to increase access to inventions developed pursuant to the provisions of the Bayh-Dole Act is to amend the Act to provide the government with a transferable non-exclusive license that can be provided by the government when a party with exclusive rights to an invention created by federal funding is unreasonably withholding a license to that invention.\textsuperscript{172} A group of authors have proposed that an anticommons problem or an access problem to patented basic research can be resolved with changes to patent law doctrine. For example, some commentators propose reinvigorating the common law experimental use doctrine or using the utility doctrine to restrict the granting of patents on basic research.\textsuperscript{173} However, biotechnology

\textsuperscript{170} Id. at 442-43.
\textsuperscript{171} Id.
companies rely on the patent rights to allow them to secure funding to operate and it is unclear whether an anticommons has developed or research has been impeded by granting patents on basic science; thus, expansive changes to patent law doctrine are likely unwarranted.\textsuperscript{174} Given that the march-in rights have never been exercised and the exceptional circumstances provision is rarely invoked, a method to increase access to inventions resulting from government-funded research should be investigated and adopted. This is particularly true given the possibility of an anticommons problem developing, which is discussed next. Further review of proposals to alter the Bayh-Dole Act to achieve its stated purpose should be continued.

2. The Tragedy of the Anticommons

In an article published in 1998, Professors Michael Heller and Rebecca Eisenberg asserted that a “tragedy of the anticommons” may develop in biotechnology innovation because of a grant of concurrent rights in potential biotechnology end-products, high transaction costs, heterogeneity of rights holders and cognitive biases.\textsuperscript{175} An unintended
consequence of the passage of the Bayh-Dole Act may be the development of an anticommons, which would result in the development of fewer biotechnology end-products. This is a problem which may arise in the embryonic stem cell arena. Professors McManis and Noh reviewed the recent literature investigating whether a tragedy of the anticommons exists in biotechnology innovation.

The tragedy of the anticommons theory holds that if you grant too many rights in a particular piece of property, then rights holders may block one another so that no one party is able to effectively use the property. In a system designed to promote innovation through the grant of proprietary rights, a problem arises, which is that a subsequent inventor may need to use the work of a prior inventor to continue to innovate. The prior inventor’s patent on a particular invention is called the dominant patent and the subsequent patent on the “improvement” is called the subservient patent. The two patents are deemed to be blocking because the prior inventor cannot exploit the subsequent inventor’s patent and the subsequent inventor cannot exploit his or her own invention because of the prior inventor’s patent. This problem can be compounded by the grant of numerous intellectual property rights in one particular product or service that may be commercialized. If parties are unable to aggregate their rights, then the product or service may never be brought to market. This results in underuse.

Ordinarily, an anticommons can be overcome by transferring rights. However, if there are transaction costs, strategic behaviors, and cognitive biases, parties may be unable to transfer their rights to

The theory has subsequently been criticized in Richard A. Epstein & Bruce N. Kuhlik, Is There a Biomedical Anticommons?, REGULATION, Summer 2004, at 54..

176 “Since 1996, Geron has invested more than $90 million pioneering the field of human embryonic stem cell research and plans to test its first embryonic stem cell therapy on humans in 2006.” Mike Lee, Geron Leads in Stem Cell Work, SACRAMENTO BEE, Dec. 19, 2004, at D1. [Geron’s] investment has generated at least 19 patents worldwide on human embryonic stem cells with 177 pending, the company reported earlier this year. That is believed to be the most extensive intellectual property collection in the industry, covering cells for the liver, heart, bone and nerves. Today, [the president of Geron] says his company is building an intellectual property “fortress” that he hopes will allow Geron to make money whenever and wherever stem cell-based therapies are commercialized.

Id. He has made public statements about the companies “broad, dominating patent estates,” and its commitment to “filing of oppositions and interference against competitors’ patents.” Id. “Geron is offering its technology free to California university researchers, a common way of getting scientists interested in technologies they otherwise couldn’t afford.” Id. “Geron still would expect royalties, of course, but Greenwood said researchers could take products to market however they want.” Id.

177 McManis & Noh, supra note 71, at 12.
178 Heller & Eisenberg, supra note 175, at 698.
179 This problem is also called a “patent thicket.” See generally Carl Shapiro, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in 1 INNOVATION POLICY AND THE ECONOMY (Adam Jaffee et al. eds., 2001).
180 Heller & Eisenberg, supra note 175, at 698.
avoid the anticommons. Heller and Eisenberg assert that because of changes in patent law doctrine allowing for the patentability of basic research discoveries, transaction costs, strategic behaviors and cognitive biases, a tragedy of the anticommons may develop in biotechnology innovation.181

Several studies have been conducted to inform the question of whether an anticommons has developed. The National Institutes of Health (NIH) formed a Working Group on Research Tools to determine if NIH researchers were encountering difficulties in accessing patented upstream inputs, such as research tools.182 The Working Group issued a report in 1998 and found that a “rising frustration” existed amongst public researchers concerning access to patented research tools and that private firms believe that access to patented research tools is impeding the progress of research. In a study published in 2002, researchers found that “drug discovery has not been substantially impeded” and that the patenting of research tools had not obstructed university research.183 The principal researchers involved in the 2002 study published a second study in September of 2005 because of the Federal Circuit’s decision in Madey v. Duke University, which limited the scope of the already narrow experimental use exception to patent infringement.184 The researchers found that, “[o]nly 1% of [the] random sample of academics had stopped a project due to the existence of third party patents on research inputs.”185 The researchers concluded that, “patenting does not seem to limit research activity significantly, particularly among those doing basic research, [although] [a]ccess to tangible research inputs from others is somewhat more problematic.”186

The National Academies of Science also published a study (NAS

181 Id. at 700-01.
183 John P. Walsh et al., Effects of Research Tool Patenting and Licensing on Biomedical Innovation, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (W.M. Cohen & S. Merrill eds., 2002). This study has been criticized by Professor Paul David. See Paul A. David, The Economic Logic of “Open Science” and the Balance Between Private Property Rights and the Public Domain in Scientific Data and Information: A Primer (2003), available at http://siepr.stanford.edu/papers/pdf/02-30.pdf. Professor David argues that The Walsh Study fails to include the questions asked of the survey participants and that evidence of an anticommons is difficult to find because the research is essentially trying to prove a counterfactual. Id. at 13-15. For further discussion of the Report of the National Institutes of Health Working Group on Research Tools, The Walsh Study and Professor David’s criticisms of The Walsh Study, see Mireles, supra note 172.
185 WALSH ET AL., supra note 184, at 2.
186 Id.
Study) in November 2005, wherein researchers were tasked with determining “the effects of patenting genomic and proteonomic inventions and/or licensing practices for inventions on research and innovation.” The researchers found that “the number of projects abandoned or delayed as a result of difficulties in technology access is reported to be small, as is the number of occasions in which investigators revise their protocols to avoid intellectual property issues or in which they pay high costs to obtain intellectual property.” The researchers concluded, in part, that “it appears that access to patented inventions or information inputs into biomedical research rarely imposes a significant burden for biomedical researchers.”

A report by the American Association for the Advancement of Science (AAAS Report) published in 2005 found that thirty-five percent of biotechnology researchers experienced difficulties with obtaining patented technology necessary for their work. The AAAS Report concluded by stating academia has been less affected than industry by more restrictive and formal licensing practices in the acquisition and distribution of patented technologies necessary for research [and] difficulties reported by bioscience industry respondents in attempting to access patented technologies outnumbered those of bioscience academic respondents by a ratio of more than 2:1.

In two recent studies, researchers examined the citation count of

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188 REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH, supra note 187, at 2.

189 Id. The report also recommends that the situation continue to be monitored and provides recommendations to lessen the probability that an access problem may develop. Id. at 2-3. A report by the Organisation for Economic Co-Operation and Development studied similar issues and arrived at similar results. See ORGANISATION FOR ECONOMIC CO-OPERATION AND DEV., GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES: EVIDENCE AND POLICIES 78 (2002), available at http://www.oecd.org/dataoecd/42/21/2491084.pdf. This continued monitoring is especially important given the impact on academic research and development of the decision in Madey v. Duke University, 307 F.3d 1351 (Fed. Cir. 2002), which limits the common law experimental use exception to patent infringement, and the “lack of substantial evidence for a patent thicket or a patent-blocking problem is associated with a general lack of awareness or concern among academic investigators about existing intellectual property.” See REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH, supra note 187, at 3.


191 Id. at 8; see also id. at 26. “However, that may be because industry respondents reported creating and holding more intellectual property than academic respondents, as well as the fact that industry relies more on licensing, which entails greater and longer negotiations than other more traditional and informal means of technology transfer still used in academia.” Id. at 8-9.
research that has been patented and the subject of a published journal article—so called “patent-paper pairs”—to determine if patenting is causing an “anticommons effect.”\textsuperscript{192} The researchers took advantage of the time lag between the filing of a patent and the granting of the patent to determine if there is a difference in the rate of citations before the patent grant and after the patent issues.\textsuperscript{193} In one study, the researchers found that, “there is robust evidence for a quantitatively modest but statistically significant anticommons effect; across different specifications, the article citation rate declines 9 to 17\% after a patent grant.”\textsuperscript{194} The second study found that, “genomic articles which are patented at a given point in time receive approximately 8 percent fewer U.S. citations than similar articles on which patents have not yet issued . . . [and f]or post-1990 sequence articles, patents cause a 14 percent decline in citations . . . .”\textsuperscript{195}

Recently, Professors McManis and Noh reviewed and evaluated the empirical evidence to date concerning the impact of upstream university patenting on downstream innovation and found that “little hard empirical evidence has been produced to substantiate . . . concerns” that an anticommons exists and that “most—though by no means all—of the most recently unveiled empirical studies suggest that these concerns are exaggerated.”\textsuperscript{196} A substantial amount of current empirical evidence supports the conclusion that an anticommons has not developed;\textsuperscript{197} however, most studies caution that an anticommons could develop, there is some evidence of an anticommons, and there are clear issues involving access to tangible property covered by a material


\textsuperscript{193} Murray & Stern, supra note 192, at 4; Sampat, supra note 29, at 5.

\textsuperscript{194} Murray & Stern, supra note 192, at 5.

\textsuperscript{195} Sampat, supra note 29, at 26. Professor McManis and Noh criticize both studies for failing to take into account the whether and to what extent the patent is being cited in the scientific literature and whether and to what extent either the article or the patent is being cited in the patent record, as the patent record is just as much a repository of accumulated public domain knowledge on which researchers may rely and build as the scientific literature is.

McManis & Noh, supra note 71, at 31-32. Professor McManis and Noh assert that:

[i]f a decline in citations in the scientific literature to an article that is part of a patent-paper pair can be shown to be offset by citations in the scientific literature to the corresponding patent and/or by citations to either the article or the patent in follow-on patent applications or academic researchers, then it would be difficult to conclude that the Sampat, Murray and Stern data accurately measure an overall decline in knowledge accumulation or that academic researchers are in fact being hindered in their ability to build (in the public domain) on a given piece of knowledge that is disclosed in a patent-paper pair.

Id. at 183.

\textsuperscript{196} Id. at 28.

\textsuperscript{197} There may be a problem with access to certain diagnostics. See generally WALSH ET AL., supra note 184.
3. Shift in Research Agendas

Some commentators have recognized and argued that the Bayh-Dole Act may have caused or will cause university researchers to shift their research agendas from pursuing basic science to applied science and that this shift will result in a net social loss. Because of that diversion, the public arguably does not receive the benefits of the spillover effects that may result from broadly applicable basic science. The lure of licensing revenues and royalties to universities and their researchers would pull their research agendas towards areas of research that may be more attractive to private industry. In a recent study entitled The Impact of Academic Patenting on the Rate, Quality, and Direction of (Public) Research, the authors found that their research did not support the claim that academic patenting has a negative effect on the creation of public science, but also found “that patenting has had

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198 Professor F. Scott Kieff proposes that a survey be conducted “of members of the basic biological science community designed to generate different types of data about the objective and subjective parameters involved when members of the biological science community participate in exchanges of material or information.” F. Scott Kieff, IP Transactions: On the Theory & Practice of Commercializing Innovation, 42 HOUS. L. REV. 727, 752-53 (2005) (“The data from this project will provide the first empirical evidence about the frequency and mechanisms of exchange failure and consummation relating to the use of patents in the basic biological research community so as to provide essential empirical evidence to help resolve the policy debate between patent critic and patent proponent theories.”).

199 See WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 316 (2003) (“Being able to earn substantial income from patent licensing has, it appears, induced universities to substitute away from basic research, and the result may have been a net social loss.”); Eisenberg, supra note 8, at 1714; see also Pierre Azoulay et al., The Impact of Academic Patenting on the Rate, Quality, and Direction of (Public) Research 1 (Nat’l Bureau of Econ. Research, Working Paper No. 11917, 2006), available at http://www.nber.org/papers/w11917 (“[S]urveys of academic scientists have found that patenting skews scientists’ research agendas towards commercial priorities, causes delay in the public dissemination of research findings, and crowds out effort devoted to producing public research results.”); see also Katherine J. Strandburg, Curiosity-Driven Research and University Technology Transfer, in ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH: UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY 53 (2005) (“The strongest motivation for a basic researchers to skew his research direction in an effort to obtain a patent is probably the possibility of industrial research funding.”). Notably, the distinction between basic and applied research is sometimes blurred particularly in some specific scientific fields, including biotechnology.

