**The Bayh-Dole Act and March-In Rights**

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## I. Summary

The Bayh-Dole Act, 18 U.S.C. section 200 et seq., enacted in 1980, was aimed at turning federally-funded research and development into useful patented inventions, in order to benefit American research institutions, industries and consumers. From the beginning, a stated objective of the Act was to protect the American public against "unreasonable use" of government-funded inventions. 18 U.S.C. section 200. The march-in rights provision was included as a means to vindicate that interest. It gives the federal agency under whose funding agreement an invention was made the right to grant a license to a responsible new applicant if, among other things, the current manufacturer has failed to make the product "available to the public on reasonable terms," 18 U.S.C. sections 201(f), 203(1)(a), or if "action is necessary to alleviate health or safety needs which are not reasonably satisfied" by the current manufacturer. 18 U.S.C. section 203(1)(b).[2]

The research and development needed to create numerous drugs now on the market was funded primarily by the American people through their tax dollars. The key patents to many of these drugs were filed by universities, and then licensed to private companies. In many cases, these private corporations have provided only a small fraction of the overall R&D investment in the products, but charge high monopoly prices. These prices do not reflect the cost of production of the drugs, which are routinely only a fraction of the sale price. In some cases, generic competitors in other countries sell the drugs at prices less than 5 percent of the U.S. price.

The exact outlay by industry licensees for licensing, research, development, production, and other expenses is typically unknown, because the licensees generally refuse to disclose such data. However, in the course of a governmental review of a product under Bayh-Dole, it should be possible to make the data public, so a complete, rational and fair assessment can be made.

Even without such disclosures, the high prices of many products currently on the market is *prima facie* unwarranted in terms of the purposes of Bayh-Dole and of federal patent law. If these laws are meant to encourage and reward investment and innovation, then the windfall profits obtained by industry licensees turn that purpose on its head:

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[2] Regulations governing the procedures for the exercise of march-in rights are at 37 CFR section 401.6.

Companies which contributed comparatively little to the R&D for particular drugs receive a monopolist's price *as if they undertook all of the R&D themselves*.

The losers under this arrangement are the American people, who have been forced to pay twice for the drugs: first, through taxpayer funding for R&D; and today, through higher Medicare and other government program expenditures, higher insurance premiums, and, higher patient out-of-pocket expenses and other costs associated with the exorbitant prices.

No federal agency has ever asserted its march-in rights with respect to a Bayh-Dole-conferred patent. Indeed, only once has a federal agency ever been petitioned to do so. (See below.) Now the Government should apply a brake to runaway prices for critical medicines created with taxpayer money.

The Secretary of Health and Human Services should take action to help restore appropriate balance to federal policy under Bayh-Dole; to help ensure that overall U.S. policy with respect to research and patents is rational and effective; and to uphold the interests of American taxpayers, insurers, and government.

**II. Argument: The Case for Exercising March-in Rights**

The 1980 Bayh-Dole Act embodied a new approach to intellectual property rights in the fruits of federally-sponsored research. Under the previous approach, much of this research remained government property or was placed in the public domain. But there was a perception that federal inventions were often underutilized. There was concern that a failure to remedy this problem would weaken the ability of U.S. firms to compete with foreign companies. There also were substantial differences among the procedures and standards used by federal agencies with respect to a funding recipient's right to obtain title to an invention created with federal monies. The process by which a contractor sought to obtain such rights was often burdensome and delayed the transformation of research into useful products.[3]

The new approach posited that encouraging patenting of the results of federal research, and licensing to private firms, would prompt greater use of federally-sponsored inventions, spur U.S. industries, and create American jobs. The Bayh-Dole Act gave incentive to non-profit entities and small businesses to patent the products of government-funded research by authorizing them to retain patent ownership for themselves, to license those patents, and to retain royalties from them.[4] Subsequently, a

[3] See S.Rep. 96-480 at 15-25; Barbara M. McGarey and Annette C. Levey, Patents*, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 Berkeley Tech.L.J. 1095, 1097-98 (1999); Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Derived in Whole or in Part from Federally Funded Research*, 75 Tulane L. Rev. 631, 640, 656 (2000); Mary Eberle, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 Marq.Intell.Prop.L.Rev. 155 (1999).
[4] Federal regulations implementing the Bayh-Dole Act are at 37 CFR section 401.1 et seq.

1983 Executive Memorandum and 1987 Executive Order extended the benefits of Bayh-Dole to all government contractors, including larger businesses.[5]

The objectives of the Bayh-Dole Act, as set out by Congress are as follows:

> to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

35 U.S.C. section 200.

The Bayh-Dole Act sought to create a uniform, streamlined process across all federal agencies for patent license transfers. Under the Act, federal contractors generally have the right to elect ownership rights to any invention created with federal funds.

As one scholar has put it, the Bayh-Dole approach is, in fundamental ways, "counterintuitive ... [I]t seems to require the public to pay twice for the same invention -- once through taxes to support the research that yielded the invention, and then again through higher monopoly prices and restricted supply when the invention reaches the market."[6]

To address such concerns, Congress built into the Act a number of obligations aimed at ensuring that the public's investment would be used in the public interest. Under the Act, contractors must disclose each subject invention to the funding agency

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[5] Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, Public Papers of the Presidents 248 (Feb. 18, 1983); Executive Order 12591, 52 Fed.Reg. 13414 (1987).

