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When Patent Rights and Health Care Regulation Collide: How the Bayh-Dole Act may Unintentionally Stifle States' Initiatives to Address the Health Care Crisis

INTRODUCTION

Health care reform has long been a brooding problem that has recently come to the forefront. Health care costs and premiums have perennially increased where burdening costs can no longer be ignored. President Bush acknowledged the looming health care crisis in his 2007 State of the Union Address.[1] Not only is the health care crisis a problem of being unable to afford insurance or health care, but health care costs also have an insidious effect on the economy. For example, General Motors (GM) has acknowledged that the rise in health care costs has impacted their ability to compete globally.[2] GM,[3] has posted significant losses the past few quarters, some of which attributed to the rise in health care costs.[4] Though GM may be more susceptible to rising health care costs as it is one of the nation's most comprehensive providers,[5] GM's fate may foreshadow what is in store for other businesses if rising health care costs continue to be a burden.[6]

To address this health care crisis, a few states have taken the initiative to offer universal health care for its citizens. Massachusetts' plan pioneered the Universal Health Care push,

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[1] George W. Bush, President of the United States of America, State of the Union Address (Jan. 23, 2007) (available at http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html) (last visited, Jan. 25, 2007) [hereinafter, State of the Union 2007].
[2] Ceci Connolly, *U.S. Firms Losing Health Care Battle, G.M. Chairman Says*, WASH. POST, Feb. 11, 2005 at E01.
[3] GM is currently the number one auto producer. However, it is projected that Toyota will overtake GM as the number one automaker in the world in 2007. *See* Ian Rowley, *Top Spot in Sight, Toyota's Not Slacking*, BusinessWeek, Dec. 13, 2006, http://www.businessweek.com/globalbiz/content/dec2006/gb20061213_806308.htm.
[4] Lee Hawkins, Jr., *GM Reports Net Loss of $286 Million*, WALL ST. J., Jul. 21, 2005 at A3.
[5] *See* Julie Appleby & Sharon Silke Carty, *Ailing GM Looks to Scale Back Generous Health Benefits*, U.S.A Today, Jun. 23, 2005, http://www.usatoday.com/money/autos/2005-06-22-gm-healthcare-usat_x.htm ("The American auto industry is one of the last bastions of generous benefits that were once part of many employers' largess: fully paid health insurance, retiree medical coverage, and pensions").
[6] *See* Connolly, *supra* note 2 ("GM is the canary in the coal mine for Medicare and everyone else. There are many, many more companies out there in trouble because of health care costs than just the auto, steel, and airline industries) (quoting Sean P. McAlinden, chief economist at the nonprofit Center for Automotive Research).

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signing a law in 2006 that provides nearly universal healthcare coverage by July of 2007.[7] Following Massachusetts' lead, California and Pennsylvania have recently made a push for universal health care.[8] Pennsylvania's proposed bill even acknowledges the effect of health care costs on the economy, citing economic reasons for proposing health care reform.[9] In offering universal health care, States appear to address both the health of their citizens, and the economic effects of rising health care costs. Thus, offering universal health care appears to be one potential solution to the national problem of rising health care costs.

Aside from state's proposing universal health care initiatives, in a smaller microcosm, there is a notion that rising health care costs have some link to the increased number of patents generated by research in areas such as biotechnology, genomics and pharmaceuticals.[10] This perceived connection between health care costs and patents in biotechnology has been noted as an unintended side effect of the Bayh-Dole Act in 1980.[11]

The Bayh-Dole Act was implemented to help with technology transfer. That is, the Act was to help bring technologies made using government funding available in the market.[12] However, the Act has drawn both praise and criticism, ranging from Congress re-affirming its commitment to the act,[13] to the criticism that people now have to pay more for uninspired

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[7] *See* KAISER COMMISSION ON MEDICAID AND THE UNINSURED (describing the Massachusetts universal health care plan), *available at* http://www.kff.org/uninsured/upload/7494.pdf [hereinafter, Kaiser Commission on the Uninsured].
[8] *See* Governor Schwarzenegger's Health Care Proposal, *available at* http://gov.ca.gov/pdf/press/Governors_HC_Proposal.pdf [hereinafter, Cal. Health Care Proposal] *See also* S. 1085, Reg. Sess. (Pa. 2006) (Senate Bill proposing Universal Health Care Plan) *available at* http://www2.legis.state.pa.us/WU01/LI/BI/BT/2005/0/SB1085P1504.pdf [hereinafter, Pa. Health Care Proposal].
[9] *See* Pa. Health Care Proposal, *supra* note 8, at 2.
[10] *See e.g.,* Simone A. Rose, *On Purple Pills, Stem Cells, and Other Market Failures: A Case for a Limited Compulsory Licensing Scheme for Patent Property*, 48 HOW. L.J. 579 (2005)
[11] *See e.g.,* Clifton Leaf, *The Law of Unintended Consequences*, FORTUNE, Sept. 19, 2005 at 250. The issue of rising costs and other criticisms of the Bayh-Dole Act will be discussed further in Section I. B. 2, *infra*.
[12] *See* Bayh-Dole Act, 35 U.S.C. § 200 (2000).
[13] H.R. Res. 319, 109th Cong. (2006) (enacted), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:hc319ih.txt.pdf.

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products.[14] Furthermore, legal scholars have dissected the Bayh-Dole Act, commenting about the unintended effects of the Act, or if those effects actually exist.[15]

Regardless of who is right about whether the negative effects of the Bayh-Dole Act outweigh the positive effects, there has been a current trend in the scientific community to avert the perceived negative consequences of the Act. For example, the National Institute of Health (NIH) is proposing a creation of a centralized databank in order to make research information derived from governmentally funded projects more available.[16] In another notable example, states that have granted funding to embryonic stem cell research have proclaimed their preference for sharing research data.[17] This open access trend appears to be a reaction to address the criticisms of the Bayh-Dole Act.

Leading the sharing initiative is the California Institute of Regenerative Medicine (CIRM). The CIRM was created through Proposition 71, an amendment allowing state funds to go towards embryonic stem cell research.[18] The CIRM Intellectual Property Policy (CIRM IP Policy) requires the most comprehensive sharing of information, ranging from sharing biomedical materials to providing access to patented inventions that result from state funded research.[19] Furthermore, the CIRM IP Policy contains other provisions that specifically address

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[14] *See e.g.*, Leaf, *supra* note 11.
[15] This issue is further discussed in Section I, *infra*
[16] *See* Proposed Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS), *available at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-094.html (last visited Jan. 27, 2007) [hereinafter NIH GWAS Proposal].
[17] *See* Erin Bryant, *State-Funded Researchers in Maryland Must Share Stem Cell Lines*, Fox News, Oct. 16, 2006, http://www.foxnews.com/story/0,2933,220918,00.html (last visited Feb. 2, 2007). *See also* email from Charles Firke, Illinois Stem Cell Research Project Manager, to Justin R. Cruz, Student at DePaul University College of Law, (Oct. 25, 2006) (requiring the sharing of stem cell lines derived from state funded research) (on file with the author).
[18] Ca. Const. art. XXXV, § 1.
[19] *See* Ca. Inst. for Regenerative Medicine, Intellectual Property for Non-Profit Organizations 4 (Feb. 2006) ("A primary objective of the CIRM [Intellectual Property Policy for Non-Profit Organizations] is to promote sharing of ally 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"), *available at* http://www.cirm.ca.gov/policies/pdf/IPPNPO.pdf [hereinafter CRIM Non-Profit IP Policy].

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the health care issue. After all, proponents of the passage of Proposition 71[20] stated that stem cell research could help cut the cost of health care.[21] Though stem cell therapies have yet to come to fruition, the policy issues that drive the intellectual property guidelines should be resolved now.

