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REASONABLE PRICING – A NEW TWIST FOR MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT

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INTRODUCTION

In 1980, the Bayh-Dole Act gave universities and small businesses the right to own their inventions created with federal funding.[1] Prior to this time, the existing statutes required certain agencies to own inventions arising from federally funded research.

The rationale of Bayh-Dole was simply this: if the law affords broad marketplace prerogatives to the developers of government funded inventions, the inventions are far more likely to be developed and so made available to the public. To achieve this goal, ownership is left with the innovators, rather than assigned to the government agency that financed the research. The innovators are then free to leverage their rights to their advantage, as intended by the patent system.

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1. This is the popular name of the law, which takes its name from the principal sponsors in the Senate: Birch Bayh and Robert Dole. The actual name is the "University and Small

been an increasing number of articles expressing this view and further suggesting that Bayh-Dole was not intended to give innovators an unfettered right to set market prices for their inventions, which has contributed to the rising cost of health care, especially for patented drugs.

One such article by Peter S. Arno and Michael H. Davis asserts that "march-in rights" were clearly intended to combat the price of drugs invented by universities with federal funds and identified to be excessive.[6] It is the purpose of this article to analyze this assertion and its consequences.

I. HISTORY OF MARCH-IN RIGHTS

A. 1947 Attorney General Report

March-in rights have a long history and were discussed in the 1947 Attorney General's Report and Recommendations to the President.[7] They were included in the proposed government patent policy which was being developed to accompany the expansion of government research and development programs after World War II,

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6. Peter Arno & Michael Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TULANE L. REV. 631 (2001). Arno and Davis presented similar arguments in an op-ed article. *See* Peter Arno & Michael Davis, *Paying Twice For the Same Drugs*, WASHINGTON POST, March 27, 2002, at A21. This was rebutted by Birch Bayh and Robert Dole in another op-ed article. *See* Birch Bayh and Robert Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASHINGTON POST, April 11, 2002, at A28, stating:

> Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government . . . . The [Arno and Davis] article also mischaracterizes the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of the resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.

7. U.S. Dept of Justice, INVESTIGATION OF GOVERNMENT PATENT PRACTICES AND POLICIES, REPORT AND RECOMMENDATIONS OF THE ATTORNEY GENERAL TO THE PRESIDENT (1947) [hereinafter RECOMMENDATIONS]. There are three volumes. The report was initiated by

application,[12] or (2) has made the invention available for licensing royalty free or on terms that are reasonable in the circumstances, or (3) can show why it should be able to retain ownership for a further period of time.[13] As in the Attorney General's Report, the fourth paragraph of the Kennedy Memorandum made clear that the reason for march-in rights was to "guard against failure to practice the invention."[14]

2. The Nixon Memorandum

The march-in rights in section 1(f) of the Nixon Memorandum are essentially the same as those in the Kennedy Memorandum,[15] except that the requirement was expanded to assignees and licensees and the Government could also require the granting of an exclusive license to a responsible applicant on terms that were reasonable under the circumstances if the invention was not being developed.

Arno and Davis note that both Presidential Memoranda require that licensing of inventions be on "reasonable terms." There is no requirement in the Memoranda that the price of a patented invention be on "reasonable terms."

C. Institutional Patent Agreements

Institutional Patent Agreements (IPAs) were first used by the National Institutes of Health (NIH) beginning in 1968 and later by the National Science Foundation (NSF) in 1973 to govern the management of inventions made with NIH/NSF support by universities with an approved patent policy. Since many of the provisions in the Bayh-Dole Act come from IPAs,[16] Bayh-Dole can

12. "To the point of practical application" is defined as: "to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine and under such conditions as to establish that the invention is being worked and that its benefits are reasonably accessible to the public." Kennedy Memorandum, *supra* note 10, § 3(g).

13. *Id.* § (1)(f). Refers to principal or exclusive rights rather than ownership because of the required irrevocable paid-up license for government purposes throughout the world.

14. *Id.*

15. Nixon Memorandum, *supra* note 10, § 1(f). The definition of "to the point of practical application" was unchanged. *Id.* § 4(g).