200 Researchers found that an “analysis of U.S. university patenting and licensing before and after 1980 also highlights the high concentration of these activities in a relatively narrow range of research fields, primarily biomedical sciences.” MOWERY ET AL., supra note 103, at 182. “The concentration of patenting and licensing in a relatively narrow array of academic fields means that the effects of increased patenting, before and after Bayh-Dole, on U.S. universities’ research culture cannot be described as pervasive.” Id. Thus, the shift in research agendas may only affect the biotechnology sector of university research.
real effects on the direction of scientific progress” by more closely tying research and development with commercial interests. In two other studies, researchers found that a significant shift from basic to applied research has not occurred since the passage of the Bayh-Dole Act. The empirical data on this question is also unclear and warrants additional scrutiny. Professors McManis and Noh suggest that the empirical evidence is not conclusive and is “at best mixed.”

The loss from that shift in research agendas may include the benefits received from advances in basic science, exploratory research that is “undertaken to discover new phenomena, or explain fundamental properties of physical systems,” that have tremendous spillover benefits, including inventions that are practically important. For example, “many important advances in instrumentation, and generic techniques, such as PCR and the use of restriction enzymes in ‘gene-splicing’ are practical applications of developments from basic research.”

Moreover, absent the proprietary system that the Bayh-Dole Act encourages, many large government-funded projects developed important technologies that were generally not subject to proprietary

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201 Azoulay et al., supra note 199, at 2. The authors of the Azoulay study do not believe that the option to patent substantially reduces academic scientists’ incentives to create public science and believe that patenting and publishing will be complementary. Id. at 4.

202 See Thursby & Thursby, supra note 86, at 5 (“In response to our question about reasons for increasing contracts with universities, almost 11% of industry respondents cite as extremely important a change in faculty research orientation toward the needs of business[, however, w]e find in a study of over 3400 faculty at 6 major research universities that the basic/applied split in research did not change over the period 1983-1999 even though licensing had increased by a factor greater than 10.”); Mowery et al., supra note 103, at 184 (“We have uncovered little evidence that the expanded patenting and licensing activities of U.S. universities since 1980 have produced significant shifts in the orientation of academic researchers away from fundamental research toward more applied, short-term research activities that might be more easily patented and licensed.”); Scott Shane, Academic-Entrepreneurship: University Spinoffs and Wealth Creation 282 (2004) (“While scholars of university spinoffs and technology transfer have not found any direct evidence to support the proposition that the opportunity to found university spinoffs leads researchers to focus on more applied research at the expense of basic science or to avoid research areas with limited commercial potential, they have found indirect evidence of these effects.”); cf. David Blumenthal, Academic-Industry Relationships in the Life Sciences: Extent, Consequences, and Management, 268 J. AM. MED. ASS’N 3344, 3346 (1992), finding:

Among respondents to the Harvard project’s faculty survey, 30% of biotechnology faculty with industrial support (compared with 7% without it) said that their choice of research topics had been influenced by the likelihood that the results would have commercial application. Since academic institutions are widely acknowledged to be the engine behind basic research advances in the biomedical area, these reports raise concerns about whether [academic industry research relationships] may compromise the unique role of the university in the development of fundamental biological knowledge.

203 See McManis & Noh, supra note 71, at 26.

204 Id.

205 David, supra note 183, at 5.

206 Id.
control and immediately accessible, such as “airline reservation systems, packet switching for high-speed telephone traffic, the Internet communication protocols, the Global Positioning System, and computer simulation methods for visualization of molecular structures.”\textsuperscript{207} The National Bureau of Economic Research study merits increased scrutiny and monitoring of the impact of the Bayh-Dole Act on a diversion of research agendas.

4. Delay in Publication or Withholding of Research Materials

Another criticism of the Act is that the change from an open science model to a proprietary rights model results in research not being immediately published and in research materials being unreasonably withheld. This may cause a delay in the advance of scientific research. The norms of open science served to encourage scientists to immediately publish their research results.\textsuperscript{208} In particular, the norm of communism includes the principles of free and open communication and disinterestedness. Free and open communication and disinterestedness together include the availability of research results to all in exchange for freedom from influence on the direction of research, which provides the motivation for researchers to freely share and distribute their research results without delay.\textsuperscript{209} “Secrecy is the antithesis of [the norm of communism]” and “[t]he scientist’s claim to ‘his’ intellectual ‘property’ is limited to that of recognition and esteem . . . .”\textsuperscript{210} The Bayh-Dole Act encourages patenting and licensing and thus has arguably altered the application of those norms because the trade secret and patent systems encourage secrecy to prevent the loss of

\textsuperscript{207} Id.


\textsuperscript{209} MERTON, supra note 208, at 273-74.

\textsuperscript{210} Id.
Trade secret or patent rights. Trade secret law generally requires that information is subject to reasonable efforts to keep information secret and that the information is not readily ascertainable by the public. The U.S. Patent Act provides a one-year grace period prior to filing a patent application during which inventors can publish their results without a loss of patent rights. If the inventor publishes his or her research results more than one year before the filing date of the patent application, the inventor will lose rights to that invention. “The suppression of invention denies the rationale of scientific production and diffusion.” The impetus to keep information secret and delay publication may come from with the university itself to protect its ability to patent government-funded inventions and thus its ability to profit from those inventions or from industry collaborators that do not want to give up an advantage to a competing firm. Loss of patent rights and restrictions from industry collaborators can result in secrecy or delays, but the norms of science can also provide an incentive for scientists to not share research results in the race to be first to publish.

In a survey released in 2002, researchers found that 47% of workers in the biotechnology field stated they encountered difficulties in accessing data or materials which delayed research. The researchers found that 28% of all geneticists “reported that they were unable to replicate published research as a direct result of another academic scientist’s unwillingness to share information, data, or materials.” “Other consequences included [ending a collaboration (28%),] having a publication significantly delayed (24%), abandoning a promising line of research (21%), delaying sharing with that person or

211 See Blumenthal, supra note 202, at 3346 (1992) (“Biotechnology faculty with industry support were more than four times as likely as colleagues without such funding (12% vs 3%) to report that trade secrets had resulted from their research.”).
213 Id.
214 MERTON, supra note 208, at 275.
215 DEREK BOK, UNIVERSITIES IN THE MARKETPLACE 66 (2003) (“Apparently, universities often hold up requests for materials in an effort to obtain a slice of any revenue that grows out of the companies’ research. When they share with universities, companies, for their part, insist on safeguards to keep their materials out of the hands of researchers under contract to rival firms. The net result is a far cry from the ideal community of scholars, freely sharing their ideas and materials in a common quest for greater knowledge and understanding.”); see Shane, supra note 202, at 281 (“Another way in which spinoff activity hinders the dissemination of knowledge created by universities is seen when the founders of university spinoffs delay publication or distribution of their research results until they have patented their inventions and transferred their academic patents to private firms intent on profiting from them.”).
216 See also David Blumenthal, Conflict of Interest in Biomedical Research, 12 HEALTH MATRIX 377, 388-89 (2002) (“Other geneticists will say they were protecting their ability to publish their next paper or were protecting one of the junior colleagues.”).
218 Id.
group (18%), and refusing to share with that person or group (13%)."219

The researchers also found that, 77% “of geneticists felt that data withholding detracted somewhat or greatly from the level of communication of science” and 73%, “that data withholding slowed the rate of progress in their field of science.”220 Moreover, withholding among geneticists may be becoming more common in recent years.221

One study found that “[f]orty-seven percent [of questioned researchers] said that their agreements sometimes require withholding of data beyond the time required to file a patent and fifty-six percent of those said that this agreement had actually been implemented at some point.”222 That same study found that “[f]aculty members are more likely to say that they delayed publications for more than six months in order to honor an industrial request if they have industry support for their research than if they do not” and that “[t]hey are also more likely to say, by a substantial margin, that trade secrets have resulted from their research.”223 “The same pattern is observed among faculty who report engaging in commercialization of research results, independent of whether they had research support from industry.”224 The AAAS Report also stated that, “[i]ndustry bioscience respondents reported the most problems, with 76 percent reporting that their research had been affected by such difficulties.”225

Of the 72 respondents who reported that their work had been affected by the technology acquisition process, . . . fifty percent reported that they had to change their research agenda, and 28 percent reported abandoning their research project as acquisition of the necessary technologies involved overly complex licensing negotiations.226

In the Walsh, Cho and Cohen study, the researchers found that patents had a negligible impact on access to biotechnology inputs, but also found that nineteen percent of respondents did not receive materials in response to material transfer requests.227 Finally, the Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation of the National Research Council of the National Academies found that the number of instances where access caused delays or abandonment of research projects was small.228 In reviewing and

219 Id.
220 Id.
221 Id.
222 Blumenthal, supra note 216, at 386-87.
223 Id.
224 Id.
225 AM. ASS’N FOR THE ADVANCEMENT OF SCIENCE, supra note 190, at 7.
226 Id.
227 WALSH ET AL., supra note 184, at 2-3.
228 REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH, supra note 187, at 2.

In a study published in 1991, a researcher found through interviews with geneticists that the
analyzing these studies, Professors McManis and Noh asserted that:

While there is at least some evidence suggesting increasing secrecy and delays in the dissemination of genetic research results over the past two decades, it is not at all clear that the concomitant increase in university patenting and licensing necessarily bears any causal relation with the increase in secrecy or continuing delays in disseminating research results, or that university patenting is significantly diminishing the public domain.\(^{229}\)

The conflicting results of the studies merits additional research and study of the question of whether increased patenting and licensing is causing research and publication delays. Professors McManis and Noh offered an interesting reason for the purported conflicting results of the studies. The authors argued, while admitting the argument is somewhat speculative, that the difference between the Blumenthal study and the Walsh, Cho, and Cohen study may be explained by the passage of amendments to the Patent Act to allow the filing of provisional applications, patent applications without claims, which effectively provides an additional year before having to file claims.\(^{230}\)

Professor Margo Bagley recently addressed the potential problem with delay in publication because of the possible loss of patent rights.\(^{231}\) Professor Bagley argued that the Patent Act should be amended to allow academic researchers to opt-in to an extended grace period under section 102(b) of the Patent Act.\(^{232}\) In exchange for an additional year to publish their research without a loss of right pursuant to section 102(b), researchers would agree that their patent application would be immediately published.\(^{233}\) Both prongs of Professor Bagley’s proposal attempt to benefit the public and increase public knowledge—although still possibly subject to proprietary rights—first by giving researchers an extra year to publish results before filing a patent application, and by disclosing information in that application immediately by publication.

Professor Bagley’s proposal is not just limited to amending the

\(^{229}\) McManis & Noh, supra note 71, at 24. One particular case involved an AIDS researcher who purposefully published in obscure journals and refused to provide materials to other researchers. See McCain, supra note 228, at 494.

\(^{230}\) Id. at 257.


\(^{232}\) Id. at 257.

\(^{233}\) Id.
Patent Act, but would also require that foreign countries adopt a similar provision in their patent legislation.\textsuperscript{234} Currently, the European countries do not have a grace period, and Japan has a six-month grace period. There is an incentive in the United States not to take advantage of the section 102(b) grace period because to do so could result in patent defeating activity in foreign markets. Further, the question of what is disclosed in the publication is a critical question, particularly when the research is subject to a university and industry collaboration. The publication may contain some information about technology that may be patented, and industry may want to protect some know-how as a trade secret. The proposal also does not impact material transfer agreements covering biological materials. As discussed \textit{supra}, according to the empirical evidence, academic and industry researchers are encountering difficulties in accessing tangible property covered by material transfer agreements. Additionally, industry may desire to keep all of the information secret and not obtain patent protection at all. Thus, the terms of the collaboration agreement must be clear on publication rights. Moreover, while disclosure may take place earlier, what is disclosed may be protected by proprietary rights. Without a robust experimental use exception or some other contractual research exemption, other academic researchers using upstream proprietary technology may be engaging in infringing activity and must obtain a license to use that technology. Accordingly, the proposal does not address the anticommons issue, but would address some of the problems with delayed publication. The issues concerning the delay in publication or failure to publish by recipients of federal funding will still persist absent acceptance of a proposal similar to that offered by Professor Bagley.

5. Conflicts of Interest

Another criticism of the Act is that it is creating conflicts of interest for academic researchers. These conflicts threaten to undermine the credibility of the academic enterprise as a neutral arbiter of scientific information and further erode the credibility of scientific research by prohibiting the replication of research. Academic researchers can encounter conflict of interest problems,\textsuperscript{235} particularly financial conflict of interest problems, when engaged in research on behalf of a

\textsuperscript{234} \textit{Id.} at 266-69.