As mentioned earlier, California citizens passed Proposition 71 as part of potential solution to rising health care costs.[22] However, the preference for open access to research and therapies in the CIRM IP Policy may create conflicts with the Bayh-Dole Act, should the federal government allow more funding to go towards embryonic stem cell research.[23] If federal funds become available for embryonic stem cell research, any resulting patents would fall within the strictures of the Bayh-Dole Act.[24] This may seem innocent, as it is within the province of the federal government to determine patent rights.[25] However, States are reserved the right to address the health of its citizens.[26] Thus, allowing federal funding for embryonic stem cell research may frustrate California's initiative to address the health of its citizens and its health care problems because the Bayh-Dole provisions would take primacy over the CIRM IP Policy's health care provisions.

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[20] The Bill that created CRIM and allocated funds for stem cell research

[21] *See* California Proposition 71 (stating the purpose and intent of the proposed law is to "[i]mprove the California health care system and reduce the long-term health care cost burden on California through the development of therapies that treat diseases and injuries with the ultimate goal to cure them), *available at* http://www.cirm.ca.gov/prop71/pdf/prop71.pdf [hereinafter, Prop. 71]. *See also* California Attorney General's Description of Proposition 71, 72, *available at* www.ss.ca.gov/elections/bp_nov04/prop_71_entire.pdf (listing health care savings through potential cures due to stem cell research as one of the arguments for suggesting the passage of Prop. 71).

[22] *See id.*

[23] The House of Representatives just passed another bill that would allow more federal funding into embryonic stem cell research entitled. Stem Cell Research Enhancement Act of 2007, H.R. 3, 110th Cong. (1st Sess. 2007), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h3ih.txt.pdf.

[24] *See generally* U.S. CONST. art. VI, cl. 2; *see also* 35 U.S.C. § 210 (describing the precedence of the Bayh-Dole Act)

[25] U.S. CONST. ART. I, § 8, cl. 8 ("Congress shall have the power to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries").

[26] *See, e.g.,* Hillsborough County, Fla. v. Automated Medical Laboratories, 471 U.S. 707, 719 (1985) (holding local ordinances and regulations concerning plasma donation not preempted by FDA regulations because "the regulation of health and safety matters is primarily, and historically, a matter for local concern").

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It should be noted that the health care issue presented is arguably an economic issue; that California is trying to save money due to the economic burden of the rise in health care costs. However, even though health care has become an economic issue, it should be remembered that saving money on health care costs is predicated on having healthy citizens. Yet, even if economic savings is a motivating reason for addressing health care, it should not be forgotten that California is trying to improve the health of its citizens *de facto*. Accordingly, this article will address how federal funding of embryonic stem cell research could stifle California's initiative to address its health care problem.[27]

In analyzing the potential conflict, this comment will discuss the perceived interplay between patent policies and health care costs. Part I of this comment will discuss the Bayh-Dole Act, its criticisms, and the criticisms' importance in current trends in IP policy. Part II will discuss current sharing trends in IP Policy and its potential link to health care costs, especially in context of California's Stem Cell IP Policy. Part III addresses the potential conflict between California's IP Policy and any Federal Legislation, should Federal Funding become available for embryonic stem cell research. Part IV provides suggestions to ensure Federal Legislation would not impinge on any State's initiatives to alleviate the health care problem.

I: THE BAYH-DOLE ACT

A. Background

The Bayh-Dole Act was one of two bills passed in 1980 to help in technology transfer. [28] Passage of the Bayh-Dole Act was to alleviate the notion that the public was not benefiting from

[27] This problem may arise in other states that allow embryonic stem cell research. However, California, at the time of the writing of this paper has the most comprehensive IP policy and it specifically addresses health care issues.
[28] *See* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996). Professor Eisenberg's article provides an excellent

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government-funded inventions because government-funded inventions were "languish[ing] in government and university archives" instead of being brought to market.[29] The Act was to provide a remedy to the government's poor track record of bringing government owned patents to the market.[30] To achieve this, the Act allowed small businesses and nonprofit organizations to keep patent rights to discoveries, given they were diligent in getting patent applications on file and promoted the commercial development of their inventions. Though the Bayh-Dole Act initially pertained to small businesses and nonprofit organizations, the scope of the Bayh-Dole Act expanded to include businesses in 1983.[31]

There were three primary purposes for passing the Bayh-Dole Act.[32] First, the Act was to ensure that the public would benefit from government-funded inventions by commercializing the inventions.[33] Second, the Act was to ensure that U.S. firms would develop U.S. sponsored discoveries, as there was a perception that foreign firms were benefiting by making products based on technologies pioneered in the U.S.[34] Third, the Act was supposed to reinvigorate U.S. industry by increasing productivity and creating new jobs from an infusion new ideas.[35]

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history of the environment leading up to the passage of the Bayh-Dole Act, and the historical discussion in this article derives significantly from Professor Eisenberg's article.

[29] *Id.* at 1664.

[30] *Id.* at 1665.

[31] *Id.*

[32] *Id.* at 1664. *See also* Michael S. Mireles, Jr., *States as Innovation System Laboratories: California, Patents, and Stem Cell Technology*, 28 CARDOZO L. REV. 1133, 1141 (2006) [hereinafter Mireles, *States as Innovation System Laboratories*].

[33] Eisenberg, *supra* note 28, at 1665.

[34] *Id.* at 1665.

[35] *Id. Cf.* 35 U.S.C. § 200 (explicitly listing the purpose of congress in enacting the Bayh-Dole Act is to "use the patent system [1] to 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 protect the public against nonuse or unreasonable use of inventions; and [7] to minimize the costs of administering policies in this area).

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In order to achieve these purposes, the Bayh-Dole Act allows research entities using government funds to keep title to the patent.[36] The shift in policy provides an ex post incentive to develop the results of federally funded research into products or services that can be brought to market.[37] Shifting ownership rights to the funding recipient creates an incentive for the recipient to bring the patented technology to the market, where the recipient can recoup the money spent on research and development (R&D). Also, a grant recipients' ability to receive a "supra-competitive" price with the exclusive rights provided by the patent lowers R&D costs and helps ensure a profit by lowering R&D costs.[38] Thus, by shifting focus from ex ante incentives to ex post incentives, the Bayh-Dole Act addresses underuse of information goods.[39]

However, a funding recipient must fulfill various conditions in order to receive title to the patent. These conditions appear to be a procedural safeguard that balance the interests of the government and the public by requiring the government to review any agency's decision to keep title to the patent.[40] For example, the Bayh-Dole Act requires timely filing requirements to ensure that there is not a forfeiture of rights to patented inventions.[41] Furthermore, the Act requires timely disclosure so the government can choose to retain title to an invention should a funding recipient fail to meet the disclosure requirement.[42] After the disclosure, the recipient must elect to retain title within two years of the disclosure.[43] Should the recipient and the government choose not to retain title, the recipient's employee inventor can elect title to the

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[36] *See* 35 U.S.C. § 202(a) (Each nonprofit organization or small business firm may, within a reasonable time . . . elect to retain title to any subject invention). *See also* Eisenberg, *supra* note 28 at 1671-1695 (discussing why the Bayh-Dole Act allowed inventors to keep title as opposed to the option of the government keeping title and the inventor receiving a license).
[37] *See* Mireles, *States as Innovation System Laboratories supra* note 32, at 1143.
[38] *Id.* at 1144.
[39] *Id.* at 1151-52.
[40] *Id.* at 1143.
[41] *Id.*
[42] *Id.* (citing 35 U.S.C. § 202(c)(1)).
[43] *See* 35 U.S.C. § 202(c)(2).