[6] Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va.L.Rev. 1663, 1666 (1996). Professor Eisenberg further states:

> Second, by calling for exclusive rights in inventions that have already been made through public funding (and thus, presumably, without the need for a profit incentive), it contravenes the conventional wisdom that patent rights on existing inventions result in a net social loss ex post, a loss that we endure only to preserve ex ante incentives to make future patentable inventions. Third, by promoting the private appropriation of federally-sponsored research discoveries as a matter of routine, it calls into question the public goods rationale for public funding of research. And fourth, by providing incentives to patent and restrict access to discoveries made in institutions that have traditionally been the principal performers of basic research, it threatens to impoverish the public domain of research science that has long been an important resource for researchers in both the public and private sectors.

Id., at 1666-67.

within a reasonable time after discovery. They must elect within two years of disclosure whether or not to retain title. They must agree to file patent applications prior to any statutory bar date. If a contractor fails to meet any of these obligations, it risks forfeiting title to the Government.[7] Moreover, under the Act the Government reserves for itself a nonexclusive, paid-up license to practice or have practiced on its behalf any subject invention, in the United States or in other countries.

In addition, the Bayh-Dole statute includes the march-in provision that is the focus of this paper. Section 203 provides, in relevant part:

> With respect to any subject invention in which a small business firm or nonprofit organization[8] has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such
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> > (a) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use; [or]

[7] A recent study by the U.S. General Accounting Office shows that contractors and universities in fact engage in regular violations of Bayh-Dole requirements, particularly widespread failure to report the patents that they obtain through government-funded research. U.S. Gen.Accounting Office, GAO/RCED-99-242, Technology Transfer: Reporting Requirements For Federally-Sponsored Inventions Need Revision 6, 10-12 (1999); see Arno & Davis at 676-679, 686-687.

[8] After the 1983 Executive Memorandum extended Bayh-Dole benefits to all federal contractors, including large corporations, Congress by statute expressly extended the march-in rights provision, along with other aspects of the Bayh-Dole law, to such entities:

> Nothing in this chapter [35 U.S.C. sections 200 et seq.] is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions except that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in [section] 202(c)(4) and section 203 [the march-in rights provision] of this title. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized.

P.L. 98-620, codified at 35 U.S.C. section 210(c).

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

The phrase "practical application," used in subsection 203(a), is defined elsewhere in the Act to mean:

> to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

18 U.S.C. section 201(f).

The march-in rights provision of the law was contained, essentially verbatim, in the original version of the bill as it was introduced by Senators Bayh and Dole on February 9, 1979.[9] However, the concept of government march-in rights, and the "reasonable terms" standard for exercising them, were much older. In 1963, President Kennedy issued a Presidential Memorandum on patent policy that allowed for exclusive licensing of government patents in some circumstances but required that such licensing be "on reasonable terms."[10] A 1968 government-commissioned report supported the use of march-in rights when a contractor failed to offer the invention "on reasonable terms."[11] President Nixon's Patent Policy Statement of 1971 tied the exercise of march-in rights to whether a licensed invention "is being worked and ... its benefits are reasonably accessible to the public."[12]

Another provision in the original Bayh-Dole bill, section 204, provided for automatic recoupment of part or all the government investment in R&D after the subject invention had earned a particular level of profits.[13] Although at least one of the bill's sponsors, Senator Thurmond, considered this provision "[p]erhaps the most significant feature of the bill,"[14] and it was included in the Senate-passed version of the bill[15], it was eventually dropped.

The legislative history of the Bayh-Dole Act and similar bills introduced in the same period shows that the march-in rights provision was repeatedly cited by bill

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[9] S.414, 96th Cong., 1st Sess.
[10] Subcommitee on Domestic and International Scientific Planning and Analysis of the House Committee on Science and Technology, 94th Cong., Background Materials on Government Patent Policies: The Ownership Of Inventions Resulting From Federally Funded Research and Development (Committee Print 1976) at 6.
[11] Id., at 196.
[12] Id., at 10, 14-16.
[13] Id.
[14] The University And Small Business Patent Procedures Act, Hearings Before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 34 (statement of Sen. Thurmond).
[15] See S.Rep. 96-480, at 34.

advocates as a meaningful and appropriate guarantee that the public interest would be protected.[16]

For example, there is this testimony from Dr. Betsy Ancker-Johnson, vice president of General Motors and former Assistant Secretary of Commerce:

> DR. ANCKER-JOHNSON. Mr. Chairman ... you have written into this legislation march-in rights which, should something go wrong, gives the Government an absolute method to correct it. It seems to me that you have made the possibility for abuse virtually nonexistent by including this section in the bill.
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> Senator BAYH. How do you perceive those march-in rights would accomplish what you suggest?
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> DR. ANCKER-JOHNSON. Should there be any abuse, Mr. Chairman, whatsoever, these criteria would be applied by the Federal Government and so make it possible for the Government to ... obtain the rights to that patent and distribute them to whoever it deemed best for the exploitation of that technology for the welfare of the people. So you have this excellent guarantee written into the bill, and it seems to me you have fully provided for any remote possibility of abuse.

It is notable that the witness spoke not of patent non-use -- the danger that the government contractor would simply leave the technology on the shelf -- but patent *abuse*.