\textsuperscript{235} “A conflict of interest occurs when two interests collide . . . Interests are things of value to somebody or something. Usually it means that pursuit of one interest detracts or has the potential to detract from the other interest; otherwise there would not be a real conflict.” Blumenthal, \textit{supra} note 216, at 389.
corporation through either ownership of the corporation or consulting for the corporation. Conflicts of interest also can be created by academic researchers who accept the right to a royalty stream from a licensed government-funded invention or receive some research funding from a corporation. For example, an academic researcher’s objectivity can be compromised when that researcher holds stock in a corporation for which the researcher is conducting research, a situation that is not uncommon since passage of the Bayh-Dole Act. Many researchers attempt to spin off companies based around a particular patented project or research agenda and license back technology from universities. In fact, universities sometimes may provide a preference to license technology to companies affiliated with a researcher. As discussed supra, a particular technology, especially one that is at the basic stage of research and development, is more likely to need the researcher or researchers help in further refining that technology. Thus, corporations, once they have licensed a particular technology, may wish to engage the services of the principal researchers that developed the technology in a consulting relationship. The Bayh-Dole Act mandates that nonprofit entities must share a portion of royalties received from the licensing of government-funded technology to the researchers involved in the invention of that technology. Thus, researchers have a direct financial interest in the success of their technology either through the hope of royalty streams, profits from ownership, or consulting salaries, which may lead to an incentive to

236 BOK, supra note 215, at 67 (“[T]hese relationships [ownership of a corporation, consulting agreements with corporations, research grants from a corporation] provide reasons to favor the company involved and hence create conflicts that threaten the objectivity of scientists when they advise the government or publish research results on matters of financial significance to their corporate sponsor.”).

237 Id. at 67 (“Faculty members, especially in the life sciences, may own a significant share of stock in a company for which they do research (perhaps a firm they founded to commercialize one of their own discoveries.”). According to one researcher, the numbers of academic researchers with an industry relationship in the form of industry funding or equity interest has not increased substantially from the time of the first study in the mid-80s to another study in between 1999 and 2000. Blumenthal, supra note 216, at 378-379; see also McManis & Noh, supra note 71, at 27 (discussing researcher’s paper concerning lack of change in number of academic-industry relationships between mid-1980s and 1999 and 2000).

238 Interestingly, a survey found that a majority of faculty members at universities do not support university spin-off activity. SHANE, supra note 202, at 277-278 (citing Y. Lee, “Technology Transfer” and the Research University: A Search for the Boundaries of University-Industry Collaboration, 25 RESEARCH POLICY 843-63 (1996)). In fact, that survey found that “only 26.5 percent [of faculty surveyed] agreed with the policy of taking equity in return for intellectual property licensed to companies founded to exploit university research.” Id. at 278. Moreover, “many university faculty expressed the belief that spinoff activity conflicts with academic values about knowledge dissemination, conflict of interest, long-term research, and scholarly freedom.” Id. at 278.

239 BOK, supra note 215, at 67 (“Short of ownership, professors may test the products of the firms from which they have received significant amounts of research funding or obtained a lucrative consulting agreement.”).
suppress negative information about their technology. Not only are actual conflict of interest problems an issue, but the perception of a conflict of interest can “undermine the credibility of their work.”

A number of highly publicized cases demonstrate how a financial conflict can arise and cause serious and damaging consequences to all involved in the transaction. The danger of conflict of interest problems is real although the issue of how frequently a worst-case or bad-case scenario results from a mismanaged conflict of interest is another question. The likely harm appears to be erosion of the public’s faith in the credibility of academics from a collection of worst-case or bad-case scenarios. While it is unclear whether Bayh-Dole is the direct cause of these worst-case or bad-case scenarios, it certainly does not dissuade academics from creating financial conflicts of interest with industry. However, the conflicts of interest, including worst-case scenarios, may have occurred without the passage of the Act based upon the evidence that universities were already engaged in patenting and licensing prior to the passage of the Bayh-Dole Act. The probability of more conflicts occurring sooner may be the impact of the Bayh-Dole Act.

It is unclear whether the increased patenting and licensing that occurred after passage of the Bayh-Dole Act is the cause of the unintended consequences discussed supra. First, whether an anticommons has developed or not is uncertain. However, almost every study that reviews the potential problem warns that an anticommons may develop. Indeed, as the biotechnology research field develops and becomes more complex, additional inputs may be needed to develop a

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240 Id.
241 One case involved a researcher at a Harvard-affiliated hospital who “minimized unfavorable results in a clinical study to test a dry-eye medication.” Id. at 67-68. The researcher owned stock in the corporation “that produced the medication” and sold the stock after his published clinical study drove up its price. Id. Another case involved the director of an institute conducting research at the University of Pennsylvania Medical School. Id. A participant and patient in a gene therapy trial died during an experiment. Id. The director of the institute was “the founder and major stockholder in the company that funded the research” and the university held an equity stake in that company. Id. Both the director and the university would have likely profited from the successful testing of the therapy. Id. Finally, a case involved a faculty member at the University of Pennsylvania “who was the inventor of Retin-A, a chemical compound used to treat acne, who had assigned his patent rights to the University of Pennsylvania” (which had made $15 million from licensing the invention). See McManis & Noh, supra note 71, at 26. The faculty member later learned that Retin-A had another beneficial use as an “anti-wrinkle cream” and received a patent for that new use. Id. The faculty member then licensed that patent to a pharmaceutical company and was subsequently sued by the university. Id. Finally, [a] study . . . in the New England Journal of Medicine in 1998 found that ninety-six percent of those who published reviews supportive of calcium channel blockers in the treatment of hypertension had a relationship with the manufacturer that made calcium channel blockers, as opposed to thirty-seven percent of those who published critical articles.

BOK, supra note 215, at 67-68.
particular research agenda. The anticommons may not exist as predicted by Heller and Eisenberg, but it may occur in the future. There does appear to be evidence of a difficulty to access diagnostics, but this is a blocking patents problem and perhaps not an anticommons issue. Moreover, answering the question of whether an anticommons exists is a difficult one because the researcher is trying to prove a counterfactual—what would have occurred without the increased patenting and licensing supposedly caused by the Bayh-Dole Act. As discussed infra, states, particularly California, have an opportunity to collect evidence of what impact increased patenting and licensing may have on biotechnology innovation with a modified Bayh-Dole Act.

It appears that there may be a diversion of research towards applied projects in academia, but it is unclear whether that is caused by the Bayh-Dole Act or would have occurred without its passage. The delay in publication and the withholding of tangible research materials appears to be occurring, but may not be solely caused by the Bayh-Dole Act. Moreover, there is some evidence of conflicts of interest arising amongst researchers, but those conflicts apparently are not developing into worst case scenarios.

Professors McManis and Noh analyzed the recent empirical evidence concerning the impact of the Bayh-Dole Act and concluded that there is insufficient empirical evidence and theoretical support to justify legislative change to the Bayh-Dole Act. Indeed, the authors believe that Professor David Adelman’s work is closer to the correct position—that there is rich commons in the biotechnology field and most of the increased patenting of biotechnology downstream inputs is “irrational.” While that may be true at this time, the danger of the a tragedy of the anticommons exists in the future as biotechnology research and development becomes more advanced and complex.

While the thrust of the objectives of the Act, to promote the wide utilization of government-funded technology, is a good one, and the Act may have been effective at achieving those objectives through increased patenting and licensing, there are potential problems and costs. This Article argues that the Act can be better tailored to meet those objectives while considering the interests of the parties involved in technology transfer. As discussed infra, states should seize the opportunity to craft a state version of the Bayh-Dole Act that recalibrates the interests of the public by addressing the failure of the utilization of the access provisions in the Bayh-Dole Act, the selection bias in the group of patents used to justify passage of the Act, and the double payment for an invention by the public. The state acts should

242 Walsh et al., supra note 183.
243 McManis & Noh, supra note 71, at 10.
244 Id.
also prevent or mitigate the development of an anticommons, the negative impact of delays in publication and the withholding of tangible research materials.

III. STATE FUNDING OF RESEARCH

States are in competition with countries and other states as locations for technology companies. The prospect of luring technology companies with attendant high paying jobs, tax revenue, and spillover economic benefits to the state is very attractive. There is a very real danger of losing technology companies to other countries through outsourcing or to other states for many reasons including lower real estate prices. Many states have enacted legislation and developed programs designed to encourage technological innovation and bring technology companies to their state.\textsuperscript{245} The legislation and programs take many forms, including small business grants and loans and tax credit programs.\textsuperscript{246} The competition between states to attract technology companies has resulted in some very creative new programs along with the investment of large amounts of financial resources.\textsuperscript{247}

The Bush Administration’s decision to limit federal funding of certain types of stem cell research creates the opportunity for states to fill a gap in the funding of basic research for a very promising technological area. Some states have decided to limit research and funding for certain stem cell research following the Bush Administration lead.\textsuperscript{248} However, several other states desiring to be the center of innovation for this technology have started stem cell research

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\textsuperscript{245} See, e.g., MO. REV. STAT. §§ 348.300 to 348.318 (2006) (providing tax credits for venture capital funding); MO. REV. STAT. §§ 620.635 to 620.653 (2006) (providing tax credits equal to 100% of the investment in a qualified fund to any accredited individual, corporation, partnership or financial institution who makes a qualified investment); MONT. CODE ANN. § 15-31-150 (2006) (providing tax credits equal to 5% of the increased qualified research expense and basic research payments for research in Montana); MONT. CODE ANN. § 15-31-103 (2006) (exempting from corporate license taxation for the five years of activity in Montana, all net income earned from research and development activities); NEB. REV. STAT. §§ 2-5402 to 2-5424 (2006) (providing grants to offset the costs of research, education, training and market development of value-added products sold by producers); N.J. STAT. ANN. § 34:1B-7.37 (2006) (providing loan guarantees and assistance in establishing lines of credit, real estate development assistance, and technical advice on locating private and public sources of funding).

\textsuperscript{246} See supra note 245.

\textsuperscript{247} Id.

or biotechnology funding programs. As competition for high paying jobs and tax revenue increases, it is only a matter of time before states begin to create funding for other specific technology fields, such as nanotechnology. Thus far, California has taken the lead in the amount of state funding provided for stem cell research. The allocation of funds for stem cell research has also prompted California to attempt to develop a comprehensive state wide technology innovation plan, including an intellectual property policy.

In 2004, California voters passed Proposition 71, which amended the California Constitution to provide three billion dollars in funding for stem cell research. The funding will be disbursed incrementally over ten years at about $300 million per year. Specifically, Proposition 71 establishes an agency, CIRM, to award funding and regulate stem cell research conducted with that funding; creates a constitutional right to conduct stem cell research; mandates a prohibition of the use of Proposition 71 funding for human reproductive cloning research; creates a committee, the Independent Citizen’s Oversight Committee (ICOC), with oversight over CIRM; authorizes the issuance of three billion dollars worth of bonds to finance CIRM and its activities; and appropriates monies from the General Fund to pay for those bonds.

The California Legislative Analyst estimates that the total cost to pay off the principal and interest generated by the bonds will be six billion dollars. Notably, Proposition 71 does not explicitly state who will own any patentable inventions developed from the sole or partial use of Proposition 71 funding. Proposition 71 does note that the ICOC will establish standards that require funding be subject to agreements that allow California to benefit from patents, royalties and licenses resulting from research funded by Proposition 71. The Legislative Analyst states that the total cost of Proposition 71 may be offset by “[u]nknown potential state and local revenue gains and cost savings to the extent that

249 Wisconsin has allocated $350 million Life Sciences Research Fund. See Transcript, IP Task Force of the ICOC 71 (Apr. 27, 2006), http://www.cirm.ca.gov/transcripts/pdf/2006/04-27-06.pdf. Pennsylvania is considering creating a $500 million Jonas Salk Legacy Fund for biosciences faculty and recruitment and facilities. Id. Missouri is proposing a $400 million Lewis and Clark Discovery Initiative. Id. Ohio has allocated $300 million to biosciences related initiatives. Id. Connecticut is investing $100 million over ten years from a tobacco settlement. Id. Florida is using a $30 million grant for biotechnology research. Id. New Jersey is considering allocating $30 million to research. Id. at 71-72. Maryland is investing $12 million and Illinois and South Carolina are investing between $5 to $10 million in research. Id. at 72. By comparison, Singapore is investing two billion in research. Id. at 72.
250 CAL. CONST. art. XXXV.
251 Id.
253 CAL. CONST., art. XXXV.
254 Id.
the research projects funded by [Proposition 71] result in additional economic activity and reduced public health care costs.” A report concerning the economic impact of Proposition 71 by the Analysis Group, which was used by the supporters of Proposition 71 to secure its passage, concluded that Proposition 71 will result in total state and health care cost savings between $6.4 billion and $12.6 billion during the payback period and generate a 120% to 236% return on the investment and Proposition 71 will create thousands of new jobs in California. The total projected revenue would be generated by tax revenues from Proposition 71 spending, tax revenues from additional biotechnology activity in California, reductions in health care costs resulting from new therapies, and royalties from discoveries funded by Proposition 71.