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invention.[44] This election provision ensures someone receives the patent rights to the government-funded invention. Though the funding recipient has the first chance to keep title in the patent, the procedure allows the government to retain title or the employee inventor to own the patent rights should the funding recipient choose not to keep title to the invention. Also, the timing requirements of the provision appear structured to protect the government's and the public's interests.[45]

The obligations required of the funding recipient after receiving title to the invention further protect Government and public interests. For example, the Bayh-Dole Act requires the funding recipient to patent the invention in a timely fashion (both in the U.S. and in other countries) and to keep the government informed of any conditions that impact patentability.[46] Should the funding recipient fail to patent inventions in a timely fashion, the U.S. government can claim title to the inventions in both the U.S. and abroad.[47] This provision protects the government's interest and the public's interest in preventing the loss of patent rights within the U.S. and in other countries.[48]

Furthermore, the Bay-Dole Act contains provisions that appear specifically tailored to ensure government funded technology is available to the public or will be commercialized. To achieve this goal, the Act provides some exceptions to rights conferred to inventors. First, the government can take intellectual property if there are "exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject

[44] *See* 35 U.S.C. § 202(d).
[45] *See* Mireles, *States as Innovation System Laboratories supra* note 32, at 1144.
[46] *See* 35 U.S.C. § 202(c)(3).
[47] 35 U.S.C. § 202(c)(3).
[48] Mireles, *States as Innovation System Laboratories supra* note 32, at 1144.

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invention will better promote the policy and objectives of [the Act]."[49] Second, the government retains a "nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."[50] Finally, Section 203 of the Act contains "march-in" rights that describe certain situations where the government has a right to mandate the patent owner of a federally funded technology to license the rights to a third party in particular situations. The most notable situations where the government may exercise these march-in rights is when the invention has not been commercialized within a reasonable time,[51] or licensing is needed to "alleviate health or safety needs."[52]

B. Praises and Criticisms

After more than twenty-five years since its passage, the Bayh-Dole Act still remains controversial. As mentioned earlier, the Bayh-Dole Act has drawn both praise and its share of criticisms. The following part will first address the praises, then discuss the criticisms that have been pertinent to current trends in IP policy.

1. Praises

The House of Representatives introduced a resolution in December of 2005 to commemorate the twenty-fifth anniversary of the Bayh-Dole Act.[53] The resolution praises the Act as accomplishing its purported goal of making government funded technology available to the public.[54] The resolution goes even further, attributing the success of technologies in

[49] Molly Silfen, *How Will California's Funding of Stem Cell Research Impact Innovation? Recommendations for an Intellectual Property Policy*, HARV. J.L. & TECH. 459, 464 (2005) (citing 35 U.S.C. § 210(a)(ii) (internal quotations omitted)).
[50] *Id.* at 464 (citing 35 U.S.C. § 210(c)(3) (internal quotations omitted)).
[51] 35 U.S.C. § 203(a)(1).
[52] 35 U.S.C. § 203(a)(2).
[53] *See* H.R. Res. 319 *supra* note 13. *See also* Mireles, *States as Innovation System Laboratories*, *supra* note 32, at 1147-50 (also discussing the Resolution).
[54] *See* H.R. Res. 319, *supra* note 13, at 2-4

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biotechnology and information communication industries are attributable to the Bayh-Dole Act.[55] Furthermore, the resolution states that

> therapies, technologies, and inventions which have resulted from the collaborative environment fostered by the Bayh-Dole Act, have directly contributed to the ability of medical researchers to discover and commercialize new treatments that alleviate patient suffering, enhance the ability of doctors to diagnose and treat disease, and target promising new medical research.[56]

The resolution concludes by reaffirming its commitment to the Act, stating 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.[57]

Though Congress reaffirmed its commitment to the Bayh-Dole Act, the language of the resolution appears to be directed at the criticisms of the Act since its passage. The resolution even includes "laudatory statements" from the Economist, the former counsel of the Wisconsin Alumni Research Fund, and the director of the Technology Transfer Office at the Massachusetts Institute of Technology.[58] The criticisms the resolution is supposed to diffuse are discussed below.

2. Criticisms

The Bayh-Dole Act has drawn criticisms from many legal commentators. The following section describes the particular criticisms of the Bayh-Dole Act that have lead to shifts in IP

[55] *See id.* at 3.
[56] *See id.*
[57] *See id.* at 6-7.
[58] Mireles, *States as Innovation System Laboratories*, *supra* note 32, at 1147-48; *See also* H.R. Res. 319, *supra* note 13 at 4-6

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Policy. This comment will focus on the criticisms of the Act that appear to have a pertinent connection to the cost of health care.

a. The Tragedy of the Anticommons

One of the most debated issues of the Bayh-Dole Act is the notion that the Act has led to a tragedy of the anticommons in biomedical research. The idea of an anticommons in biomedical research was proposed as a contrast to the Tragedy of the Commons metaphor. The Tragedy of the Commons metaphor argues that people overuse communal resources because there is no incentive to conserve that resource.[59] Since people do not appreciate the true value of a communal resource, people would overuse that resource.[60] The anticommons theory, in contrast, proposes that an underuse of property would develop if too many rights were grated to a particular piece of property.[61] The notion of an anticommons suggests that more intellectual property rights could lead to fewer useful products because of the underuse of property.[62] This underuse arises when patent right holders "block" one another. Blocking occurs when an inventor of a prior patent (the original patent) cannot use improvements on that invention because another person owns the patent rights on the subsequent improvement (the improvement patent).[63] These patent rights are "blocking patents," as neither party can fully utilize his or her own invention because of the other's patents rights.[64] Therefore, an underuse of developed

[59] *See generally* Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243 (1968).
[60] *Id.*
[61] *See* Heller and Eisenberg, *supra* note 62 at 698.
[62] Michael Heller and Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*. 280 SCI. 698 (1998).
[63] Mireles, *States as Innovation System Laboratories*, *supra* note 32 at 164. Also, the owner of an original patent may "block" the owner of the improvement patent by not licensing the use of the original patent to the inventor of the improvement patent. Thus, any use of the improvement patent would infringe because use of the improvement patent requires use of the original patent. Another blocking scenario arises when one inventor owns the patent rights to one piece of an invention, and a different inventor owns another piece to the invention. By creating the whole invention, each inventor would be infringing on the other's patent.
[64] *Id.* at 164.

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technology may arise if the parties are unable to resolve this issue, and the product or service is never brought to market.[65]

Giving patent rights to "upstream" research tools is one of the primary conditions that would precipitate an anticommons in biomedical research.[66] The concern that too many upstream patents would lead to an anticommons situation arises from patent owners' ability to charge high licensing premiums for patents on technology required to conduct further research.[67] This, in turn, would impede research, as cost would become a more restrictive factor.[68] Furthermore, granting too many upstream patents would produce a "patent thicket," since a researcher would be required to obtain multiple licenses before being able to start research.[69] Should a patent thicket arise, it is a logical conclusion that the end consumer would have to pay the higher costs. That is, health care products or services would reflect the increased cost to obtain a multiple licenses, and the consumer would have to pay this higher cost.[70]

b. Failure to Exercise March-In Rights

Another equally important criticism of the Bayh-Dole Act is the government's reluctance to exercise march-in rights. As discussed above, one of the march-in provisions is supposed to

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[65] *Id.*
[66] Upstream research tools are basic research tools that everybody would need to use to further research. *See* Heller and Eisenberg, *supra* note 62 at 699.
[67] *See id.*
[68] Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 295-97 (2003) (discussing the Cohen-Boyer patent on basic recombinant DNA techniques) [hereinafter Rai & Eisenberg].
[69] *Id.* at 297.
[70] Many law scholars have proposed ways to address this issue. *See* Rai & Eisenberg *supra* note 66 (proposing an ex ante determination about which discoveries should be patentable; Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J.L. SCI. & TECH 393 (2006) (proposing alternative approach to Rai & Eisenberg, and arguing to focus on user of technology to classify technology into categories such as research tools and end products); Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, And The Tragedy of The Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141 (2004) (discussing other proposed approaches such as using a heightened utility requirement, fair use exception, and patent pools); *but see* David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985 (2005) (arguing that an anticommons in biotechnology patenting will not arise anytime soon because "[b]iomedical science remains a relatively unexplored territory in which the frontier is nowhere near an obvious geographical boundary").