As Professors Arno and Davis, who exhaustively reviewed the legislative history, conclude, "there was never any doubt" that the "reasonable terms" standard for march-in rights "meant the control of profits, prices and competitive conditions."[17] As they note[18], there are many references in the legislative record to the value of march-in rights for maintaining competitive market conditions. James E. Denny, Assistant General Counsel

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[16] See The University And Small Business Patent Procedures Act, Hearings Before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 44 (statement of Elmer B. Staats, Comptroller General of the United States), 70 (statement of Dr. Hector F. DeLuca, chairman, biochemistry department, University of Wisconsin Madison), 187 (statement of Howard Bremer, president, Society of University Patent Administrators); Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science and Transportation, 96th Cong., 1st Sess. at 182 (statement of Gerald J. Mossinghoff, Deputy General Counsel, NASA); Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science and Transportation, 96th Cong., 1st Sess., at 366 (statement of Dale W. Church, Deputy Under Secretary of Defense for Acquisition Policy); Government Patent Policy, Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong., 1st Sess., 1979, at 54 (statement of John E. Maurer, director, Patent Department, Monsanto Corp.) ; Government Patent Policy, Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong., 1st Sess., 1979, at 182 (statement of Dr. Ralph L. Davis, Purdue Research Foundation); 1977 Small Business Hearings at 189-95 (statement of John H. Shenefield, Asst. Attorney General, Antitrust Div., Dept. of Justice).

[17] Arno & Davis, at 662.

[18] Id.

for Patents, U.S. Energy Research and Development Agency, testified that march-in rights were appropriate "where the contractor is misusing the invention to the detriment of competitive market forces."[19] Ky P. Ewing, Assistant Attorney General for the Antitrust Division, testified, "'[M]arch in' provisions should help assure that the availability of exclusive rights ... does not disrupt competition in the marketplace."[20]

Harry F. Manbeck, General Patent Counsel for General Electric Company, emphasized the connection between unwarranted prices and the exercise of march-in rights: "[I]f [a contractor] fails to supply the market adequately at a fair price, then there is reason for requiring it to license both the background patents and the patents stemming from the contract work."[21]

Other testimony expressly linked the invocation of march-in rights to the existence of "windfall profits" on a subject invention. Written responses to the Senate from U.S. Comptroller General Staats reported that the Department of Energy "said that march-in rights to protect the public's interest were developed to take care of and address the patent policy issues of *contractor's windfall profits*, suppression of technology, *and the detrimental effects to competition from granting contractors rights to inventions*."[22] Mr. Manbeck of General Electric testified as to march-in rights, "We think it is part of the answer to the so-called windfall situation."[23]

Questioning Comptroller General Staats, Senator Bayh noted that a criticism of the bill, "comes from those that feel that this bill is a front to allow the large, wealthy, corporation to take advantage of Government research and thus to profit at taxpayers' expense. We thought we had drafted the bill in such a way that this was not possible." Staats replied, "In my opinion, the bill does have adequate safeguards."[24]

Another witness, R. Tenney Johnson, who had served as chief or deputy legal counsel to five cabinet departments or agencies (and subsequently served in the Reagan Administration as general counsel at the Department of Energy), discussed the bill's

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[19] Patent Policy: Hearings on S.1215 Before the Subcommittee on Science, Technology and Space of the Senate Committee on Commerce, Science and Transportation, 96th Cong. 150 (1979).

[20] Patent and Trademark Law Amendments of 1980: Hearings Before a Subcommittee of the House Committee on Government Operations at 102 (1980)

[21] Government Patent Policy: Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong. at 48 (1979)

[22] The University And Small Business Patent Procedures Act, Hearings Before the Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 56 (responses of Mr. Staat). Mr. Staat's further characterized DOE's view as follows: "The Department believes that march-in rights, although available to the Government for more than 10 years, have not been utilized because such problems are illusionary and not actual. If and when negative effects result from allowing a contractor to retain title to an invention of commercial importance, march-in rights are there to address them. Otherwise, DOE believes they will never be used." Id. We submit that the situation posited by this discussion -- negative effects result from allowing a contractor to retain title to an invention of commercial importance -- has now become reality and compels Government action.

[23] Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Committee on Commerce, Science and Transportation, 96th Cong., 1st Sess. At 317 (statement of Mr. Manbeck).

[24] The University And Small Business Patent Procedures Act, Hearings Before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 44.

provision for the assertion of government rights in connection with need for the Government to take action to protect public health or safety[25]:

> Whenever you discuss patent policy, you very quickly come up with the question of what do you do with a cure for cancer? Are you going to let one company have that? Obviously, a priceless invention. As I say, you are likely not to have a single patent on that, but you need to have some protection against that possibility.
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> I think that such a possibility might arise in a contract where the work was expressly at the point of discovering whether there was an answer to cancer. The Government might need to acquire title, because that would be an exceptional circumstance.

Admiral Hyman Rickover, the father of the nuclear Navy and an opponent of the Bayh-Dole approach ("These inventions are paid for by the public and therefore should be available for any citizen to use or not as he sees fit"[26]), had a different view. He prophetically argued that the march-in rights provision would not be enforced[27]:

> The Government has had march-in rights since 1963, but to my knowledge has never used them. To be in a position to exercise these rights a Government agency would have to stay involved in the plans and actions of its patent holders and check up on them.
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> If a Government agency ever decided to exercise its march-in rights and the patent holder contested the action, no doubt the dispute could be litigated for years. For this reason, I believe this safeguard is largely cosmetic. It would result in much additional paperwork but would probably be used no more than in the past.