Passage of Proposition 71 has prompted the California Legislature to consider whether and how the state should develop an intellectual property policy. The California Legislature passed Assembly Concurrent Resolution (ACR) 252 in September of 2004, which tasked the California Council on Science and Technology (CCST) with providing recommendations for whether or how the state should develop a statewide intellectual property policy. The Legislature also passed ACR 24 with subsequent amendments generally directing the CCST to also examine California intellectual property policy directly relating to the funds distributed by Proposition 71. Since enactment of ACR 24, the CCST has issued two reports that analyze whether and how California should develop an intellectual property policy. The general recommendation of both reports was to adopt a similar model to the federal model, the Bayh-Dole Act, for promoting technology transfer. This Article will review and analyze the reports.

After the release of the two CCST reports, CIRM, the agency tasked with developing rules for distributing Proposition 71 funds, issued its CIRM Intellectual Property Policy for Non-Profit Organizations (CIRM Interim Policy), which was approved by the ICOC. The CIRM Interim Policy deviates from the recommendations

255 ANALYSIS BY THE LEGISLATIVE ANALYST, supra note 252, at 68.
256 Laurence Baker & Bruce Deal, Economic Impact Analysis: Proposition 71 California Stem Cell Research and Cures Initiative 2-3 (Sept. 14, 2004). The total project revenue would be generated by tax revenues from Proposition 71 spending, tax revenues from additional biotechnology activity in California, reductions in health care costs resulting from new therapies, and royalties from discoveries funded by Proposition 71.
257 Id. at 6-9.
258 CCST INTERIM REPORT, supra note 7, at 5.
259 Id.
260 CCST FINAL REPORT, supra note 7, at 9 (“Clearly, consistency with federal statutes and policy suggests that ownership of IP resulting from state-sponsored research also should reside with the grantee.”).
261 The ICOC is responsible for developing policies for intellectual property rights arising
in the CCST reports in several ways, but also follows some of the CCST’s recommendations that modify some of the provisions of the Bayh-Dole Act. The CIRM Interim Policy is considered an “interim draft policy” and has recently completed the public comment period. There are proposed changes to the CIRM Interim Policy that are open for public comment. The CIRM Interim Policy will be reviewed and analyzed below. Notably, CIRM’s Interim Policy includes provisions allowing California to receive a direct royalty stream, and provisions creating a research exemption, among other important provisions.

A. The CCST Reports

In August 2005, the study group formed by the CCST to examine California intellectual property policy relating to Proposition 71 (Study Group) issued an Interim Report. The CCST issued its final report concerning California’s statewide policy in December 2005 (Final Report). “The purpose of the Interim Report is to discuss the likely benefits associated with IP created under CIRM funding, describe some existing models for handling IP, and suggest some approaches to the treatment of IP that benefit CIRM and the state.” The Final Report has a similar purpose, but is not limited to CIRM funding and extends to all state funding of research. The Study Group reports provide an excellent opportunity to frame the debate and examine the issues surrounding state-supported research and development and the ownership of intellectual property arising from that research and development.

Notably, the Study Group in the Interim Report attempted to lower the expectations for the development of new therapies of the ICOC members and the public by stating that a “significant portion of the funding” will benefit basic research and a “small number of research discoveries may lead to therapeutic or scientific technologies.” In all likelihood, the development of effective therapies from CIRM-sponsored research is at least ten to twenty years away." That statement is a far cry from the statements

264 CCST INTERIM REPORT, supra note 7, at 5-6.
265 Id. at 6.
266 Id. at 7.
267 Id.
268 Id.
made in support of Proposition 71 of the incredible benefits to humanity that the state’s three billion dollars of funding would provide. The Study Group hastened to add that Proposition 71 is only allocating about $300 million a year to research for ten years, which is a very small amount in comparison to the fourteen billion dollars annually paid by the federal government and the forty-five billion dollars annually paid by private industry for research purposes. The Study Group also noted that California’s total expenditure of funding for research purposes, including the $300 million from Proposition 71, is $600 million per year. However, $300 million a year to fund just one area of research, particularly an area that the federal government is not funding, is substantial. Moreover, this amount is substantially more than the research funding provided by other states, such as Pennsylvania and Wisconsin.

According to the Interim Report, the “return on investment” to California will be the retention and recruitment of top researchers, general creation of new jobs with resulting tax benefits to the state, and “gains associated with the treatment and prevention of disease.”

The Study Group recommended that California follow the thrust of the Bayh-Dole Act, which is to provide ownership of the intellectual property developed from government funding in the grantee. The Study Group supported this allocation of ownership rights for several reasons. First, it would make California policy consistent with Bayh-Dole. Second, IP management should ideally be placed “as close to the researcher as possible,” which also places the burden of paying filing fees with institutions that are able to bear that burden. The Study Group also asserts that, “[t]he common attribute of both the public domain movement and the intellectual property rules it challenges is that ownership of IP, if retained, should reside with the creator of the knowledge.”

The Study Group stated that present California policy is similar to pre-Bayh-Dole Act federal policy, because California does not have a uniform policy with respect to the ownership of state funded innovation. The Study Group argues that prior to the passage of the Bayh-Dole Act many federally owned inventions were not being

269 Id. at 8.
270 CCST FINAL REPORT, supra note 7, at 19.
271 IP Task Force of the ICOC, supra note 249, at 71.
272 CCST FINAL REPORT, supra note 7, at 32.
273 Id.
274 Id. at 9-10.
275 CCST INTERIM REPORT, supra note 7, at 10; CCST FINAL REPORT, supra note 7, at 9, 21.
276 Id. at 27.
277 CCST INTERIM REPORT, supra note 7, at 23; CCST FINAL REPORT, supra note 7, at 27.
commercialized. As discussed supra, this point is subject to question. According to the Study Group, commercialization has not occurred for two reasons. First, each federal agency essentially had its own policy for transferring technology to private industry, which led to inconsistencies and transaction costs. Second, prior to Bayh-Dole, there were insufficient or ineffective incentives for private industry and other entities to invest in the commercialization of an invention developed from federal funding because private industry or other entities were unable to claim ownership in those inventions. However, the Study Group also noted that, “it is difficult to measure the direct effect of Bayh-Dole on technology transfer.”

The Study Group also argued that if California adopts a different approach than Bayh-Dole, that this could lead to increased transaction costs because some research is likely to be conducted with several sources of funding. Moreover, since federal policy drives most publicly funded research, most recipients of funding have developed their respective institutional policies in response to federal policy. The possibility of states developing their own policies could lead to inconsistencies and confusion. The Study Group also cautioned that alternative approaches to handling IP, such as the public domain for science, patent pooling, and experimentation with licensing, have not been adequately tested, although they appear promising.

Instead, [the Study Group] recommend[ed] that the state, given the basic and early applied nature of the research it funds, has goals much more aligned with federal agencies than with private or public charities. Therefore, consistency with the objectives the Bayh-Dole Act would provide the best incentives to researchers to develop new knowledge and protect it, and to commercial entities to license IP, invest the financial resources required to develop it, and commercialize new products and applications.

However, one of the complicated problems in biotechnology research

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278 CCST INTERIM REPORT, supra note 7, at 23; CCST FINAL REPORT, supra note 7, at 9, 25. The Final Report states, “many promising federally funded research discoveries were not being licensed for further development. One result is that by 1980, an inventory of about 28,000 patents developed with federal funding had built up, with less than 5% licensed and developed into useful products.” Id. at 25. As discussed supra, the numbers of licensed and developed government patents was subject to a selection bias. See Eisenberg, supra note 8, at 1669-1704.
279 See generally Eisenberg, supra note 8, and MOWERY ET AL., supra note 103.
280 CCST INTERIM REPORT, supra note 7, at 23; CCST FINAL REPORT, supra note 7, at 9 & 25.
281 CCST INTERIM REPORT, supra note 7, at 23; CCST FINAL REPORT, supra note 7, at 9.
282 CCST INTERIM REPORT, supra note 7, at 23.
283 Id. at 24; CCST FINAL REPORT, supra note 7, at 27.
284 CCST INTERIM REPORT, supra note 7, at 24.
285 Id. at 24.
286 CCST FINAL REPORT, supra note 7, at 33.
287 Id.
and development is that basic research also has commercial applications, and thus the state and CIRM may be situated similarly to private and public charities in some instances.

The Study Group also addressed several arguments made in favor of ensuring that Californians receive a return on their three billion dollar investment. The first argument was that CIRM or California should retain some type of royalty stream. The Bayh-Dole Act does not provide for a return royalty stream to the federal government. Generally, the Study Group argues against any retention of a royalty stream, because it may serve as a disincentive to invest in developing and commercializing basic research to therapeutics. Moreover, the Study Group supported its position by stating that a University of California study found that only one in 400 inventions bring in over one million dollars in funding and that an AUTM study found that “universities, on average, produce one commercially significant invention for every $2.5 million of research funding.” The Study Group’s conclusion from these findings was that “if CIRM were to award the full $3 billion in research funding . . . one might expect around 1,200 total inventions from this investment, of which only 3 to 4 might earn more than $1 million in licensing income over their entire lifetimes.” In the Final Report, the Study Group stated that

    in those exceptional cases where the licensing royalties are large (for example, with net revenues to the licensor greater than $500K), we recommend the state policy include a revenue sharing agreement between the institution owning the IP and the state agency, with an agreed fraction of the returns going to the agency to support further research within their charter.

Interestingly, the Interim Report states that 2,600 biotech companies in California generate $32.3 billion in worldwide revenues to support the argument that states will receive a return on its investment in the form of jobs and tax revenue. The second argument the Study Group addressed concerns an attempt by CIRM or California to obtain favorable pricing from

\[288\] “[A]fter considerable debate, the NIH decided that the single most important goal for biomedical research was the rapid development and commercialization of products, and that direct financial considerations should be secondary.” CCST INTERIM REPORT, supra note 7, at 33.

\[289\] Id. at 12, 33.

\[290\] Id. at 33 (citing ASS’N OF UNIV. TECH. MANGERS, AUTM LICENSING SURVEY: FY 2002 (2003); CCST FINAL REPORT, supra note 7, at 43.

\[291\] CCST INTERIM REPORT, supra note 7, at 33-34. The report also states that Breast Cancer Research Program that is administered by the State of California “ultimately decide[d] not to impose any [royalty] requirement, preferring instead to encourage maximum participation in the program.” Id. at 34; see also CCST FINAL REPORT, supra note 7, at 43.

\[292\] CCST FINAL REPORT, supra note 7, at 11.

\[293\] CCST INTERIM REPORT, supra note 7, at 32.
industry recipients of funding. The Study Group argued that the goal of obtaining favorable pricing is a health care policy issue not an IP policy issue. The Study Group also pointed to the NIH’s lack of success in attempting to use a similar plan to obtain favorable pricing with its Cooperative Research and Development Agreements.

The Study Group also cautioned that IP policy should be developed with recognition that there are different types of IP. For example, in the case of research tools, the Study Group stated that inventors of research tools have several options. The inventor can publicly disseminate the research tool and not obtain any intellectual property law protection for it. The inventor can secure intellectual property law protection and then non-exclusively license the tool with a license requiring a royalty or exclusively license the tool “to encourage a company to further develop and commercialize” the tool. However, it is unlikely the inventor who will have the choice; it is the employer/recipient of the funding who will make that decision. The Group recommended that if an exclusive license is used it “should retain rights for the grantee and the research community to continue to use the IP for research purposes.” Notably, the thrust of the position of the CCST is that if further commercialization or development is not needed, then the research tool or other piece of technology does not need to be exclusively licensed. On the other hand, if an additional investment must be made to continue to refine or develop the product or prepare it for the market, then an exclusive license may be necessary to ensure that the invention is commercialized.

Finally, the Study Group in the Interim Report and Final Report set forth several recommendations for policies that CIRM should adopt: 1) permit grantees to own IP rights from CIRM/state-funded research; 2) require grantees (institutions, individuals, or both) to provide a plan describing how IP will be managed for the advancement of science and California public benefit; 3) grant basic research funds without requiring grantees to commit to providing a revenue stream to the state. If, however, a revenue stream develops over time (and only if the percentage of net revenues is over a reasonable threshold), revenues will be reinvested in research and education; 4) generally make CIRM/state-

294 *Id.* at 13.
295 *Id.*
296 *Id.*
297 *Id.* at 27.
298 *Id.*
299 *Id.*
300 *Id.*
301 *Id.* at 29.
302 *Id.*
303 *Id.* at 39-40.
developed research tools widely available to other researchers;\textsuperscript{304} 5) require diligent efforts to develop CIRM/state-funded IP into therapeutics and diagnostics that can benefit the public;\textsuperscript{305} 6) retain within CIRM/state Bayh-Dole-like rights to step in if the owner of the IP is not undertaking appropriate steps to transfer technology to benefit the public;\textsuperscript{306} 7) leave license particulars to the owner who is in the best position to judge how best to ensure that discoveries are made widely available through commercialization or otherwise;\textsuperscript{307} 8) reserve the right to use IP by or on behalf of CIRM/the state;\textsuperscript{308} and 9) establish and maintain a CIRM/state database to track all IP generated through CIRM/state funding.\textsuperscript{309} The Final Report also recommends that the state should establish a single office dedicated to four functions: “track IP generated by state employees; track IP that emerges through research funding; monitor the use of that IP; and collect and manage any revenues that the state may receive.”\textsuperscript{310}

B. CIRM Interim Policy

The CIRM Interim Policy was approved by the ICOC on February 10, 2006\textsuperscript{311} and generally follows the recommendations of the CCST reports. However, as discussed supra, the CIRM Interim Policy deviates from the Bayh-Dole Act in several important areas. First, the CIRM Interim Policy includes a provision concerning a royalty stream to the state. Second, the CIRM Interim Policy includes a research exemption for all California research institutes to use CIRM-funded inventions. Third, the CIRM Interim Policy includes provisions designed to ensure the timely development of inventions licensed exclusively. Fourth, the CIRM Interim Policy includes broader march-in rights than Bayh-Dole, which are apparently not as encumbered with appeals processes. Fifth, the CIRM Interim Policy requires the sharing of tangible research materials. Finally, the CIRM Interim Policy also includes some provisions concerning access to affordable products and services developed with CIRM funding under exclusive licenses. These provisions, along with other important provisions of the CIRM Interim Policy, will be discussed in this section.