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help provide access to government funded inventions when needed to "alleviate health of safety needs."[71] So far, it appears that only three petitions have been filed to exercise march-in rights. However, the government has yet to exercise these march in rights.

i. Johns Hopkins University v. CellPro, Inc.

The first petition requesting the government exercise march-in rights regarded a patent on a stem purification and suspension technology owned by Johns Hopkins University (Hopkins) and Baxter Healthcare Corporation (Baxter).[72] The petition arose out of litigation regarding patent infringement,[73] and failed licensing agreements between the patents owned by Hopkins and Baxter, and biotechnology company, CellPro, Inc. (Cell Pro). The infringement litigation arose because CellPro's stem cell purification device infringed on the patent license agreement between Hopkins and Baxter. CellPro brought a petition to exercise march-in rights, alleging that Hopkins and Baxter failed to take reasonable steps to commercialize the stem cell technology, and because march in was necessary to alleviate health and safety needs.[74] In denying the petition to exercise march-in rights, the NIH first found that Hopkins and Baxter took effective steps to achieve practical application "as demonstrated by Hopkin's licensing, Baxter's manufacture, practice, and operation [of the patented device], and the devices availability to and use by the public to the extent permitted at this time under applicable law (i.e., foreign sales as well as widespread clinical research in the U.S.)."[75]

Second, the NIH also found that march-in was not required to ensure health or safety needs. The NIH noted that it was still unclear if the patented technology provided improved

[71] 35 U.S.C. § 203.
[72] Nat'l Inst. of Health, Determination in the Case of Petition of CellPro, Inc. (Aug. 1, 1997) *available at* http://www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf [hereinafter, CellPro march-in petition].
[73] *See* Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342 (Fed. Dist. 1998) (litigation concerning CellPro allegedly infringing on Johns Hopkins patents and CellPro challenging validity of Johns Hopkins patents).
[74] *See* CellPro march-in petition, *supra* note 72, at 4.
[75] *Id.* at 5.

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results, such as disease-free survival of stem cells or overall survival of stem cells.[76] Thus, it was premature to determine if there were any patient benefits from the use of the machine.[77] The NIH also rejected CellPro's argument that paying Baxter for sales of the device under Baxter's proposed terms would force CellPro out of business, thus depriving the public of the benefit of the device. The NIH, in a deferential tone, stated that the marketplace was the best regulator for price in the private sector.[78] Furthermore, the NIH took note how CellPro risked patent infringement litigation, despite having the opportunity to enter a licensing agreement.[79] Though there may have been some unclean hands issues in this case, the NIH made clear that it would defer to the market place in terms of pricing.

ii. Essential Inventions, Inc. and Abbot Laboratories

The second formal march-in petition involved patents in Abbott Laboratories' (Abbot) Novir AIDS drug. While CellPro primarily predicated its petition to exercise march-in rights on failing to take steps to commercialize the technology, cost-restrictive drug prices was the primary reason Essential Inventions, Inc. (Essential Inventions) brought the petition against Abbot.[80] Again, the NIH refused the petition for march-in rights, finding that Norvir had reached practical

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[76] *Id.*
[77] *Id.*
[78] Specifically, the NIH commented:

> We are wary, however, of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies . . . In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research.
>
> On balance, we believe it 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. . . . 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 commercial terms than it can otherwise obtain from the Court or from the patent owners. *Id.* at 8.

[79] *Id.*
[80] Sean M. O'Connor, *Intellectual Property Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, NEW ENG. L. REV. 665, 704 (2005).

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application, as the drug had been on the market and available for at least eight years.[81] Furthermore, the NIH did not find a need to use march-in rights to alleviate any health or safety needs because Essential Inventions did not present any evidence that march-in rights would alleviate any health or safety needs Abbot did not reasonably satisfy.[82] Rather, Essential Inventions predicated its argument for the necessity to exercise march-in rights solely on a dramatic price increase in Norvir's drug, midway through the patent term.[83] The petition based its argument on the idea that the government could use the march-in provisions of the Bayh-Dole Act as price regulators.[84] This derived from a law review article by Professors Arno and Davis that concluded that the legislative intent of the march-in provisions was to provide a "reasonable pricing requirement."[85]

The NIH went on to reject the argument, stating "that the extraordinary remedy of march-in is not an appropriate means of controlling prices,"[86] and it would be more appropriate for Congress to address the issue of drug pricing.[87] This decision clarified the notion that the march-in provisions were not intended to regulate pricing. Again, the NIH stood by the policy that the cost-restrictiveness of medication does not appear to rise to the level of alleviating a health need.

iii. Xalatan

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[81] Nat'l Inst. of Health, Opinion in the Case of Norvir, Manufactured by Abbot Laboratories, Inc. 5 (Jul. 29, 2004) *available at* http://www.ott.nih.gov/policy/March-in-norvir.pdf [hereinafter Norvir march-in petition].
[82] *Id.* Norvir march-in petition, *supra* note 81
[83] O'Connor, *supra* note 80, at 704.
[84] *See id.* at 704 (citing Norvir march-in petition).
[85] *See* Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Requirements Imposed Upon Patents Deriving in Whole or in Part From Federally Funded Research*, 75 TUL. L. REV. 631 (2001). Professor O'Connor discusses the deficiencies of this law review article, *supra* note 80 at 704-05.
[86] Norvir march-in petition, *supra* note 81, at 5-6.
[87] *Id. at* 6. It is also important to note that Senator Birch Bayh made a statement during the march-in petition hearing, explicitly stating that Professors Arno and Davis did not accurately state the legislative intent behind the Bayh-Dole Act. Senator Bayh's statement rejects the idea that the march-in provisions were intended to serve as price control mechanisms. *See* Statement of Senator Birch Bayh to the National Institutes of Health (May 25, 2004), *available at* http://www.ott.nih.gov/policy/meeting/Senator-Birch-Bayh.pdf.

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In the third petition, the NIH upheld the policy that march-in provisions are not intended to regulate prices regarding the drug Xalatan.[88] Again, the basis for the march-in petition regarded price control, as Xalatan was available for a much lower price in Canada and Europe.[89] The NIH's decision to decline exercising the march-in rights was almost a carbon copy of the Norvir decision, practically replacing "Norvir" with "Xalatan."[90] Given the NIH's refusal to use march-in rights to regulate prices, it is clear that cost-restrictiveness is not a "health-need" within the meaning of the Bayh-Dole Act.

b. Paying Twice

Another important criticism of the Bayh-Dole Act is the notion of "paying twice." The paying twice criticism contends that consumers are first paying to develop the technologies with their tax dollars.[91] Then, consumers are charged again by paying higher prices if someone that has a patent on a blockbuster product or therapy. As Professor O'Connor notes, this issue was debated in the legislative history.[92] The counterargument goes that it is better to "pay twice" than not have the technology at all.[93] Though Congress addressed the paying twice argument in the legislative history of the Bayh-Dole Act, the issue of paying twice is still one of the major criticisms of the Bay-Dole Act.