In fact the legislative history of the Bayh-Dole Act reveals at least one instance where a government agency, the Department of Defense, had exercised march-in rights.[28] But Admiral Rickover's cynicism on this point now appears, unfortunately, well-grounded. The bill's sponsors and supporters were not cynical about the march-in rights provision, and their expectations deserve to be vindicated now.

The record also reveals that the march-in rights provision was retained despite the fact that a number of industry representatives argued aggressively against that provision,

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[25] Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Committee on Commerce, Science and Transportation, 96th Cong., 1st Sess. At 44 (statement of Mr. Johnson).

[26] The University And Small Business Patent Procedures Act, Hearings Before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 157 (statement of Adm. Rickover).

[27] The University And Small Business Patent Procedures Act, Hearings Before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 159-60 (statement of Adm. Rickover).

[28] Patent Policy, Hearings Before the Subcommittee on Science, Technology, and Space of the Committee on Commerce, Science and Transportation, 96th Cong., 1st Sess., at 366 (statement of Dale W. Church, Deputy Under Secretary of Defense for Acquisition Policy). ("Only once can I recall there was a case where we exercised march-in rights. It was a case involving two patents held by MIT. There was a complainant who felt as though the patents were not being utilized. As to one of the patents, it was found that MIT was using it and was allowed to retain exclusive title. In the case of the other, we found that MIT was not effectively using it, and they did provide for the complainant to use the patent." )

as well as the provision allowing the government to revoke a contractor's license.[29] The fact that Congress, in the face of industry complaints, nevertheless retained the march-in rights provision demonstrates that these provision were not included casually, that they were not simply boilerplate.

In the course of the hearings on the legislation, the Electronic Industry Association urged Congress to redefine the phrase "practical application" -- a trigger for the exercise of march-in rights -- to reduce the obligations of the contractor and thus the risk that the government would actually assert march-in rights: "The definition of 'practical application' appears too stringent. We would suggest a rewrite to indicate that 'application' means ... 'that the invention is being worked *or* that its benefits are available to the public either on reasonable terms or through reasonable licensing ...."[30] Congress declined to adopt this change, and maintained the standard that a "practical application" is achieved -- and march-in rights conditions are avoided only if the invention is being practiced *and* it is available to the public on reasonable terms. [31]

There is nothing to suggest that Congress kept the provision and yet expected it to lay dormant forever. Indeed, the language of the Senate report suggests an expectation that march-in rights would indeed be asserted from time to time: "'March-in' is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or other outside parties, although it is expected that *in most cases complaints from third-parties will be the basis* for the initiation of agency action." S.Rep. No. 96-480, at 34 (1979) (emphasis added).

It also is worth noting that the Bayh-Dole bill, as enacted in 1980, limited benefits to non-profit institutions and small businesses. The bill's sponsors believed that to extend benefits to large corporations would doom the bill, because consumer and antitrust advocates worried that big companies, on balance, did not need the help and in fact could use Bayh-Dole benefits to weaken market competition and hurt the public welfare.[32] The extension of Bayh-Dole to large corporations came not through a carefully-considered legislative process, but through executive action by the Reagan Administration. In 1984, Congress effectively ratified this action by the Administration, but at the same time it expressly provided that, if the Government was going to give Bayh-Dole benefits to large

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[29] See, e.g., Government Patent Policy, Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong., 1st Sess., 1979, at 169-71 (statement of Patrick Iannotta, president, Ecolotrol, Inc.); Government Patent Policy: Hearings Before the Subcommittee on Domestic and International Scientific Planning and Analysis of the House Committee on Science and Technology, 94th Cong. At 173 (statement of Charles S. Haughey, Patent Counsel, Hughes Aircraft Co.); 1980 Joint Hearing at 523-24 (testimony of Robert B. Benson, Director, Patent Dept., Allis-Chambers Corp.). As James E. Denny, Assistant General Counsel for Patents, U.S. Energy Research and Development Agency, stated, "[I]ndustry does not like either the concept of a revocable license or the 'march-in' rights, and views them with great suspicion." 1976 Hearings at 435.

[30] Patent Policy: Hearings on S.1215 Before the Subcommittee on Science, Technology and Space of the Senate Committee on Commerce, Science and Transportation, 96th Cong. at 221 (1979) (statement of Peter F. McCloskey, President, Electronic Industry Assn.) (emphasis added).

[31] See Arno & Davis, at 666.

[32] See Eisenberg, 82 Va.L.Rev. at 1695-96; Bradley Graham, Patent Bill Seeks Shift To Bolster Innovation, Washington Post, Apr. 8, 1979, at .

businesses, then the Government would retain the rights it had with respect to other Bayh-Dole inventions: (1) a nonexclusive, paid-up license to practice on behalf of the United States the subject invention; and (2) march-in rights.[33] The views expressed in 1980 -- regarding the potential for large corporations to abuse Bayh-Dole rights -- should be taken into account: In the case of large corporations, the Government has a particularly strong obligation to consider whether Bayh-Dole patent monopolies are serving the public interest.