\textsuperscript{304} Id.
\textsuperscript{305} Id. at 40-41.
\textsuperscript{306} Id. at 41.
\textsuperscript{307} Id.
\textsuperscript{308} Id. at 41-42.
\textsuperscript{309} Id. at 14-15, 39-42; CCST FINAL REPORT, supra note 7, at 12-13.
\textsuperscript{310} Id. at 47. The Final Report also states that the state could contract with a private entity to manage its intellectual property or contract with the University of California. Id. at 48.
\textsuperscript{311} CIRM INTERIM POLICY, supra note 25, at 1.
The CIRM Interim Policy sets forth the statement of policy for intellectual property under grants awarded from CIRM, and also contains the terms and conditions for those awards.\textsuperscript{312} The CIRM Interim Policy terms and conditions are generally consistent with those mandated by the Bayh-Dole Act.\textsuperscript{313} There are three asserted objectives for the CIRM Interim Policy: (1) “promote sharing of all types of intellectual property created as a consequence of CIRM funding for use in research conducted by both academic and commercial research and development organizations”; (2) “facilitate the commercialization of CIRM-funded discoveries without impeding the progress of stem cell research”; and (3) “provide a financial benefit to the State of California through revenue sharing in the event that CIRM-funded discoveries lead to valuable diagnostics and/or medical therapies.”\textsuperscript{314} The first two policy objectives are closely aligned to the Bayh-Dole policy objectives and are consistent with the recommendations in the CCST Final Report.\textsuperscript{315} The third principle is new which directly takes into account the public interest.

The CIRM Interim Policy has two main parts. First, the CIRM Interim Policy includes “Intellectual Property Terms and Conditions” that must be complied with by grantee organizations and grantees.\textsuperscript{316} The Intellectual Property Terms and Conditions will be formal regulations adopted pursuant to the California Administrative Procedure Act.\textsuperscript{317} Second, the “Intellectual Property Policy” contains regulatory and aspirational policies behind the terms and conditions.\textsuperscript{318}

The Intellectual Property Terms and Conditions contain three major parts: Invention Reporting Requirements, Sharing of CIRM-Funded Intellectual Property, and March-in Rights Requirements. The Invention Reporting Requirements include several obligations for grant recipients: (1) grant recipient organizations must require written agreements requiring prompt disclosure of inventions by researchers; (2) the grant recipient must within sixty days of inventor disclosure notify CIRM of the invention; (3) grant recipient organizations “must notify CIRM on an annual basis regarding the filing of patent applications that claim inventions [and execution of any licensing agreements of inventions] made in the performance of CIRM-funded research”; and (4) “[i]f relevant, grantee organizations must submit

\textsuperscript{312} Id. at 2.
\textsuperscript{313} Id.
\textsuperscript{314} Id. at 4-5.
\textsuperscript{315} CCST FINAL REPORT, supra note 7, at 12, 51.
\textsuperscript{316} CIRM INTERIM POLICY, supra note 25, at 15.
\textsuperscript{317} Id. at 15. The Intellectual Property Terms and Conditions are interim regulations and have not been formally adopted pursuant to the APA. See Cal. Inst. for Regenerative Med., Regulations, available at http://www.cirm.ca.gov/laws/.
\textsuperscript{318} CIRM INTERIM POLICY, supra note 25, at 21.
annually the Invention Utilization Report . . . that lists all CIRM-funded inventions, patents claiming such inventions and a statement of efforts made to utilize CIRM-funded inventions.” These provisions are very similar to Bayh-Dole provisions that ensure inventions are disclosed. The terms and conditions do not specify the consequences of noncompliance. One would assume that noncompliance would lead to the possibility that a grant recipient may not receive another grant from CIRM. The terms and conditions further do not state whether the inventor can apply for a patent if the grant recipient does not exercise its rights and do not explicitly state that California has that right. Arguably, the terms and conditions are less pro-patent that the Bayh-Dole Act, which explicitly contemplates that the grant recipient, inventor or government can patent a government-funded invention. This appears to lean toward favoring the public domain.

The Sharing of CIRM-Funded Intellectual Property Requirements include several obligations such as: publication requirements; publication-related biomedical materials requirements; patent applications requirements; requirements for licensing of CIRM-funded patented inventions; requirements to enable research exemption for CIRM-funded patented inventions; revenue sharing requirements; and press release requirements. The publication-related biomedical materials requirements include the following:

Grantees shall share biomedical materials described in published scientific articles for research purposes in California within 60 days of receipt of a request and without bias as to the affiliation of the requestor unless legally precluded. Under special circumstances, exceptions to the above are possible with approval by CIRM. Alternatively, authors may provide requestors with information on how to reconstruct or obtain the material. Materials are to be shared without cost or at cost.

This provision is especially important considering the empirical evidence of potential issues with obtaining biomedical materials. The patent applications requirements include grant recipient organizations assuming responsibility for patent and patent application costs and

319 Id. at 15.

320 The Core Principles of the CIRM Sharing Policy are:
(1) Protect academic freedom and promote publication; (2) Minimize impediments to stem cell research; (3) Allow grantees to conform to Bayh-Dole obligations with respect to inventions that result from research funded by both CIRM and federal funds; (4) Encourage broad dissemination of CIRM-funded intellectual property of all types beyond practices commonly used in 2005 to promote scientific progress; (5) Facilitate the translation of CIRM-funded discoveries to medical therapies; (6) Ensure broad access for California research institutions to patented inventions made under CIRM funding for research purposes through a research exemption.

Id. at 25-26.

321 Id. at 16.
reporting on an annual basis the filings of patent applications that claim inventions made with CIRM funding.\textsuperscript{322}

The requirements for licensing of CIRM-funded patented inventions include: (1) grant recipient organizations assume the responsibility for licensing and must report on licensing activities annually; (2) grantee recipient organizations “shall negotiate non-exclusive licenses of CIRM-funded inventions whenever possible[,] but may negotiate and award exclusive licenses for CIRM-funded inventions if such licenses are necessary to provide economic incentives required to enable commercial development and availability of the inventions”\textsuperscript{323}; and (3) exclusive license agreements will include terms “for commercial development plans to bring the invention to practical application.”\textsuperscript{324} Notably, the CIRM Interim Policy includes two important additional provisions. The first provision provides:

Grantee organizations shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies and diagnostics only to organizations with plans to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, such licensees will agree to provide to patients whose therapies and diagnostics will be purchased in California by public funds the therapies and diagnostics at a cost not to exceed the federal Medicaid price.\textsuperscript{325} The CIRM may make access plans available for review by the ICOC on an annual basis.\textsuperscript{326}

The second provision provides:

Grantee organizations shall monitor the performance of exclusive licensees of CIRM-funded patented inventions to ensure that the licensed invention is developed in a timely fashion. Remedies for failure to develop may include modification or termination of a license in the event that a licensee is unable to fully develop the rights granted. (I) Grantee organizations shall negotiate relevant and specific grounds for modification or termination of the license. Examples would include failure to meet agreed-upon commercialization benchmarks, failure to keep the licensed invention reasonably accessible to the public for research purposes, and failure to reasonably meet the agreed-upon plan for access to resultant therapies as described in H(d)4. (II) Grantee organizations shall monitor the commercial development activities of the licensees

\textsuperscript{322} \textit{Id.} at 17.

\textsuperscript{323} \textit{Id.} “In due diligence relating to such exclusive licenses, grantee organizations shall document development and commercialization capabilities of the intended licensee, and include terms in the license agreement addressing all relevant therapeutic and diagnostic uses for which the invention is applicable.” \textit{Id.}

\textsuperscript{324} \textit{Id.}

\textsuperscript{325} For a discussion of federal Medicaid pricing, see U.S. Dep’t of Health & Human Services, Overview, Medicaid Drug Rebate Program, \url{http://www.cms.hhs.gov/medicaiddrugrebateprogram} (last visited Nov. 20, 2006).

\textsuperscript{326} \textit{CIRM INTERIM POLICY}, supra note 25, at 17.
to determine compliance with the terms of the license agreement and include reports of monitoring activities annually. . . . (III) Grantee organizations shall take administrative action to modify or terminate license rights where necessary and report such action to the SPO.327

These two provisions place additional obligations on the grant recipient and the licensee to ensure timely commercialization of an invention as well as access to California uninsured patients and affordable cost for patients whose therapies and diagnostics are purchased in California with public funds. It is unclear what consequences exist for grant recipients’ failure to monitor. The provisions also provide some direction to grant recipients to help ensure timely commercialization. The Bayh-Dole Act is not as detailed on this subject.

Another notable provision concerning licensing includes a research exemption for CIRM-funded patented inventions, which provides: “Grantee organizations agree that California research institutions may use their CIRM-funded patented inventions for research purposes at no cost. Grantee organizations shall ensure that such use is preserved in their licenses of CIRM-funded patented inventions.”328 This provision is not included in the Bayh-Dole Act. Finally, the licensing requirements include a final obligation concerning revenue sharing requirements. This provision provides:

In the event of the creation of revenue streams from CIRM-funded patented inventions: (1) Grantee organizations shall share a fraction of any net revenues with the inventor(s) in accordance with their established policies. . . . (2) The grantee organization may retain a threshold amount of its share (after payments to inventors) of any revenues received under a license agreement or agreements of any CIRM-funded patented invention(s). Thereafter, the grantee organization shall pay 25% of its share after payments to inventors of such revenues to the State of California for deposit into the State’s General Fund unless such action violates any federal law.329 (3) If funding sources in addition to CIRM were used in the creation of a CIRM-funded patented invention, the return to the State of California of any resultant revenues shall be proportionate to the support provided by CIRM for the discovery of the invention. (4) Grantees shall apply the grantee organization’s share of any revenues earned as a result of CIRM-funded patented inventions to the support

327 Id. at 18.
328 Id.
329 Id. at 18-19 (“The threshold amount is $500,000 (in the aggregate) multiplied by a fraction, the denominator of which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the Bureau of Labor Statistics of the United States Department of Labor and published for the month of February, 2006, and the numerator of which is such Index published for the month in which the grant award is accepted by the grantee.”).
of scientific research or education.\textsuperscript{330}

The provision concerning the allocation of resultant revenues “proportionate to the support provided by CIRM for the discovery of the invention” is vague and could serve as a disincentive to use CIRM funding.

The third and final set of terms and conditions apply to “March-in Rights requirements.” That provision provides:

With regard to CIRM-funded patented inventions, CIRM shall have the right to require the grantee organization, or exclusive licensee of a CIRM-funded 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 grantee organization, or exclusive licensee refuses such request, to grant the license itself, if the CIRM determines that such an action is required: (1) Because the grantee organization or the licensee has not made responsible efforts in a reasonable time to achieve practical application of a CIRM-funded patented invention. (2) Because the licensee has failed to adhere to the agreed-upon plan for access to resultant therapies as described in H(d)(4). (3) To meet requirements for public use and the requirements have not been satisfied by the grantee organization or its licensee. (4) To alleviate public health and safety needs which are not reasonably satisfied by the grantee organization or its licensee and which needs constitute a public health emergency. CIRM will give to the grantee or licensee notice of such determination and the basis on which it was made. CIRM will not exercise its rights described above if the grantee or licensee takes diligent action promptly to cure the deficiency and such deficiency is cured sooner than one year from receipt of notice (or longer period by mutual agreement). With respect to a deficiency described in I, 4 (above), CIRM may exercise such right at any time in the event of a public health or safety emergency.\textsuperscript{331}

The review process in the CIRM Interim Policy for march-in rights is not as cumbersome as the review procedure for march-in rights in the Bayh-Dole Act. However, delays could result because of the one year period to cure a deficiency.