II: How the Criticisms of the Bayh-Dole Act Have Influenced Current IP Policy

[88] Xalatan is a drug used in the treatment of glaucoma. *See* Nat'l Insts. of Health, Opinion in the Case of Xalatan Manufactured by Pfizer, Inc. 1 (Sept. 17, 2004), *available at* http://www.ott.nih.gov/policy/march-in-xalatan.pdf [hereinafter Xalatan march-in petition].
[89] *See* Xalatan march-in petition at 6.
[90] *Compare* Norvir march-in petition *with* Xalatan march-in petition (wording in decisions almost identical).
[91] *See e.g.*, Eisenberg *supra* note 28 at 1666-67.
[92] *See* O'Connor *supra* note 80 at 704-06. *See also* Statement of Senator Birch Bayh to the National Institutes of Health (May 25, 2004), *available at* http://www.ott.nih.gov/policy/meeting/Senator-Birch-Bayh.pdf.
[93] *See* Statement of Birch Bayh, *supra* note 90, at 2 (stating that taxpayers were not receiving any benefit from government funded research pre-Bayh-Dole Act because taxpayer money was spent on patents which were "collecting dust at the PTO").

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Though showing an anticommons actually exists is elusive, the criticisms of the Bayh-Dole Act have resulted in a philosophical shift in IP Policy. Though there may not be conclusive evidence of an anticommons existing, or patent thickets are to blame for higher prices, the examples of broad patents provide an availability heuristic that an anticommons will develop. One example is the restrictive licensing agreements for the BRCA1/BRCA2 gene patent. The BRCA1 and BRCA 2 genes determine the likelihood of developing breast cancer.[94] Myriad Genetics holds the patents for the two genes.[95] This means that if anyone besides Myriad Genetics screens for the presence of the BRCA1 or BRCA2 gene, they would be infringing on the patent. Thus, Myriad Genetics has a monopoly on the diagnostic process and can enjoin others from performing the diagnostic process.[96] Furthermore, it appears that Myriad genetics has restrictive licensing practices.[97] Because Myriad has this monopoly, they can charge as much as they want for the screening process.[98] Though this is only one example, it is a concise illustration of what problems could arise if, instead of a diagnostic procedure, a company held an exclusive license to a cure for a debilitating disease.

A. Trends favoring the sharing of research

There has been a trend in recent IP policy to provide more open access to research and the resultant products. This may be a reaction to the both the scholarly criticisms and scenarios such as the BRCA gene patents. Though studies have concluded there has yet to be a large obstacle for obtaining technologies necessary for research, [99] IP policies appear to be taking a

[94] *See* Leaf, *supra* note 11. *See also* LORI ANDREWS & DOROTHY NELKIN, BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE 42-44 (2001) [hereinafter, ANDREWS & NELKIN, BODY BAZAAR].
[95] ANDREWS & NELKIN, BODY BAZAAR *supra* note 94 at 44.
[96] *Id.*
[97] *See id.*
[98] This charge is roughly close to $3,000 for testing for the presence of either gene. *See* Leaf, *supra* note 10; *see also* ANDREWS & NELKIN, BODY BAZAAR *supra* note 94 at 44.
[99] *See* Mireles, *States as Innovation System Laboratories supra* note 32 at 1163-79 (discussing studies that have examined whether an anticommons in research has developed).

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proactive approach to avert scenarios similar to the BRCA gene patent problem. For example, the NIH has proposed a policy that favors more sharing of the information gathered through Genomic research.[100] Furthermore, states that have granted funding for embryonic stem cell research have stated that they would instill an IP policy that required sharing of stem cell lines derived from state-funded research.[101] Equally important, and maybe in lieu of the criticisms mentioned above, the Wisconsin Alumni Research Foundation (WARF) recently relaxed its licensing requirements for the patents it holds on Stem Cell research tools.[102] This has significant impact on states that fund embryonic stem cell research, particularly California.[103]

B. The California Institute of Regenerative Medicine Intellectual Property Policy

Though there may be a trend to share in recent IP policy, the details are still in the works. However, the CIRM IP Policy is a notable illustration of this trend to open access, as it is the most detailed IP Policy currently released.[104] The importance of this policy is twofold. First, patent rights regarding embryonic stem cells will probably be extremely valuable, as stem cells are considered to have the ability to cure a myriad of diseases that currently have no cures such as Parkinson's, Alzheimer's, and diabetes.[105] Second, the CIRM IP Policy models itself after the Bayh-Dole Act, but varies in ways that appear to deal with specific deficits in the Bayh-Dole

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[100] *See* NIH GWAS Proposal, *supra* note 16.
[101] *See supra*, note 17 and accompanying text.
[102] *See* Kathleen Gallagher and Susanne Rust, *Rules on Stem Cell Licensing Loosened: Lower Research Cost Possible*, MILWAUKEE J. SENTINEL at D1 (Jan. 23, 2007) (quoting Wisconsin Alumni Research Foundation managing director as stating " [t]he new policy will allow companies to perform stem cell research for a lower cost . . .") [hereinafter, *Rules on Stem Cell Licensing Loosened*]; *see also* Mary Engel, *Stem Cell Institute Clears a Hurdle: University of Wisconsin Group Says it Will Not Seek Licensing Fees on Researchers' Discoveries*, L.A. TIMES, Jan. 23, 2007 at 4 [hereinafter *Stem Cell Institute Clears a Hurdle*].
[103] *Id.*
[104] This comment focuses on the CIRM IP Policy as it is the most detailed IP policy of the states that have allocated funds to embryonic stem cell research. The conflicts between the Bayh-Dole Act and the CIRM IP Policy may also arise in other state's IP Policies, should states like Illinois or Maryland include provisions in the CIRM IP Policy that specifically address health care issues.
[105] *See e.g.*, Nat'l Inst. of Health, Stem Cells and Diseases [Stem Cell Information], available at http://stemcells.nih.gov/info/health.asp (last visited Mar. 19, 2007) [hereinafter NIH Stem Cell Information].

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Act.[106] This comment will focus on the differences of the CIRM IP Policy that address the notion of a link between health care costs and patent rights.

1. The Research Exemption

The first notable difference between the Bayh-Dole Act and the CIRM IP Policy is the research exemption. This provision allows California research institutions to use CIRM-funded patented inventions at no cost if used for research.[107] This provision appears to be an action to avert restrictive licensing practices. By addressing potential patent thickets and restrictive licensing, there would be a trickle effect on the savings of potentially costly licensing agreements. Because companies would not have to recoup as much R&D costs, that savings, in theory, could be passed onto the consumer. If companies do not have to pay prime prices for technology needed to proceed in their research, the end product would be theoretically cheaper for the consumer.

2. Licensing Agreements

Equally important, the CIRM IP Policy contains key provisions regarding licensing agreements that address proposed problems that result from the Bayh-Dole Act.[108] First, though the CIRM policy does not ban exclusive licenses, it disfavors exclusive licensing of inventions derived from CIRM funded research.[109] This provision states that exclusive licenses can be granted if an exclusive license is required to provide incentive to commercially develop the invention and bring it to market.[110] In an apparent reaction to restrictive licensing agreements, this policy disfavors exclusive licenses. The policy averts potential monopolies created by

[106] *See* Mireles, *States as Innovation System Laboratories*, *supra* note 32, at 1196-1207.
[107] *See* CIRM Non-Profit IP Policy *supra* note 19, at 18.
[108] Though there are multiple provisions that address the Bayh-Dole Act, there are only a few that are the focus of this Article, as this article addresses the health care implications of the CIRM policy as opposed to other articles that focus on the patent rights issues.
[109] *See* CIRM Non-Profit IP Policy *supra* note 19 at 17 ("Grantee organizations shall negotiate non-exclusive licenses of CIRM-funded inventions whenever possible").
[110] *Id.*

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restrictive licensing practices by granting exclusive licenses in special cases only. Again, in theory, without a monopoly on a product or technology, the product or technology should be cheaper and more accessible to the end consumer.