American pharmaceutical companies have profited greatly from the Government benefits provided under Bayh-Dole and the subsequent extension of Bayh-Dole to large corporations. And these benefits to drug companies have come on top of other substantial federal aid through the tax code.[34] A company's own R&D expenditures can be deducted annually from taxable income. Internal Revenue Code section 174. The pharmaceutical industry, in particular, has benefited enormously from specific tax code provisions, including the foreign tax credit, the orphan drug tax credit, the general business tax credit, and a tax code provision that offers substantial benefits for manufacturing products in Puerto Rico. A 1999 analysis concluded that pharmaceutical makers have one of the lowest effective tax rates and one of the highest after-tax profit rates of any industry.[35]

The American public has received little direct financial return on its investment in health care research and development. Indeed, in the years 1985 through 1994, NIH received slightly less than $76 million in royalties, $40 million of which came from a single license for the HIV antibody test kit. From 1993 through 1999, royalties reached a total of nearly $200 million, reaching $45 million in 1999. But that figure still represents less than one percent of NIH's funding for 1999.[36]

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[33] The provision, codified at 35 U.S.C. section 210(c), states:

> Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions except that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in paragraph 202(c)(4) and section 203 of this title. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized.

[34] See U.S. Office of Tech. Assessment, Pharmaceutical R&D: Costs, Risks and Rewards 183-99 (1983); Arno and Davis, 75 Tulane L.Rev. at 638-39.

[35] Memorandum from Gary Guenther, Analyst in Business Taxation and Finance, to Joint Economic Committee 1-7 (Dec. 13, 1999), cited in Arno and Davis, 75 Tulane L.Rev. at 639.

[36] Arno & Davis at 639-40, citing Nat'l Insts. Of Health, NIH Technology Transfer Activities FY 1993-FY1999, available at http://ott.od.nih.gov/newpages/webstats99.pdf; Nat'l Insts. Of Health, Federal Obligations For Health R&D, By Source or Performer: Fiscal Years 1985-1999, available at http://silk.nih.gov/public/cbz2zoz@www.awards.sourfund.htm.

Of course, the public has also benefited from Bayh-Dole in other ways -- to the extent the law has helped create jobs, spur research, and bring to market useful products.[37] But in at least some cases the price for these benefits has been too high.

Two scholars who recently conducted a careful review of the overall record under the Bayh-Dole regime conclude[38]:

> [P]erhaps more important than the absence of any [direct return on taxpayer investment] is the inevitability of even greater public or consumer expenditures demanded by the monopolies obtained by industry over publicly financed inventions, and the resulting supracompetitive profits and prices. The public has already paid for the costs of research. The government's failure to police these economic abuses is the untold scandal of federally financed inventions and of the failure of the Bayh-Dole Act, which was meant to provide that policing.

In many instances, the taxpayers have not received their due benefits from the Bayh-Dole bargain. That is because industry licensees have ignored their obligations under the statute to sell the fruits of taxpayer research on reasonable terms and consistent with public health and safety needs. As a result, the only way for the taxpayers' interests to be vindicated, the only way to bring publicly-funded medicine to citizens at a fair price, is for the Secretary to take action and exercise march-in rights.

Only once before has the Government received a petition for Bayh-Dole march-in rights: a petition filed with the Secretary of Health and Human Services in 1997 by CellPro, Inc. seeking a license for certain patents for stem cell separation technology created by Johns Hopkins University with support from the National Institutes of Health ("NIH").[39] CellPro was already manufacturing an FDA-approved device based on the

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[37] One recent scholarly account summarizes the following progress in the years since Congress enacted Bayh-Dole: Although the federal government still provides the bulk of funding for university research, industry funding for such research has grown by a factor of five since passage of the Act. Licenses granted by universities have increased by a factor of ten. Royalties paid to universities increased nearly four-fold from 1981 to 1992 and more than doubled between 1991 and 1995. However, as this account notes, it is not clear how much of this expansion is the result of Bayh-Dole and how much expansion would have occurred in any case, because of a general increase in intellectual property patenting and licensing and advances in biotechnology and other fields. Tamsen Valoir, *Government Funded Inventions: The Bayh-Dole Act and the Hopkins v. CellPro March-in Rights Controversy*, 8 Tex.Intell.Prop.L.J. 211, 234-36 (2000). As this account notes, though the Bayh-Dole era has brought substantial increases in patents, licensing and royalties in fields that have benefited from the law, "this growth parallels that seen in other industries that are generally independent of government funding." Id. at 239.

[38] Arno & Davis at 640.

[39] As Barbara McGarey, Deputy Director, Office of Technology Transfer, National Institutes of Health has noted, the legislative history of Bayh-Dole shows that Congress anticipated that the petition of a private party would be the likely trigger for the Government to consider asserting march-in rights. McGarey and Levey, 14 Berkeley Tech.L.J. at 1099, citing S.Rep. No. 96-480, at 34 ("'March-in' is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or other outside parties, although it is expected that in most cases complaints from third-parties will be the basis for the initiation of agency action.") McGary and Levey report in their article that, though they are aware of no

technology.[40] Hopkins' licensee, Baxter, had obtained approval to market and was marketing its device in Europe, had filed for U.S. FDA Pre-Market Approval with respect to its device, and its device was in use in clinical trials in the United States. Determination In The Case of Petition of CellPro, Inc., National Institutes of Health, Office of the Director, August 1, 1997, at 5. Dr. Harold Varmus, director of NIH, concluded that the exercise of march-in rights was "not warranted at this time." Id., at 1. But NIH retained jurisdiction over the matter "until such time as a comparable alternative product becomes available for sale in the United States." Id.