The CIRM Interim Policy recalibrates the interests of the public in light of the potential negative unintended consequences of the Bayh-Dole Act. The CIRM Interim Policy does this through its objectives and terms. The CIRM Interim Policy ensures that the public receives some benefit through a revenue stream and with a provision to ensure access to products or services developed with CIRM funding for the

\textsuperscript{330} Id. The license requirements also include an obligation for CIRM grantees to notify CIRM prior to any press releases that refer to activities that arise as a consequence of CIRM funding. \textit{Id.}

\textsuperscript{331} Id. at 20.
underprivileged. Additionally, given the concerns about an impediment to the development of downstream products because of patents on upstream developments, the provisions ensure access through a research exemption, march-in rights and ensuring commercialization. The explicit requirement to negotiate commercialization terms is helpful, but recipients of federal funds have the incentive to include terms to ensure timely development of an invention or that recipient may not receive any royalties from that invention. Notably, the CIRM terms and conditions do not contain provisions for “exceptional circumstances,” retention of a nonexclusive license to use the invention or a small business preference.

IV. STATES AS INNOVATION SYSTEM LABORATORIES: CALIFORNIA AND STEM CELL TECHNOLOGY

In a well-known dissenting opinion, Justice Brandeis stated, “It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”

The Bush Administration’s decision to limit the funding for stem cell research has provided the impetus for states to step in and provide funding for that type of research and importantly, this decision has also provided a unique opportunity for states to create new models for the treatment of government-funded inventions. States, particularly California, have an opportunity to attempt to avoid or mitigate the risks presented by the Bayh-Dole Act and better account for the interests of the public. Moreover, a reformed system can be studied and inform changes to the Bayh-Dole Act.

This section is divided into two parts. The first part argues that states should be encouraged to develop systems of innovation for government-funded invention that are different from the federal model, the Bayh-Dole Act. The impact of the new systems can be studied over time and may inform changes to the Bayh-Dole Act. As discussed

332 New Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). Justice Brandeis’s position has been criticized in Susan Rose-Ackerman, Risk Taking and Reelection: Does Federalism Promote Innovation?, 9 J. LEGAL STUD. 593 (1980). But see Barry Friedman, Valuing Federalism, 82 MINN. L. REV. 317, 397-99 (1997) (“It seems apparent that government officials can and do innovate, and that good ideas are picked up by other governmental units and replicated. Welfare reform was born in the states, as a response to inadequate funding. So was Social Security for that matter. But those are only the most prominent examples. What about bookmobiles, pre-election day ‘early’ voting, town meetings, televised court proceedings, greenways, community agenda programs, leadership programs, and the like? Common intuition suggests that the vast majority of techniques used today to govern were developed at the state and local level.”)
supra, California is considering several new provisions which are substantial modifications of the system established by the Bayh-Dole Act. This part includes a further analysis of those sections with additional recommendations for states to consider adopting. The second part asserts that any increased transaction costs and risks of the creation of an anticommons or the danger of a “race to the bottom” are well worth the opportunity to develop empirical evidence that may support modification of the Bayh-Dole Act or staying the course.

A. Development of Alternate Systems for the Treatment of Government-Funded Invention

As discussed supra, the provisions of the Bayh-Dole Act attempt to provide for the wide dissemination of government-funded inventions by taking into account the necessary incentives to encourage participants in the technology development and transfer process to commercialize inventions. The Bayh-Dole Act was also carefully crafted to ensure that the interests of each party to the technology transfer process were taken into account and protected: the inventor, the inventor’s employer, the licensee, and the investor, the public. Since passage of the Bayh-Dole Act, supporters of the Act have pointed to increased patenting and licensing, new products and services, and general economic growth to argue that the Act has been a success. Detractors of the Act have argued that the Act has resulted in numerous unintended consequences that were not considered when the provisions of the Act were crafted. The unintended consequences stem from the purported effect that the Act has had on universities and their public service mission, and the impact the Act may have on innovation. When the unintended consequences are taken into account, the purported benefits of the Act may not be worth the danger of the development of the unintended consequences. This is particularly true when other considerations and arguments are taken into account. Some have argued that the Act is fundamentally unfair because it requires the public to pay twice for an invention—once through funding the creation of the invention and second through a supra-competitive price—and assert that the empirical evidence used to support passage of the Act is subject to a selection-bias.333 Those two arguments have particularly strong force because of the failure of the provisions designed to allow for access to patented government inventions.334 Finally, one major study argues that the purported benefits of the Act may have occurred without passage of the

333 Eisenberg, supra note 8, at 1699-1704.
334 See generally Rai & Eisenberg, supra note 24.
Accordingly, we might have received some of the benefits of the Act without having to endure some of the negative unintended consequences of the Act.

Professors McManis and Noh expressed dismay concerning the debate surrounding the Bayh-Dole Act, particularly the asserted unintended consequences of the Act, and assert that there “is the widespread reliance on what might charitably be called ‘anecdota,’ and the ‘evident lack of concern (let alone embarrassment) about the dearth of empirical evidence on the subject in question.” The authors focused their inquiry on “who should bear the burden of proof on the specific aspects of” “the theoretical arguments for and against patenting upstream genetic research and vesting of presumptive patent ownership in the recipients of federal fund[s and] . . . will also evaluate the weight of the available empirical evidence, with a view to determining how that evidence seems to preponderate at the moment.” The authors asserted that the burden to produce empirical evidence to justify changes to the Bayh-Dole Act should be on the proponents for change and according to the authors, they have failed to meet that burden. This is, in part, because of the difficulty of proving a counterfactual—what would occur if the Bayh-Dole Act was not in effect.

Because of the Bush Administration’s decision to limit government funding for stem cell research, states have stepped forward to fill that funding gap. States have several reasons for investing in the development of stem cell technologies, including creating new jobs and tax revenue for their state and developing life saving therapies that might lower rising health care costs for their residents. In addition to the benefit of providing much-needed government funding for embryonic stem cell research, states are presented with an opportunity to develop new systems for the treatment of government-funded inventions. Not only may these new systems avoid some of the potential problems raised by the Bayh-Dole Act, but the systems may also serve to inform modification of the Act. This is critically important because the purported success of the Bayh-Dole Act, and the entrenched supporters and beneficiaries of the Act, make it highly unlikely that the Act itself will be subject to major reform.
substantially criticized by some, whether some of the fears concerning potential unintended consequences of the Act will develop or not is unclear. However, it is clear that substantial risks exist—the unintended consequences of the Act ultimately may erode any of the short term benefits the Act may produce and result in the exact opposite of the intended purposes of the Act. Instead of wide dissemination of government-funded research for the public good, we end up with a clogged pipeline of new biotechnology product development, erosion of the public domain, and a distortion of the goals of universities.

The opportunity for states to develop policies that are different from the Bayh-Dole Act provides interested groups and policy makers the ability to create, design and study systems designed to promote innovation and may eventually provide adequate support to justify changes to the Bayh-Dole Act itself. States are well positioned to serve as laboratories for the development of innovations systems because the universities within the state, the likely recipients of government funding, are actually part of the U.S. system of universities. This makes states better suited to serve as laboratories than foreign countries. The history, norms, and general ways of doing business by universities in the United States are very similar. Moreover, the relationship between universities and industry in other industrial economies is different than in the United States. U.S. universities generally are more oriented towards the utilitarian rather than oriented towards the theoretical as European universities often are. Also, U.S. universities tend to be decentralized and choose their mission and research agendas based on local needs. U.S. universities are generally under the control of state governments and there are substantially more universities in the United States than in other nations.

339 \textit{National Research Council of the National Academies, A Patent System for the 21st Century} 115 (2005) ("Realistically, the likelihood that Congress will pass research-exemption legislation in the absence of compelling circumstances is small. Accordingly, we recommend consideration of administrative action."). "Whichever body institutes the change would have to pay close attention to timing issues. Suddenly changing the rules of who can freely use patents raises the specter of unwelcome takings claims under the Fifth amendment." \textit{Id.} This provides another reason to avoid changing Bayh-Dole or needing a very good reason to do so. "A patent is generally considered a strong property right, and thus a government-imposed restriction on against whom it can be asserted would almost certainly be resisted by patentees as a taking of a property without compensation." Pulsinelli, \textit{supra} note 24, at 467.

340 \textit{Mowery et al., supra} note 103, at 4. ("One particularly important factor supporting the development of research links and two-way flows of knowledge and technology between U.S. universities and industry throughout the twentieth century is the structure of the U.S. university system, which differs in important ways from those of other industrial economies.").

341 \textit{Id.}

342 \textit{Id.}

343 \textit{Id.}
industrialized countries. Further, institutional mobility in the U.S. university system “meant that faculty moved among universities...more frequently than was true of faculty in other national systems of higher education.” These structural characteristics of U.S. higher education created powerful incentives for university researchers to establish close relationships with industry. Additionally, states are good candidates for laboratories because states are subject to the same patent law. Foreign countries may have patent laws which impact university research in different ways, such as a more robust experimental use exception. Accordingly, modification of a piece of legislation similar to Bayh-Dole in other countries may in fact not be in sufficiently analogous circumstances to inform change of the Bayh-Dole Act.

The decision by the Bush Administration not to provide funding for most embryonic stem cell research also provides a specific area of research to study. Thus, the impact of a modified Bayh-Dole Act can be studied in a discrete research area generally without interference from federal policy.

1. California’s Experiment

California has invested the largest amount of funds for the development of stem cell research, is home to one of the most successful university systems in the world and is known for technological innovation. California has also apparently spent the most resources in considering developing a state innovation policy and its experience is instructive. As discussed supra, state legislators in California requested expert opinion from a public policy institution for recommendations concerning this issue and received advice through an Interim Report and Final Report. The thrust of both reports included a recommendation that California adopt provisions similar to those of the Bayh-Dole Act. Both reports stressed that California should embrace the Bayh-Dole Act’s granting of ownership of government-funded inventions to the recipient of the grant funding and the importance of ownership to the grant recipient for the commercialization of those inventions. The reports did provide some room for modification of the Bayh-Dole Act, but those modifications would be slight. CIRM generally followed the followed the thrust of the Bayh-Dole Act by allowing the grant recipient to retain ownership of government-funded

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344 Id. at 13.
345 Id.
346 Id.
347 Id. at 10.
inventions. However, the CIRM Interim Policy includes several modifications to the Bayh-Dole Act such as a research exemption, retention of a royalty for the state, march-in rights without a cumbersome review process, a requirement that biomedical materials are shared within 60 days with limited exception, and a provision that requires grantees of exclusive licensees to provide “plans to provide access to resultant therapies and diagnostics for uninsured California patients,” and those licensees must agree to provide “patients whose therapies and diagnostics at a cost not to exceed the federal Medicaid price.” Several of the proposals directly address some of the potential negative consequences of the Bayh-Dole Act, including a potential anticommons, and delays in providing and withholding research materials. California also rejected several novel licensing approaches along with a ban on exclusive licensing. This section will review the CIRM Interim Policy and provide recommendations for additional change.

a. Ownership

The thrust of the Bayh-Dole Act is the provision of ownership to the recipient of government funding.348 The alternatives to this approach would be dedication of the invention to the public domain, thus there would be no owner; another option would be allowing the government to own the invention. A final option could include giving ownership to the inventor. States developing innovation policies can choose any of the alternatives, but each approach has its own set of consequences. Dedication of inventions to the public domain may result in those inventions not being commercialized, but the inventions would be free for everyone to use. The government or the inventor

348 The rules concerning the allocation of ownership of patentable inventions is relatively clear in U.S. patent law. U.S. patent law provides that ownership of a patent initially vests in the inventor or inventors of the invention claimed in the patent. 35 U.S.C. § 261 (2000). This is generally true even for an employee that invents within the scope of her employment. U.S. v. Dubilier Condenser Corp., 289 U.S. 178 (1933). Thus, an employee that conceives of or reduces an invention to practice will own that invention. Id. However, if the employee uses some of her employer’s resources to invent, the employer will receive a “shop right” to the invention. Wommack v. Durham Pecan Co., Inc., 715 F.2d 962 (5th Cir. 1988). A “shop right” is the non-exclusive, royalty-free, non-transferable license to make and use the invention. Id. The “shop right” is not an ownership right. Id. There are, at least, two exceptions to the general rule that an employee will own an invention invented within the scope of employment. First, if an employee is initially hired to invent, directed to solve a specific problem, or hired to exercise her inventive capabilities, then the employee must assign patent rights to her employer. Standard Parts Co. v. Peck, 264 U.S. 52 (1924). Second, if an employee signs an assignment agreement, he must assign his rights to his employer. United Aircraft Prods., Inc. v. Warrick, 72 N.E.2d 669 (Ohio 1945). Copyright law vests ownership in the author, but expressly recognizes that works created during the scope of employment by an employee are owned by the employer. 17 U.S.C. § 201(b).
could own the invention, but the government and the inventor are not always best positioned to commercialize an invention. The inventor may also not be able to fund patent prosecution costs. Critics argue that the numerous unintended consequences of the Bayh-Dole Act likely result from the allocation of ownership to the grant recipient. However, California’s adoption of the Bayh-Dole’s provision of ownership to the grant recipient is not surprising. In 2003, the California Technology, Trade and Commerce Agency prepared a report entitled, “Recommendations on Streamlining the University of California Technology Transfer Process.” The report proposed that the University of California decentralize its technology transfer process to keep it closer to the grant recipient, the local university instead of the central University of California office.349 This kept the intellectual property management close to the researcher. Providing ownership to the grant recipient provides a strong incentive by the interested participants in the technology transfer process to ensure commercialization of a nascent technology. As discussed supra, ownership of the invention and the right to receive royalties provides the university with an incentive to find out about the development of patentable inventions, secure patent rights from the inventor through an assignment agreement, and attempt to license those rights for commercialization. The faculty researcher is provided an incentive to disclose her inventions to the university to potentially receive a royalty stream. Perhaps more importantly, the faculty member is encouraged to ensure that the invention is successfully commercialized. Some commentators have gone as far as to state that, “Although the licensee must eventually commit resources to attempt to commercialize the invention, further development by the inventor is essential early on if it is to succeed.”350 Thus, providing an incentive to the inventor to participate in the further commercialization of an invention is critical to bringing that invention to market. However, providing ownership to the recipient of funding with royalties shared with the inventor may result in a diversion of research agendas and conflicts of interest which may not be mitigated by modifications to the Bayh-Dole Act or the CIRM Interim Policy concerning increased access to government-funded inventions.