Second, an overlooked but extremely important provision in the CIRM licensing policy is a requirement providing access to resulting stem cell therapies. Specifically, the licensing policy requires a recipient of an exclusive license to provide uninsured California patients access to therapies and diagnostics that result from state funded research.[111] This provision addresses major criticisms of the Bayh-Dole Act. The provision addresses the criticism that a patent thicket could make resultant therapies cost restrictive. Furthermore, this provision addresses the paying twice criticism as uninsured patients have access to treatments funded by tax dollars.[112]

More importantly, this provision directly addresses the concern that there is less access to proper health care. As discussed above, health care costs have dramatically increased in recent years.[113] By providing access to therapies that result from stem cell research, California hopes to avert a potential health care crisis. Stem cells are considered to have a totipotent ability to cure many diseases.[114] Though still theoretical, stem cells therapies may not only treat diseases, but also cure them. If stem cells live up to their billing, stem cell therapies could cure diseases like

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[111] *Id.* However, "access" to therapies is very vague and will probably be the focus of litigation in the future. For-profit entities are also required to provide patients similar access. Ca. Inst. for Regenerative Medicine, Policy for For-Profit Organizations (Dec. 7, 2006), *available at* http://www.cirm.ca.gov/policies/pdf/ForProfitOrg.pdf [hereinafter CRIM For-Profit IP Policy].

[112] This provision may be rendered moot, if Governor Schwarzenegger's Universal Health Care proposal passes. The author acknowledges that there is probably a greater likelihood of instilling Universal Health Care before stem cell research will result in any tangible product or therapy, but this provision would likely be modified to accommodate the change. For example, the current provision also states that "[exclusive] licensees [of CIRM-funded technology] provide to patients whose therapies and diagnostics . . . purchased in California by public funds . . . at a cost not to exceed the federal Medicaid practice." CIRM Non-Profit IP Policy, *supra* note 19 at 17. Thus, the over-all theme of the provision is to ensure that some price regulation on technology created through CIRM funds and that price does not become cost restrictive in accessing the therapies.

[113] *See supra* notes 1-6 and accompanying text.

[114] See e.g., NIH Stem Cell Information *supra* note 105; *see also* Francesca Crisera, *Federal Regulation of Embryonic Stem Cells: Can Government Do It? An Examination of Potential Regulation Through The Eyes of California's Recent Legislation*, 31 HASTINGS CONST. L.Q. 355, 357-60 (2004). [MAY CUT OUT IF NOT REFERED TO LATER]

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Parkinson's, Alzheimer's, and Diabetes.[115] Curing chronic disease would alleviate costs of consistent treatment. This, in turn, would turn into an economic benefit to the state. By providing more access to such therapies to more people, there would be fewer people with chronic diseases. Thus, by having healthy citizens that do not require consistent medical care, California would benefit economically because less money spent on health care.

3. March-in provisions

The CIRM IP Policy contains march-in rights that are similar to those of the Bayh-Dole Act. However, the march-in rights differ in some significant ways. First, there does not appear to be an elaborate review process.[116] This could make it more likely that the march-in rights would be exercised.[117] Having less restrictive march-in rights could allow California to use its march-in provisions to regulate over-restrictive costs — a significant difference from the way the federal government uses (or has not used) the Bayh-Dole provisions. Second, the CIRM IP Policy march-in rights can be exercised, should the grantee fail to "adhere to the agreed-upon plan for access to resultant therapies."[118] Specifically allowing march-in to provide uninsured patients to access appears to be a response to the NIH's failure to exercise march-in rights. Furthermore, this provision is in line with the focus of a primary policy in founding the CIRM; promoting the health of California's citizens and providing access to health care.

3. Sharing Biomedical Materials

The CIRM IP Policy also requires funding recipients to share biomedical materials.[119] A funding recipient must share biomedical materials, for research purposes, described in a

[115] NIH Stem Cell Information *supra* note 105.
[116] Mireles, *States as Innovation System Laboratories supra* note 32, at 1205.
[117] *Id.*
[118] CRIM Non-Profit IP Policy *supra* note 19, at 20.
[119] *Id.* at 16.

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published scientific article, unless legally precluded.[120] This provision follows the open-access theme that drives the CIRM IP Policy by allowing researchers to obtain research materials from other CIRM funding recipients.[121] This provision may also mitigate problems associated with the potential withholding of research materials.[122]

III: When Patent Rights and Health Care Collide

Unfortunately, California's initiative to address its health care problem may be stifled in multiple ways. Congress may explicitly regulate embryonic stem cell research through its Commerce Clause powers. Furthermore, there is a more likely scenario, where federal funding may have an unintended affect of stifling California's initiative in addressing its health care problem. The CIRM IP Policy would probably be superseded should federal funds become available for embryonic stem cell research. Because embryonic stem cell research in California does not receive federal funds, the Bayh-Dole Act does not apply and the CIRM IP Policy governs the allocation of patent rights. However, should the federal government allow funding for embryonic stem cell research, any research performed using federal funds would be subject to the provisions of the Bayh-Dole Act. Even though the CIRM IP Policy is similar to the Bayh-Dole Act in many ways,[123] the critical conflict does not regard the ownership rights, but rather the conflict between the right to exclude granted by the patent rights and the ability to regulate health care. This confrontation would test the boundaries of federalism. Accordingly, the following section will discuss what impact the federal government's involvement in embryonic stem cell research would have, and how that would conflict with the CIRM IP Policy.

A. Government's Ability to Regulate through the Commerce Clause

[120] *Id.*
[121] Mireles, *States as Innovation System Laboratories*, *supra* note 32 at 1204.
[122] *Id.*
[123] *See id.* at 1180.

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1. Commerce Clause Background

Congress has the "power to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."[124] Through formalistic classification, early Supreme Court decisions limited Congress's Commerce Clause powers to regulation of activities that had a direct affect on interstate commerce.[125] However, the Supreme Court shifted from its formalistic approach to a balancing test in the early in the 20th Century. This shift allowed Congress to regulate more than activities that directly affected interstate commerce. Congress could now regulate any activity that had a substantial effect on interstate commerce.[126] With the Supreme Court shifting to a balancing approach, Congress had almost unfettered power to regulate activities under its Commerce Clause powers for the latter half of the 20th Century.[127]

Recently, the Supreme Court has returned to a more formalistic approach in its latest Commerce Clause decisions. In *United States v. Lopez*,[128] the Supreme Court invalidated the Gun-Free School Zones Act of 1990.[129] In the decision, the late Chief Justice Rehnquist proscribed what Congress could regulate in through its Commerce Clause powers. Congress could regulate: (1) the use of channels of interstate commerce; (2) the instrumentalities of

[124] U.S. CONST. art. I, § 8, cl. 2
[125] *See, e.g.,* United States v. E.C. Knight Co., 156 U.S. 1 (1895) (holding it was outside of Congress' powers to stop an acquisition that would result in one company manufacturing 98% of the Nation's sugar because manufacturing sugar was different from selling sugar, and Congress could only regulate the sale of sugar). *See also* Hammer v. Dagenhart, 247 U.S. 251 (1918) (holding that Congress could not proscribe regulations for products manufactured with child labor because the production of articles is a matter of local regulation, even though the products are intended for interstate commerce).
[126] *See* United States v. Darby, 312 U.S. 100 (1941) (repudiating direct-indirect test and applying substantial effects test to uphold Congressional act that regulated hours and wages of employees in manufacturing plant).
[127] *E.g.,* Calvin Massey, *Federalism and the Rehnquist Court*, 53 HASTINGS L.J.431, 471 (2002).
[128] 514 U.S. 549 (1995).
[129] The court gave three reasons as to why the Act was not within the Commerce Clause power: (1) Congress was trying to regulate Possession of a gun in a school zone, and possession is not a commercial transaction; (2) The Act was not directed towards interstate commerce, but rather a local activity of possessing a gun within a school zone; (3) No Congressional Findings on how possession of a gun in a school zone affected interstate commerce. Even though not required, the court was less willing to defer to Congress because of the lack of Congressional Findings. *Id.* at 561-64