The facts and equities in the CellPro case were very different than they are with respect to some drugs today. That case was about alleged failure to exploit a patent, while today there are products that are widely available to the public but not, it appears, on reasonable terms and not in accordance with public health and safety needs. In CellPro, NIH concluded that Baxter had met the requirements of Bayh-Dole, because it was "vigorously pursuing" FDA approval of its product. Id., at 5. Moreover, in separate civil proceedings, a court had held CellPro liable for willfully infringing Hopkins' patents, after negotiations between Baxter and CellPro for a licensing agreement had failed. Id., at 1, 5. Finally, Hopkins and Baxter changed the equities in the CellPro case by agreeing, notwithstanding their victory in the civil patent case, to refrain from enforcing their patent rights in order to allow the continuing sale of the CellPro device until the comparable Baxter product was approved for sale by the FDA. Id., at 6-7. In those circumstances, it would have been difficult for NIH to justify the need for march-in rights.

The Bayh-Dole Act calls for the assertion of federal march-in rights where such action "is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in [the applicable] field of use." In terms of specific request for the exercise of march-in rights, this is the standard to which decision-makers must look.

"Practical application" means "that the invention is being utilized *and* that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms." (emphasis added). 18 U.S.C. section 201(f).

The requirement that a Bayh-Dole contractor make inventions available "on reasonable terms," must be read to include the obligation to sell at a reasonable price. In comparable legal contexts, the phrase "reasonable terms" has been considered to include price. See, e.g., *Byars v. Bluff City News Co*., 609 F.2d 843, 864 n. 58 (5th Cir. 1979) (in applying a reasonable terms requirement in a particular antitrust context, citing "[t]he difficulty of setting reasonable terms, especially price"); *American Liberty Oil Co. v.*

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other formal petitions for march-in rights, "There have been various inquiries to federal agencies from third parties regarding possible march-in, but all have been resolved informally." 14 Berkeley Tech.L.J. at n.79.

[40] See McGarey and Levey, 14 Berkeley Tech.L.J. passim; Mary Eberle, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 Marq.Intell.Prop.L.Rev. 155 (1999); Tamsen Valoir, *Government Funded Inventions: The Bayh-Dole Act and the Hopkins v. CellPro March-in Rights Controversy*, 8 Tex.Intell.Prop.L.J. 211 (2000).

*Federal Power Commission*, 301 F.2d 15, 18 (5th Cir. 1962) (holding that, under statute authorizing the FPC to establish reasonable terms and conditions, the "price ... must be reasonable").

A reasonable price for a product is one that covers costs, accounts for risk, and allows a reasonable profit. See, e.g., *Williston Basin Interstate Pipeline Co. v. FERC*, 165 F.3d 54, 57 (D.C.Cir. 1999). In evaluating whether the price of a medicine, one critical to keeping people alive, is reasonable, one should consider also whether the price imposes substantial hardships on patients who need it and the health care system working to support those patients.

In the context of a medical product, risk factors would include: the risk that research and development might not produce a safe and effective product; the risk that the FDA might fail to approve a product for such reason; and the possibility that a competitor might produce a comparable product that is better, cheaper or both.

A reasonable profit would be one that accounted for risk and ensured that the assignee of the patent would indeed have sufficient incentive to make the product. In the Bayh-Dole context, a reasonable profit would be less than a "windfall" profit, a level of profit comparable to that enjoyed by a monopolist who had done all the research and development itself.

Given the strong concern expressed throughout the legislative history of Bayh-Dole that taxpayers' interests be vindicated, when it comes to a critical, life-saving medicine, evaluation of the reasonableness of the price must also take into account the ability of purchasers to afford the good. In the Bayh-Dole context, it is reasonable to assert that a reasonable price for critical good financed by the public is not a price that creates hardship for the overall public or for individual members of the public.

These factors must be assessed on a case-by-case basis.

The government might be reluctant to engage in the practice of scrutinizing the prices of goods offered by government contractors. But such practice is a regular responsibility of government -- agencies as well as courts -- in many spheres. And it is a practice that is manageable in this context. Moreover, as discussed above, it is a practice that is part of the applicable law, under the march-in rights and "reasonable terms" provisions of the Bayh-Dole Act.

Government evaluates and sets prices or rates in a number of contexts. Price-setting is standard procedure for utilities and other regulated industries that are granted monopoly or substantial market power by government. Section 2-305(1) of the Uniform Commercial Code provides that if a contract price is not settled, "the price is a reasonable price at the time for delivery...." The UCC, in force in 49 states, gives courts the authority to determine reasonable prices where the parties have failed to set prices, and courts have regularly done just that. See, e.g., Koch Hydrocarbon Co. v. MDU Res. Group Inc., 988 F.2d 1529, 1534-35 (8th Cir. 1993) (evaluating, pursuant to UCC section

2-305, what constitutes a reasonable price for natural gas); N.Cent. Airlines, Inc. v. Cont'l Oil Co., 574 F.2d 582, 592-93 (D.C.Cir. 1978) (evaluating under UCC section 2-305 what constitutes a reasonable price for aviation fuel). The Patent Act directs courts, upon a finding of infringement, to award at least "a reasonably royalty" to the patent owner.