349 Cal. Tech., Trade & Commerce Agency, Recommendations on Streamlining the University of California Technology Transfer Process (Sept. 19, 2003) (manuscript on file with author); see CCST INTERIM REPORT, supra note 7, at 15.
b. Research Exemption

The CIRM Interim Policy also includes a research exemption. As discussed supra, there are concerns about the failure of provisions in the Bayh-Dole Act, which are supposed to protect the interest of the public by ensuring access to patented government-funded inventions. This is particularly important in the biotechnology field where many patented government-funded inventions tend to be inputs for further research, such as research tools that are broadly enabling. Restrictive licensing practices can delay research or potentially impact the direction of a research agenda. Additionally, reach-through royalty clauses can potentially drive up the cost to develop commercial applications and may result in a particular research agenda being deemed not economically worth pursuing. The CIRM Interim Policy attempts to address this issue by including a research exemption. The research exemption is designed to allow California research institutions to use CIRM-funded patented inventions for research purposes for no cost. The CCST Interim and Final Reports advocate for a research exemption for the grantee and research community to use the intellectual property for research purposes if an exclusive license has been granted. The CIRM Interim Policy exemption is somewhat broader than that proposed by the CCST because it applies to all licenses and not just exclusive licenses. However, the CIRM Interim Policy is also narrower because it only applies to California research institutions and not all recipients of CIRM funding. The research exemption does not appear to extend to private commercial entities that may receive CIRM funding. The CIRM exemption appears merely to favor California public institutions over the private sector. Moreover, California public institutions likely will benefit from Eleventh Amendment immunity from patent infringement suits, and thus may already use research tools without fear of suit. Thus, the research exemption is likely very narrow in scope and may be hollow.

Moreover, “California research institutions” is not defined and may be interpreted to include only public institutions and not other non-profit institutions. The limited nature of the research exemption may make more sense when analyzed in light of the absence in the CIRM Policy of the Bayh-Dole Act’s retention of a non-exclusive license to practice the invention for government purposes. However, the CIRM

351 The CIRM Interim Policy applies to non-profits. CIRM is working on developing an intellectual property policy for for-profit entities.
353 35 U.S.C. § 202(c)(4) (the government retains a non exclusive, non transferable right to practice the invention and have the invention practiced on behalf of the government for government activities or purposes).
research exemption is more focused and may apply to somewhat different purposes than the Bayh-Dole Act’s non-exclusive license because the Act’s provision only applies to government purposes. Under the Bayh-Dole Act, government purposes could include a research purpose, but only research for an ultimate government purpose. The Bayh-Dole Act provision is ambiguous. The limited nature of the CIRM exemption counters arguments that the market for research tools only includes other researchers and thus there should not be a broad patent law experimental use exception or a generally applicable research exemption such as the one advocated by Professor Pulsinelli. Indeed, CIRM specifically rejected a provision requiring research tools to be licensed at a low cost in the face of industry complaints that the provision would deprive them of revenue from their potential customers—other California stem cell researchers.  

Professor Pulsinelli’s proposed research exemption is much broader and applies to all recipients of government funding. States should consider adopting a provision similar to that advocated by Professor Pulsinelli. Additionally, a broader exemption may also include a distinction between researching with a patented invention and on a patented invention. The former would be infringement and the latter would be permissible. This may help clarify what is an appropriate research purpose while maintaining the incentive to commercialize the invention by preserving the researcher market for research tools.

There are potential issues concerning the scope of the exemption, but the research exemption provides an opportunity to collect data on the impact of such a provision on the development of an anticommons and whether the exemption will deter researchers and organizations from accepting CIRM funding. Empirical evidence may justify the extension of the scope of the exemption. The success of this exemption can inform policy makers on whether a broader exemption should be added to the Bayh-Dole Act.

c. Royalty Stream

The CIRM Interim Policy also retains a royalty stream for the state, which was generally opposed by the CCST. The CCST argued that the Bayh-Dole Act does not include a royalty sharing clause because it may serve as a disincentive to commercializing basic

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354 Jim Downing, Biotech Profit Plan is OK’d: State Will Share in Firms’ Earnings Based on Fruits of University Research, SACRAMENTO BEE, July 15, 2005.  
355 See generally Pulsinelli, supra note 24.
The CCST Interim and Final reports provide a very limited royalty which is adopted by the CIRM Interim Policy. For example, the royalty is only applied after the grantee organization is paid a threshold amount. After the grantee organization receives royalties that reach a certain amount, the grantee organization pays to California twenty-five percent of its share after payments to inventors. Thus, this provision appears to be directed to inventions that end up generating large amounts of royalties and thus will apply to very few inventions. If the grantee organization is a public institution, it is unlikely that this provision will provide much of a disincentive for that institution to accept CIRM funds. It is important to recognize that this provision does not appear to operate as a separate royalty clause on top of the grantee organization’s royalty clause. The CIRM Interim Policy’s retention of a royalty stream acts as a tax on the grantee organization’s share—not an additional tax on the eventual price of a commercial application.

However, if this provision is adopted in the rules for private recipients and the grantee organization is a private entity, a tax on the grantee organization’s share will directly impact its profits, for example, from the licensing of a research tool to another private entity or the use of a research tool to develop a commercial application. The application of this provision will need to be studied for its impact. The provision may provide a disincentive for the best researchers and research organizations to accept funding from CIRM. But this should not be a substantial problem because the federal government is not funding most embryonic stem cell research and California is one of a few states funding this type of research. A broader royalty provision may be justified because of the investment of substantial amounts of public funding in research and development. Given that the public interest may not have been properly weighed in the crafting of the Bayh-Dole Act’s provisions, the Bayh-Dole Act should be amended to require a royalty back to the U.S. government.

356 See CCST INTERIM REPORT, supra note 7, at 33.
357 Id. at 34.
358 For all university technologies, an average royalty rate of 2% is common. For pharmaceuticals the maximum rate one typically encounters for university technologies is 5%; however, the rates are usually closer to 1.5%. Standard and well-known economic analysis shows that the profit-maximizing price would rise for running royalties, but the increase in price would be less than the royalty rate. In other words, a 2% royalty rate would increase price by less than 2%. The amount price would rise depends on the sensitivity of buyers to price changes; the less sensitive are buyers, the closer to 2% would be the profit maximizing price increase. Thursby & Thursby, supra note 86, at 4.
The CIRM Interim Policy falls short of banning exclusive licenses, but states that grantee organizations should only grant exclusive licenses when the licensed invention requires economic incentives to commercialize the invention.\(^{359}\) When exclusive licenses are not absolutely necessary for commercialization, those licenses “may excessively limit the diversity of further experimentation and development in the context when multiple, rivalrous development efforts may be more socially desirable.”\(^{360}\)

The CIRM Interim Policy is consistent with the NIH’s Best Practices for the Licensing of Genomic Inventions and the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources.\(^{361}\) The CIRM Interim Policy requires that if an exclusive license is granted, the license must include “commercial development plans to bring the invention to practical application.”\(^{362}\) The CIRM Interim Policy also includes provisions requiring grantee organizations to submit “plans to provide access to resultant therapies and diagnostics for uninsured California patients and “such licensees will agree to provide to patients whose therapies and diagnostics . . . purchased in California by public funds . . . at a cost not to exceed the federal Medicaid price.”\(^{363}\)

\(^{359}\) CIRM INTERIM POLICY, supra note 25, at 17. An example of an exclusively licensed government-funded inventions include the stem cell patents owned by the Wisconsin Alumni Research Foundation. See Rai & Eisenberg, supra note 11, at 301-02 (“A prominent example of exclusive licensing on a broadly enabling research tool is the previously noted patent on primate embryonic stem cell lines held by the Wisconsin Alumni Research Foundation (WARF). Under an agreement that provided one million dollars of research support for subsequent work by the inventor, WARF granted a broad exclusive license for commercial use of six important cell types that could be derived from these cell lines to a single private firm, Geron.”).

\(^{360}\) MOWERY ET AL., supra note 103, at 191.

\(^{361}\) NAT’L INSTS. OF HEALTH, BEST PRACTICES FOR THE LICENSING OF GENOMIC INVENTIONS (2005), available at http://www.ott.nih.gov/policy/lic_gen.html#best (“Whenever possible, non-exclusive licensing should be pursued as a best practice. . . . In those cases where exclusive licensing is necessary to encourage research and development by private partners, best practices dictate that exclusive licenses should be appropriately tailored to ensure expeditious development of as many aspects of the technology as possible.”); NAT’L INSTS. OF HEALTH, PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES (1999), available at http://www.ott.nih.gov/policy/rt_guide_final.html (“[T]he goals of the Act can be met through publication, deposit in an appropriate databank or repository, widespread non-exclusive licensing or any other number of dissemination techniques. Restrictive licensing of such an invention, such as to a for-profit sponsor for exclusive internal use, is antithetical to the goals of the Bayh-Dole Act. . . . Exclusive licensing of such an invention, such as to a distributor that will sell the tool or to a company that will invest in the development of a tool from the nascent invention, can be consistent with the goals of the Bayh-Dole Act.”).

\(^{362}\) CIRM INTERIM POLICY, supra note 25, at 17.

\(^{363}\) Id.
deviates from the recommendations of the CCST Interim Report.\textsuperscript{364} According to one commentator, the CIRM Interim Policy requiring the cost not to exceed the federal Medicaid price is a good compromise between calls for the state to negotiate favorable pricing terms for therapies and diagnostics developed with CIRM funding.\textsuperscript{365} This provision clearly creates an expectation in the grant recipient that the recipient must provide some access to uninsured California patients and that therapies and diagnostics purchased by public funds are not to exceed the federal Medicaid price. This ensures that the public’s interest in providing resources to the indigent and controlling the price of therapies and diagnostics is protected. These provisions are relatively clear and the question of price controls is not ambiguously lost within the broad circumstances that may justify the use of march-in rights as expressed in the Bayh-Dole Act and NIH march-in rights decisions. It is unclear what the impact of these provisions will be on nonprofit grant recipients or potential licensees. However, given the cost of health care in the United States and the enormous investment in invention that the public makes through government funding of invention, such a provision may be a welcome addition to the Bayh-Dole Act.

The requirement of commercial development plans likely mandates that the license must include terms such as positive or negative milestones to provide an incentive for commercialization. However, while licenses can be written with performance milestones, “the early stage at which university technologies tend to be licensed makes it difficult to write contracts with effective performance clauses that avoid this problem.”\textsuperscript{366} And, the inventions at that nascent stage could be the inventions that need an exclusive license to obtain investment for further commercialization. However, it is important to remember that there is a distinction between government-funded research tools and privately funded research tools. A strong patent ensures that the private owner of a privately funded research tool is reimbursed for research and development costs of the tool. The owner of the research tool funded by the government does not need to be reimbursed for research and development costs of the tool and will likely not need to spend additional funds to commercialize the tool itself.\textsuperscript{367} A market likely

\textsuperscript{364} See CCST INTERIM REPORT, supra note 7, at 13.
\textsuperscript{366} SHANE, supra note 202, at 282.
\textsuperscript{367} But see Rai & Eisenberg, supra note 24, at 301-02 (“But some discoveries, including some important research tools and enabling technologies generated in the course of publicly-sponsored research, undoubtedly require substantial commercial investment for reliable mass-production and widespread distribution. For example, technologies and machines for DNA sequencing and
already exists for that tool. Moreover, Rai and Eisenberg argue:

It is also unclear whether such exclusive licenses are necessary to further the Bayh-Dole Act’s goal of promoting commercial product development. The farther removed university-based research discoveries are from end-product development, the more likely it is that subsequent research will generate additional patents that will be more important to the profit expectations of private investors than patents on the prior research. Indeed, patents on the many discoveries that enable product development are more likely to add to a product’s cost than to enhance its profitability. Given that the long course of biopharmaceutical product development typically generates a great many patented inventions on the road to market, Congress’ fear that potential new products would never be developed if the early discoveries from which they sprang remained unpatented seems quaintly out of touch with contemporary R&D and patenting practices.\(^{368}\)

Accordingly, access through one proposal or another is absolutely necessary in exclusive licenses to balance the realities of biotechnology development and the public interest.

e. Sharing Biomedical Materials

The CIRM Interim Policy also requires that, “[g]rantees shall share biomedical materials described in published scientific articles for research purposes in California within 60 days of receipt of a request unless legally precluded.”\(^{369}\) This provision is mandatory, but CIRM can provide exceptions to this rule.\(^{370}\) One of the exceptions may include protecting junior researchers. The “unless legally precluded” language appears to allow some materials used perhaps in an industry-university collaboration to be withheld by contract. As discussed supra, there is empirical evidence demonstrating that some researchers are having difficulty obtaining research materials that are tangible property. While it is unclear whether the cause of that difficulty in accessing materials is because of increased patenting or licensing, this provision should enable researchers to obtain research materials from CIRM grant recipients and mitigate the problems associated to withholding research materials.\(^{371}\)

\(^{368}\) Rai & Eisenberg, supra note 24, at 301-02.