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interstate commerce; and (3) activities that have an effect on interstate commerce.[130] Furthermore, the Court stated that an activity has to be more than labeled as an economic activity, it must also "substantially affect[] interstate commerce."[131]

2. The Ability of Congress to Regulate Stem Cell Research through the Commerce Clause

Even though *Lopez* limited Congress's Commerce Clause powers, embryonic stem cell research still falls within the aspects of commerce Congress may regulate described in *Lopez*. Particularly, stem cell research is an activity that has a substantial effect on interstate commerce. Licensing agreements between research institutions is one example of how stem cell research could be considered an activity that substantially effect interstate commerce. One illustration is the WARF decision to ease its licensing agreements.[132] Licensing agreements, particularly in stem cell research, can be costly.[133] Relaxing the licensing agreement affects any institution that partakes in embryonic stem cell research, as the research institution would benefit from the relaxed licensing agreements.[134] Congress could thus be able to regulate embryonic stem cell research because licensing agreements are economic in nature and often occur between interstate entities.

Furthermore, there is nuanced justification that would allow Congress to regulate stem cell research. Arguably, research itself is commercial.[135] As discussed earlier, the purpose of

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[130] *Lopez* at 558-59

[131] *Lopez* at 560. In a subsequent decision, the Supreme Court appeared to somewhat expand Congress' Commerce Clause powers by holding Congress has the ability to regulate a local activity if "it is in a class of activities that have a 'substantial effect' on interstate commerce. Gonzales v. Raich, 545 U.S. 1, 17 (2005) (citing Wickard v. Filburn, 317 U.S. 111, 125 (1942) (holding that Congress could regulate home grown wheat, even if just for personal consumption because even if an activity is local "and though it may not be regarded as commerce, it may still, whatever its nature be reached by Congress if it exerts a substantial economic effect on interstate commerce")).

[132] *See* Gallagher & Rust, *Stem Cell Licensing Loosened*; Engel, *Stem Cell Institute Clears a Hurdle*, *supra* note 102.

[133] *See* Associated Press Release, *Fees Relaxed to Boost Research*, PITT. POST-GAZETTE, Jan. 27, 2007 at A8 (licensing fees can cost up to $400,000).

[134] The relaxed licensing agreements would particularly benefit the California Institute of Regenerative Medicine. Engel, *Stem Cell Institute Clears a Hurdle*, *supra* note 102

[135] *See e.g.*, Sheldon Krimsky, *The Profit of Scientific Discovery and its Normative Implications*, 75 CHI-KENT L. REV. 15 (1999) (discussing the commercialization of university research).

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the Bayh-Dole Act is to make patented technologies available in the market. Or phrased differently, the Act is to ensure the commercialization of inventions that resulted from government-funded research. Thus, research itself has become a commercial endeavor. Because research collaboration can occur between the institutions in different states, it would be an interstate commercial endeavor. And, as discussed above, the patent rights and licensing agreements that result from this interstate commercial endeavor substantially affect interstate commerce. Therefore, research (within the realm of the Bayh-Dole Act) would be a type of activity that Congress could regulate through its Commerce Clause powers.

Congress could also regulate the products that result from embryonic stem cell research. Therapies that would result from stem cell research would most likely "substantially effect" interstate commerce. Not only do stem cells have the potential of curing diseases, biotech firms will probably reap the economic benefits of any therapies they develop. If WARF can charge $400,000 just for its patents on stem cell lines,[136] it is not hard to imagine that a therapy that resulted from stem cell research would command an even higher price.[137] Also, it is not too speculative to assume these therapies would be sold on a national scale. Should California's research endeavors produce a therapy,[138] those therapies would enter interstate commerce, allowing Congress to regulate those products.

B. Possible Preemption of California's Policy through the Supremacy Clause

Preemption through the Supremacy Clause could be problematic to open access policies behind States' embryonic stem cell research initiatives. The Supremacy Clause provides that any

[136] *See* Associated Press Release, *Fees Relaxed to Boost Research*, *supra* note 133.
[137] The BRCA gene license is another example of how lucrative a therapy derived from stem cell research could potentially be. *See supra* note 94 and accompanying text. If a diagnostic procedure costs close to $3,000 (even though the price is inflated because of Myriad Genetics' monopoly on the license), a stem cell therapy could cost even more.
[138] Or Illinois or Maryland, but California has the most resources allocated into developing therapies from stem cell research.

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legislation enacted by Congress "shall be the supreme Law of the Land."[139] The Supreme Court has stated, "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield."[140] Preemption can occur if a federal law expressly preempts state law. Preemption can also occur implicitly if there is a clear congressional intent to preempt state law.[141] Implicit preemption occurs in two ways: (1) when it would be physically impossible to comply with both the federal regulation and the state regulation; and (2) when a state law is an obstacle to "accomplishment and execution of the full purpose or objectives of Congress."[142]

The CIRM IP Policy is especially vulnerable to preemption through the Supremacy Clause. The federal government could pass legislation under its Commerce Clause powers that would be more restrictive than current research policies. For example, Congress could decide to ban research on embryonic stem cells. However, this is unlikely, as Congress is currently trying to pass a bill that relaxes the restriction on federal funding.[143]

The more likely scenario would be preemption of the CIRM IP Policy by the Bayh-Dole Act, should Congress lift current restrictions on federal funding. Though the CIRM IP Policy is just a policy and not a law, allowing federal funding to embryonic stem cell research could frustrate the Policy in two ways. First, researchers may be less willing to follow the CIRM IP policy because the Bayh-Dole Act is more inventor friendly in the sense that it provides a greater right to exclude others from using the patented invention. Though the ownership of the patent

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[139] U.S. CONST. art. VI, cl. 2 .
[140] Felder v. Casey, 487 U.S. 131, 138 (1988) (citation an internal quotations omitted).
[141] *See* Lauren Thuy Nguyen, *The Fate of Stem Cell Research and a Proposal for Future Legislative Regulation*, 46 SANTA CLARA L. REV. 419, 429-30 (2006).
[142] *See e.g.*, *id.* at 29-30 (citing Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963) and Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).
[143] *See* Rick Weiss, *House Passes Bill Relaxing Limits on Stem Cell Research*, WASH. POST, Jan. 12, 2007 at A04. The legislation is the Stem Cell Research Enhancement Act of 2007, H.R. 3, 110th Cong. (2007), *available at* http://thomas.loc.gov/cgi-bin/query/D?c110:2:./temp/~c110ceqARO:: (last visited Mar. 19, 2007).

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rights are similar to the Bayh-Dole Act,[144] the CIRM IP Policy provides a weaker right to exclude because the Policy requires recipients of exclusive licensees to provide uninsured patients access to therapies that result from state funded research.[145] If the Bayh-Dole Provisions govern, then inventors would not have to share patented inventions. Inventors would have the right to exclude uninsured patients from therapies because the federal provisions do not ensure uninsured patients access to stem cell therapies derived from government funds. This may deter inventors from accepting state funds, as grantees would have stronger rights (through the Bayh-Dole Act) by accepting only federal funds. Allowing federal funding for embryonic stem cell research would provide a disincentive to accept state funds because researchers would probably chose federal funds to avoid the less exclusive patent rights conferred by the CIRM IP Policy. As a result, researchers could circumvent the CIRM IP Policy by accepting only federal funds. This would frustrate California's scheme of more open access to state-funded research — particularly the access to health care provided to uninsured citizens.