After public outcry over the pricing of AZT, the first Bush Administration adopted the policy of requiring firms to sign "reasonable pricing" clauses in return for entering into Cooperative Research and Development Agreements (CRADAs) with the federal government, or exclusive licenses to federal government owned research on pharmaceuticals.[41] This policy went further than the Bayh-Dole Act in some respects. First, it created reasonable pricing requirements even in cases where there were no patents to license. Second, the policy introduced a specific obligation to demonstrate that prices were reasonable in light of the government support for the development of the product.[42]

One of the first drugs to be commercialized with this reasonable pricing clause was the cancer drug Taxol, which was subject to a US government CRADA with BMS. The US government did not own patents on Taxol, but gave BMS the exclusive rights to data from US government funded clinical trials, which BMS used to establish safety and efficacy of Taxol with the US FDA. This effectively gave BMS a five year monopoly on Taxol sales in the US. The NIH was criticized by consumer groups for its management of the Taxol reasonable pricing obligation, and specifically for allowing BMS to charge prices that were roughly twenty times the prices the U.S. government had previously paid for generic supplies of Taxol.[43]

In 1995 the NIH decided that it would abandon the reasonable pricing clause, rather than enforce it. There were several efforts in the U.S. Congress to restore the reasonable pricing clause, but those efforts failed.

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[41] An account of the experience and debate over this policy is found in the *Reports of the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development,* July 21, 1994 and September 8, 1994, National Institutes of Health.

[42] The Public Health Service (PHS) adopted, as Section 16 of Appendix A of the model PHS CRADA Agreement, a statement that "NIH/ADAMHA have a concern that there be a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for NIH/ADAHMA intellectual property rights may require that this relationship be supported by reasonable evidence."

[43] U.S. Congress, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, *Exclusive Agreements Between Federal Agencies and Bristol-Myers Squibb Co. for Drug Development: Is the Public Interest Protected?* Hearings, July 29, 1991, Serial No. 102-35; HHS-OIG, Technology Transfer and the Public Interest: Cooperative Research and Development Agreements at NIH, OEI-01-92-01100, Washington, DC, November 1993; James Love, "Pricing of Drugs Developed with Public Funds, Comments Presented to the Second NIH CRADA Forum, September 8, 1994; James P. Love, "Health Registration Data Exclusivity, Biomedical Research, and Restrictions on the Introduction of Generic Drugs," statement to Subcommittee on Labor, Health and Human Services and Education and Related Agencies Committee on Appropriations U.S. Senate, October 21, 1997.

In 2000, the House of Representatives considered an amendment by Rep. Sanders prohibiting the use of NIH funding to grant exclusive or partially exclusive patent licenses under Bayh-Dole except in accordance with the Bayh-Dole Act provision, 35 U.S.C. section 209, requiring that a federally owned invention and its benefits be made available to the public "on reasonable terms."[44] It was, in essence, an amendment that called on NIH simply to enforce existing law.[45] The House debate on the amendment returned repeatedly to the Bayh-Dole requirement that medicines made with federal research dollars be sold on "reasonable terms."[46] Rep. Sanders told his colleagues:

> Our amendment requires that the NIH abide by current law and ensure that a company that receives federally owned research or a federally owned drug provide that product to the American public on reasonable terms. This is not a new issue ...
>
> While a reasonable pricing clause is not the only device that will protect the investment that American taxpayers have made in numerous profitable drugs, this amendment makes clear that Congress will not stand by while NIH turns over valuable research without some evaluation that the price charged to consumers will be reasonable as is required by current law.

This amendment requiring NIH to enforce "reasonable terms" requirements with respect to pharmaceutical makers passed the House last year by a vote of 313-109.

Opponents to the exercise of march-in rights can be expected to argue just what some industry representatives asserted in opposing the inclusion of the march-in rights provision in the original Bayh-Dole legislation: That the assertion of Bayh-Dole rights would, henceforth, discourage businesses from licensing, developing, and creating products based on, federally funded research. One is tempted to respond that industry representatives who want to make this claim, after march-in rights have been asserted by a federal agency, should be required to put their money where their mouth is, and refrain from entering into agreements where any federal research money is involved. Such enterprises would quickly realize the folly in rejecting still-profitable contracts and allowing willing competitors to scoop them up.

If the Government acted to apply a brake to runaway profits now, companies might see the wisdom in cutting prices for particular products to reflect better such factors as the ratio between the federal contribution to research and development and the company's own contribution; costs; risk; and the public interest. But there would still be the potential to make healthy, attractive profits. And thus there would still be incentive to participate with the federal Government in funding research, and to patent and license products in which the Government played a role.

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[44] See 146 Cong.Rec. H4291-93; 35 U.S.C. sections 209(c)(1)(A) (license granted "only if ... the interests of the Federal Government and the public will best be served by the proposed license, in view of the applicant's intentions, plans and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public") and 201(f) (defining "practical application" to include the "reasonable terms" requirement).

[45] Arno & Davis, at 666-67.

[46] 146 Cong.Rec. at H4291-93.

Indeed, in asserting march-in rights in appropriate cases, the Government could actually spur private industry to increase its contribution to research and development on efforts in which the federal Government also has provided or is providing support. The reason why is plain: If the Government makes clear that the relative contributions of Government and the contractor are a factor in determining, for purposes of Bayh-Dole, whether the contractor is making the product available on "reasonable terms," then the more the contractor contributes to research, the weaker the potential argument for anyone claiming that the contractor's price is unreasonable.

At least some industry representatives shared this view at the time Congress considered the Bayh-Dole legislation. H.F. Manbeck, general patent counsel at General Electric, said during hearings on the bill, "I am in agreement ... that march-in rights will not hurt the affected contractor and not act as a disincentive to the innovation process. Absolutely."[47]

And one recent scholarly analysis agreed that "companies will not refuse to invest in federally funded research if a funding agency exercises march-in rights."[48] Why? Because the Bayh-Dole license transfers remain a good bargain for industry:

> For federally funded technology a balance must be struck between permitting licensees to commercialize their technology and disrupting this development by compelling patent owners to license their technology to third parties. Granted, this forced licensing will arguably generate some uncertainty in the licensing of federally funded research. However, companies will not turn their backs on this cost-effective resource of federally-subsidized university technology.