\(^{369}\) CIRM INTERIM POLICY, supra note 25, at 16.

\(^{370}\) Id.

\(^{371}\) The delay in publication of research results may be partially addressed through Professor Bagely’s proposal. See generally Bagley, supra note 231. For a discussion of issues concerning
f. March-In Rights

The CIRM Interim Policy also includes “march-in” rights similar to those of the Bayh-Dole Act. However, the CIRM Interim Policy does not appear to include the cumbersome review processes of the Bayh-Dole Act. This may make it more likely that “march-in” rights will be utilized. Moreover, the importance of “march-in” rights is somewhat mitigated given the addition of a research exemption and some focus on access to and pricing of diagnostics and therapeutics developed with CIRM funding. The CIRM Interim Policy should be modified to remove the one year grace period to cure a deficiency because of concerns with delays in access to government-funded inventions.

g. Multiple Funding Sources

The CIRM Interim Policy does not include clear terms concerning conflicts in funding sources. California and other states must develop a method to determine which funders’ terms control in the event of multiple funding sources with one research project. For example, if the federal government and a state allocate funds to a project, which entities’ march-in rights will apply? A simply way to resolve this problem is to allow federal funding and terms to have primacy over the state terms.

h. Consequences for Noncompliance

The CIRM Interim Policy also does not include clear terms outlining the consequences for failure to comply with the policy. CIRM should include express consequences for failure to comply with the terms, beyond the threat of the exercise of march-in rights. The CIRM Interim Policy should include a provision which mandates that if the terms and conditions are violated by a grant recipient, then CIRM may refuse to grant additional funds to that offending recipient.

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material transfer agreements, see Sean O’Connor, The Use of Material Transfer Agreements to Control Commercialization of Stem Cell Diagnostics and Therapeutics, 21 BERKELEY TECH. J. 1017 (2006).

372 O’Connor, supra note 66.

373 See id.
i. Preference for Research and Manufacturing in California

The CIRM Interim Policy does not include a preference for distributing funding to nonprofits that conduct research and manufacturing or that have a primary place of business in California. This is somewhat surprising given that the proponents for Proposition 71 argued that the primary benefit of the proposition would be increased jobs and tax revenue in California. The Bayh-Dole Act provides that licensees that receive exclusive licenses must conduct manufacturing in the United States. There is an argument that a state with this type of requirement would limit itself to a lower number of qualified entities to conduct this type of research. This may reduce the likelihood of commercial success of a research agenda funded by CIRM. If this type of provision is not included in the CIRM Interim Policy or similar policy, then the state should retain a royalty, perhaps even broader than the one currently adopted by CIRM.

j. Exceptional Circumstances

Notably, the CIRM Interim Policy makes no mention of an “exceptional circumstances” provision. The “exceptional circumstances” provision may be excluded because the CIRM Interim Policy is primarily concerned with the terms and conditions that may be included within a grant agreement or license agreement. As discussed supra, it also may be because the “exceptional circumstances” provision is very difficult to exercise given the uncertain nature of biotechnology research and development. An exceptional circumstances type provision should be included in the CIRM policy along with the removal of the term “exceptional” as discussed in Professors Rai and Eisenberg’s proposal. This will enable the state to dedicate some state funded inventions to the public domain. The state should not adopt an onerous review process for research that is deemed to be placed in the public domain because it may provide a disincentive to use the provision.

k. Retention of Non-Exclusive License

The CIRM Interim Policy also does not retain a non-exclusive license to practice the invention or have it practiced on the state’s behalf for government purposes. The exclusion of the retention of the non-exclusive license provision may be because of the presence of a research exemption and march-in rights that are not encumbered by an
extensive review process. The CIRM Interim Policy should include this provision along with specific guidance on what will include a “government purpose.”

2. Building on California’s Experiment

In developing a comprehensive innovation policy for a state, the state should engage in an analysis that goes beyond a consideration of how to allocate ownership of inventions created with state funding. For example, the federal government not only promotes innovation through the provision of intellectual property rights and funding for invention, but also provides prizes and tax incentives. States already provide tax incentives, but states should study the impact of tax incentive programs alongside funding programs. Moreover, as analyzed by the CCST, novel licensing programs have been developed to develop life saving products and services and to ensure access to the underprivileged.

B. Concerns with Development of an Anticommons or Race to the Bottom

First, this section argues that the opportunity to create and study different models for the treatment of government-funded invention outweighs the risks concerning the development of an anticommons. Second, this section also argues that those opportunities also outweigh the risk of a “race to the bottom” among states.

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374 All forms of funding are implicitly incentive schemes, since they set the direction of research and encourage people to do it. Some funding is given ex ante, such as grants, whereas other funding is given ex post, such as patents and prizes. Prizes were eclipsed by patents during the Industrial Revolution, but they have never vanished as an incentive mechanism. For example, the Defense Advanced Research Projects Agency, which is the research arm of the Department of Defense, has offered a $1 million prize to elicit a fortyfold improvement in robotic vehicles for rough terrain. (Defense Advanced Research Projects Agency, 2003). Suzan Scocchmer, Innovation and Incentives 2 (2004). One author argues that the Bayh-Dole Act operates as a prize system because of the prospect of future grant awards. See Molly Silfen, How Will California’s Funding of Stem Cell Research Impact Innovation? Recommendations for An Intellectual Property Policy, 18 Harv. J. Law & Tech. 459, 466 (2005).

375 See generally Frischmann, supra note 32.
1. Anticommons

Professor Sean O’Connor argues that complex questions concerning the ownership of patentable inventions arising from stem cell research, because of the potential availability of multiple funding sources, has the potential to lead to “nasty battles over ownership and control of whatever medical breakthroughs arise from [embryonic stem cell research].” O’Connor states that this is likely to happen if states do not develop rules concerning ownership before creating programs designed to distribute funding for stem cell research, particularly in the face of promises by proponents of these programs that the state will receive some return such as royalty payments. Ultimately, O’Connor argues programs without a clear allocation of ownership rights could “add another layer of uncertainty to the ownership of crucial research [and] paradoxically, hinder the commercialization of these breakthroughs.” At least nine states are allocating funding to stem cell research and each state will likely develop its own policies concerning the ownership of any patentable inventions resulting from that research. O’Connor’s argument appears to be directed to determining ownership early as opposed to after a stem cell research funding program is established, thus shaping public expectations early. O’Connor admits that a broad legislative grant of authority to an agency can prevent “legislative paralysis . . . working out the fine details of a new program’s implementation” and “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.” To the extent the failure of prior allocation is a problem, California and CIRM, while still working out the allocation, appear to be developing ownership rules which account for the interests of the public while at the same time following the general thrust of the Bayh-Dole Act. Absent the prior allocation issue, the next issue that arises

376 O’Connor, supra note 66, at 679; see also CCST INTERIM REPORT, supra note 7, at 25 (a different approach from the Bayh-Dole approach to handling IP by California could lead to additional transaction costs and problems with conflicting sources of funding).
378 Id. at 2. O’Connor argues, “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.” O’Connor, supra note 66, at 707.
379 Id. at 678.
380 Id.
381 O’Connor suggests that “state and local initiatives like Proposition 71 should explicitly incorporate the Bayh-Dole rights allocation framework, including . . . intergovernmental combinations of federal, state, and local funding.” Id. at 708. According to O’Connor, the foregoing proposal also does nothing to remove potential conflicts over IP rights.
concerns the added layer of uncertainty and additional transaction costs of having another potential funder and claimant to a patentable invention. University technology transfer offices routinely confront ownership issues surrounding patentable inventions arising from multiple funding sources and have developed some expertise in handling those issues. However, additional transaction costs may contribute to the development of an anticommons in biotechnology innovation and should be monitored. As discussed supra, whether an anticommons has developed or not is unclear. Moreover, participants in the biotechnology industry appear able to avoid an anticommons. The anticommons impact in the stem cell research area will also be mitigated by the fact that many states, in fact a substantial number, are restricting stem cell research in one form or another. Furthermore, assuming that the CIRM Interim Policy becomes final, the addition of a research exemption and march-in rights without a cumbersome review process may mitigate any additional risk of an anticommons and may actually serve to prevent an anticommons from developing. Other states may adopt similar provisions, which may serve to lessen the chance of the development of an anticommons.

2. Race to the Bottom

A common argument against utilizing states as laboratories is that there will be a “race to the bottom” among the states, which will result in inefficient and socially destructive competition. This debate has occurred in many fields, including corporate law, international antitrust law, taxation, tort law, patent law, and environmental law. “The
theory of the race to the bottom is that in enacting otherwise sensible
regulations, states may disadvantage themselves by raising the cost of
doing business in the state, thus driving the business to states that
regulate less rigorously.386 “Yet, the more stringent regulation may be
desirable for gross reasons of efficiency, or for other reasons of social
welfare.”387 The race to the bottom in the design of systems concerning
the treatment of government-funded inventions may include the failure
to adopt a research exemption for patentable inventions created with
government funding, not including price controls for diagnostics and
therapeutics created with government funding or not adopting a
retention of royalty for the state. However, a race to the bottom may
not be a substantial risk with innovation systems concerning the
treatment of government-funded inventions, particularly those directed
to embryonic stem cell research. The ability to allocate substantial
amounts of funding for research and development is not something that
most states have the resources to do, especially at the level of
California’s investment. This is particularly true with regard to one area
of research; California will invest $300 million per year for ten years in
one discrete area of research. Moreover, most states do not have the
quantity and quality of research institutions in California and there are a
limited number of states with those resources. Also, many states have
restricted embryonic stem cell research and will not be viable players in
providing funding for embryonic stem cell research. Thus, there are a
very limited number of states with the resources or ability to compete
for increased jobs and tax revenue that may result from increased
embryonic stem cell research and development.

Furthermore, states may have an incentive to design systems
allowing for increased access to government-funded inventions.
Recipients of government funding for research and development may
desire to accept funding from states that have a robust research
exemption that includes all recipients of funding from that state. That
type of research exemption may insulate a recipient of state funding
from infringement and permit access to state funded technology,
including research tools, owned by other recipients of that state’s
funding. Thus, state design of additional systems could increase access

386 Friedman, supra note 332, at 408-09.
387 Id. at 408.
to research tools and other technology through the design of a broad research exemption.

As discussed supra, the substantial risks of the supposed unintended consequences of the Bayh-Dole Act may occur and threaten to impede biotechnology research and development, reduce the production of basic research and undermine the credibility of the academia. The substantial reliance interests in the Bayh-Dole Act along with the difficulty of producing definitive evidence of the impact of the Act make the opportunity to study the impact of biotechnology patenting and licensing with a discrete research area critically important. Innovation at the state level may lead to new systems for the treatment of government-funded invention that may mitigate some of the unintended consequences of the Act. Moreover, the development of new systems at the state level may lead to reform of the Bayh-Dole Act, which may also avoid many of the unintended consequences of the Act. The risks of the development of an anticommons or a race to the bottom are outweighed by the benefits of the opportunity for the development of new systems that may mitigate the serious risks presented by the Bayh-Dole Act and to study the new systems to propose changes to the Bayh-Dole Act.

CONCLUSION

The decision to limit the funding of embryonic stem cell research by the Bush Administration has presented an opportunity for states to develop alternate systems for the treatment of government-funded invention. The benefits from this opportunity include the ability to avoid or mitigate the risk of development of many of the asserted negative unintended consequences of the Bayh-Dole Act. Moreover, modified versions of the Bayh-Dole Act will allow researchers to study the impact of the new provisions and may inform modifications to the federal policy, the Bayh-Dole Act. These benefits outweigh the risks that contributing to an anticommons or a race to the bottom may present. States, particularly California, should take advantage of the opportunity to not only ensure that the interests of its citizens are protected, but to contribute to the development of improved federal policy.