Second, there may be a direct conflict between the Bayh-Dole Act's march-in provisions and the CIRM IP Policy march-in provisions. As discussed above, The CIRM IP Policy has less restrictive march-in provisions. California may opt to use the march-in provisions as a market regulator. This conflicts with the federal government's use (or non-use) of the march-in rights, as it has refused to use the Bayh-Dole march-in provisions as a market regulator. The CIRM IP Policy could thus be implicitly superseded because using the march-in provisions as a market

[144] Both the Bayh-Dole Act and CIRM IP Policy state that the inventor is the owner of the patent rights, not the government. *Compare* 35 U.S.C. 202(a) (Bayh-Dole provision that allows inventors to keep title to government-funded inventions) *with* CIRM non-profit IP Policy at 22 (stating that grantee will own intellectual property rights that arise from CIRM-funded research).

[145] *See* Section II B 2, *supra*. There may be another similar conflict found in the For-Profit IP policy that also requires for-profit entities to provide access. However, the Bayh-Dole Act treats the disposition of rights of non-profits and small businesses different. *See* 35 U.S.C. § 210(c)

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regulator would be contrary to the federal march-in provisions, where they are explicitly not a market regulator.

Perhaps more importantly, the CIRM march-in rights may be superseded because they strengthen the policy of providing access to uninsured California patients. As discussed above, march-in rights may be used should a grantee fail to meet the requirement of providing access to state funded therapies. It is unclear if this would be superseded as contrary to the theme of the Bayh-Dole Act, but it is important to note that allowing the Bayh-Dole Act to have total primacy would stifle this provision. As a result, allowing the Bayh-Dole Act to regulate patent rights would deprive California of an avenue it has chosen to regulate the health of its citizens and address its health care issues.

IV: PROPOSALS TO ENSURE CALIFORNIA'S INITIATIVE IN ADDRESSING HEALTH CARE ARE NOT STIFLED

Because of this conflict between federal and state powers, the following section will propose solutions to ensure that the federal government does not stifle California's initiative address its health care issue. The proposals include an amendment to the Bayh-Dole Act and suggesting that any Congressional act that allows more funding to embryonic stem cell research should acknowledge the potential conflict with the CIRM IP policy.[146]

A. Amendment to the Bayh-Dole Act

Congress should amend the Bayh-Dole Act to ensure that the Act only regulates patent rights. The amendment to the Act should read, "the patent rights granted within this Act are limited to the rights that the Federal Government is able to enact, and shall not truncate any rights that are reserved to the states." Adding such an amendment would explicitly define the

[146] Or any other States' policies

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boundaries between Congress' power to grant patent rights and California's right to regulate the health of its citizens. Though a minor change to the Act, it would have a profound effect. The change would prevent the Act from stifling California's initiative to address the health care problem by preserving the rights of uninsured patients to access stem cell therapies developed with state funds. Should more federal funds become available for embryonic stem cell research, the Bayh-Dole Act could, in effect, take something from the public and confer a benefit onto a private party. The public would be deprived of access to health care therapies derived from public funds, whereas private entities would have a stronger right to exclude because the inventors would not have to "share" (provide access) the invention.[147] Thus, by adding such an amendment, the patent powers granted by Constitution to the federal government would not conflict with California's reserved right to address the health of its citizens.[148]

B. Addressing the Superseding Effect of Federal Funding

Congress should acknowledge the potential conflict with the Bayh-Dole Act in any bill that allows more federal funding to embryonic stem cell research. As mentioned earlier, the House of Representatives has passed a bill that would relieve the restrictions on federal funding. However, this bill does not address the potential unintended consequence of stifling California's initiative to address the health of its citizens and its health care problem. The final version of this bill (or any future legislation) should make a distinction allowing certain state provisions to control instead of granting complete primacy to the Bayh-Dole Act. Other Congressional acts

[147] This would be a particularly ironic result as there is a policy in patent law that strongly disfavors taking away from the public domain. *See e.g.,* Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (using policy rationale that allowing patents on metabolite would effectively take something away from the public since mere act of ingesting Claritin would infringe on the patent in holding claims on Claritin metabolite were inherently anticipated).

[148] This would also apply to other states, should they chose to follow California's lead. However, as mentioned earlier, California is the only state that has a detailed IP Policy. Thus, it is the most tangible example of how State's rights and Federal powers may conflict should more federal funds become available.

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can explicitly supersede the Bayh-Dole Act.[149] Therefore, Congress could mention the Bayh-Dole Act still controls but explicitly mention that a state's IP policy would control where allowing the Bayh-Dole Act to supersede would conflict with powers reserved to the states.[150] This would not be too burdensome on the government, because, as discussed above, the CIRM IP Policy models its patent ownership rights after the Bayh-Dole Act's allocation of rights. Allowing uninsured patients access to therapies developed with both federal and state funds does not appear to significantly conflict with the Bayh-Dole Act. Still, providing access to uninsured patients may conflict with the Act's purpose of "ensur[ing] 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."[151] However, the threshold question in this argument would be if allowing access to uninsured patients would provide such a disincentive to research stem cell therapies that researchers would no longer pursue this line of research. It is unclear, at best, if providing access to resultant stem cell therapies would frustrate the Bayh-Dole Act's policy of promoting free competition without unduly encumbering future research. However, Congress should not frustrate California's initiative without actual findings that allowing uninsured patients access to therapies in fact frustrates this purpose of the Bayh-Dole Act.

Congress should not suddenly stifle California's (or any other state's) initiative to address its health care issues by ignoring any unintended effects created by allowing the Bayh-Dole Act supersede completely. Thus, Congress should specifically mention that federal funding would

[149] Section 210(a) states, "The Act creating this chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act."
[150] Here, the health of its citizens
[151] 35 U.S.C. § 200.

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not abrogate any of the state's funding agreement policies in any future bills that relieve funding restrictions on embryonic stem cell research.

V: CONCLUSION

Rising health care costs have become so burdensome that the problem can no longer be ignored. There is a perceived link between the rise in health care costs and the Bayh-Dole Act. Recent trends in intellectual property policy have attempted to address this unintended consequence of the Bayh-Dole Act. One illustration is California's CIRM IP Policy. The CIRM IP Policy takes a proactive approach in addressing the proposed unintended effects of the Bayh-Dole Act, particularly in the context of access to health care.

However, this proactive approach may be short lived. Should federal funding become available for stem cell research, the Bayh-Dole Act may supersede key aspects of California's policy, specifically the provisions that intend to regulate health care. Thus, Congress should take action to ensure that California's right to address the health of its citizens is not stifled. First, Congress should amend to Bayh-Dole Act to clarify the scope of the rights conferred by the Act to not conflict with any rights reserved to the states. Second, Congress should explicitly mention in any future legislation that allows federal funding to embryonic stem cell research that Bayh-Dole Act does not supersede any state policies where the Bayh-Dole Act conflicts with powers reserved to the states. Though the link between health care costs and intellectual property rights may be elusive, Congress should take the initiative to address the issue now. The rise in health care costs is an issue that has been ignored long enough. Thus, Congress should be proactive to ensure that any future legislation does not impinge on the state's initiative to remedy a problem that Congress has ignored for so long.

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If Senate addition makes the second suggestion moot, can still argue amendment to the Bayh-Dole Act. Furthermore, can still argue the paper, but argue from the angle of a veto by president Bush, and why it is critical that such a provision remains in all future legislation regarding embryonic stem cell research.