And, also, because the grant of march-in rights "when necessary" is critical to maintaining public support for this bargain.[49] In other words, if the Government declines to thoroughly review the evidence and act in the face of evidence of drugs sold at high monopoly prices, it would weaken the public's confidence in the fairness and efficiency of the Bayh-Dole Act regime and the overall regime governing the creation and sale of critical medicines. The public may conclude that there no circumstances under which a Bayh-Dole beneficiary company will be scrutinized for charging unwarranted prices. In that light, the public, and then perhaps the public's representatives in Congress, may decide that Bayh-Dole bargain, as so redefined, is not such a good deal for the taxpayers after all. That could create momentum for repealing laws that give the fruits of public research to private industry. In the long run, industry would be better served by the Government taking action now on behalf of fair prices for consumers and a fair return for taxpayers.

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[47] Government Patent Policy, Hearings Before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Cong., 1st Sess., 1979, at 157 (statement of H.F. Manbeck)

[48] Eberble, March-In Rights, 3 Marq.Intell.Prop.L.Rev. at 178.

[49] Eberble, March-In Rights, 3 Marq.Intell.Prop.L.Rev. at 173-74.

Just as evaluating prices for reasonableness is an appropriate government function in certain circumstances, the granting of a license to a responsible party, where a Bayh-Dole contractor has not met its responsibilities, is comparable to government action in related contexts. Courts have ordered compulsory licenses, at reasonable royalty rates, as a remedy for antitrust violations. See United States v. Glaxo Group Ltd., 410 U.S. 52, 64 (1973) ("Mandatory selling on specified terms and compulsory patent licensing at reasonable charges are recognized antitrust remedies). United States law provides for the grant of compulsory licenses under certain conditions in a range of situations: with respect to copyrights, for secondary transmissions by cable television systems[50], for making and distributing phonorecords of certain musical works[51], and for performance of sound recordings via digital audio transmissions[52]; with respect to patents, for certain air pollution prevention inventions[53] and for inventions related to nuclear energy.[54]

## III. Conclusion

The 1980 Bayh-Dole bill struck a bargain between Government, research institutions, industry, taxpayers and consumers, aimed at spurring research and bringing new inventions to the market for the benefit of all. The bargain was amended by the Reagan Administration in 1983 to extend the benefits of Bayh-Dole licensing to large corporations. Now it is time for the bargain to be enforced. It is time to correct an imbalance that has led to unjust enrichment and unwarranted hardship.

Two NIH officials recently concluded that the "greatest value" of the march-in rights provision of Bayh-Dole likely is its "in terrorem effect," its use "as the proverbial Sword of Damocles, suspended over the federally-funded invention licensing process...."[55] But this deterrent value has been diminished over time.

If the Government maintains its record of never exercising march-in rights, then government contractors will understand that there are few if any foreseeable circumstances in which such march-in rights ever will be granted. They will understand that they can obtain on the cheap tremendous benefits from taxpayer-funded research and then, without risk of sanction, turn around and charge the same taxpayers highly-inflated monopoly prices, even for medicines critical to combating fatal diseases. They will understand that devoting great resources to research is only the second-best strategy for reaping big profits; the better one being to let federally-funded research labs carry the research load and expense and then to charge a patent-holder's monopoly price anyway.

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[50] 17 U.S.C. section 111.
[51] 17 U.S.C. section 115.
[52] 17 U.S.C. section 114(f); see Recording Indus. Ass'n of Am. v. Librarian of Congress, 176 F.3d 528 (D.C.Cir. 1999).
[53] 42 U.S.C. section 7608.
[54] 42 U.S.C. section 2183.
[55] McGary and Levey, 14 Berkeley Tech.L.J. at 1116.

Continued government inaction will confirm once and for all the worst fears of Bayh-Dole's harshest critics back in 1980: that, as Senator Long then put it, the bill was a massive "giveaway," a law "deleterious to the public interest," a regime under which Americans are "forced to subsidize a private monopoly twice: first for the research and development and then through monopoly prices."[56]

By contrast, if the Government finally acts to exercise march-in rights in appropriate circumstances, it could produce a critical change with respect to medicines and medical technologies created with federal funding. Patent holders and licensees might begin adjusting their prices to better reflect their actual contributions to research. This could produce substantial cost savings for insurers, governments, and patients, and allow more resources to go to other health care costs -- and, in the case of the global AIDS crisis, also to those overseas suffering from this disease. If industry concluded it could no longer enjoy an almost totally free ride on federal research dollars, and that larger profits depended on making a greater contribution to research and development, that should encourage industry to devote greater, not fewer, resources to R&D. And there will remain strong profits and thus tremendous incentive for industry to continue marketing patented products made mostly with federal research and development money.

[56] Hearings Before the Subcommittee on Monopoly & Anticompetitive Activities of the Senate Select Committee on Small Business, 95th Cong. At 233 (1977) (statement of Sen. Long); Patent Policy: Joint Hearing Before the Senate Committee on Commerce, Science and Transportation and the Senate Committee on the Judiciary, 96th Cong. 463-65 (statement of Sen. Long).