16. There are a number of common elements: (1) restriction against assignment of inventions except to a patent management organization, (2) limitation on the term of an exclusive license, which was removed when Bayh-Dole was amended in 1984, (3) requirement that royalty income must be shared with inventors and the remainder used for education and

> Much has been said about march-in rights . . . . The point has been raised that march-in rights have been available for 10 years, and they have never been used; ergo, they are a failure. We submit that is not the case. There is no evidence to indicate that march-in rights should have been used in a specific situation and were not used. In fact, we submit the high probability is quite the contrary. Where an invention is significant, we submit that the marketplace will take care of the situation. Competitors who want to use a given piece of technology follow a standard routine procedure. They first determine whether there is any patent cover on the development, and then they evaluate the patent cover. If they feel they want to get into the field, they will try to get a license. If they cannot get a license in a Government-owned situation, they will go to the Government agency involved, and they will say, 'I cannot get a license.' They will point to the conditions which the IPA specify as to when march-in rights should be applied; they will provide the information necessary for that evaluation to be made, and we submit in any given situation where march-in should be applied, they will be applied.[21]

II. MARCH-IN RIGHTS UNDER BAYH-DOLE

Under Bayh-Dole, the Government's march-in rights are described in 35 U.S.C. § 203. The funding agency may take action if the contractor, grantee, or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application in a field of use.[22] This was clearly intended to follow the precedent established in both Presidential Memoranda and the IPAs. "Practical application" is defined in 35 U.S.C. § 201(f) to mean:

> [T]o 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

21. *IPA Hearings*, *supra* note 18, at 577.

22. *See generally* 35 U.S.C. § 203 (2000). It is interesting that § 203 does not mention "licensee" in addition to contractor, grantee, or assignee, as did the Nixon Memorandum and so does not directly consider the commercialization activities of the contractor's licensee. There are three other bases for exercising march-in rights. *Id.* § 203(1)(a). Two relate to health, safety or public use and so are similar to the Nixon Memorandum except that they come into play only if

initiate one.[29] However, before initiating a proceeding, the agency is required to notify the contractor and request its comments.[30]

Since 1980, the government has not exercised march-in rights.[31] This might be an indication that march-in is simply ineffective.[32] The ineffectiveness is demonstrated by the discovery made by the Government Accountability Office (GAO), which pointed out that agencies do not seek commercialization reports from contractors and so do not know if inventions are being commercialized.[33] Nevertheless, there have been three petitions to the Department of Health and Human Services (HHS) in recent years.

On March 3, 1997, CellPro, Inc. asked HHS to march-in against Johns Hopkins University. The matter involved Johns Hopkins' exclusive licensee Baxter Healthcare Corporation on four patents covering an antibody useful for the treatment of cancer (U.S. Patent Nos. 4,965,204, 4,714,680, 5,035,994 and 5,130,144).[34] The petition was referred to NIH, which funded the research resulting in the inventions. Dr. Harold Varmus, the Director of NIH, concluded that march-in proceedings were not warranted in a decision dated August 1, 1997.[35] Dr. Varmus argued that march-in proceedings were not necessary because Baxter Healthcare Corporation, an exclusive

29. Failure to enforce a statute is presumptively discretionary and therefore unreviewable under the Administrative Procedure Act. Heckler v. Chaney, 470 U.S. 821, 837-38 (1985). However, Arno & Davis, *supra* note 6, 689-90 n.366, suggested that an argument could be made that the detailed requirements in 35 U.S.C. § 202 (2000) amount to the kind of guidelines that would render the agencies' actions reviewable.

30. 37 CFR § 401.6(b) (2004).

31. Several authors have suggested that the Government will never exercise these rights. *See generally* Bar-Shalom and Cook-Deegan, *supra* note 27 and Kevin W. McCabe, *Implications of the CellPro Determination on Inventions Made with Federal Assistance: Will the Government Ever Exercise Its March-in Rights?*, 27 PUB. CONTR. L.J. 645 (1998). *See also University Hearing*, *supra* note 5, at 160 (Admiral Rickover, no supporter of the Bayh-Dole Act, considered that march-in as a safeguard was "largely cosmetic" because in the rare case of an agency exercising march-in, it would take years of litigation).

32. To the contrary, Mr. Dunner has suggested that the lack of any march-in by an agency does not mean it is a failure because there is no evidence of when it should have been used and that the marketplace would take care of the need for march-in with significant inventions. *See University Hearing*, *supra* note 5, at 577.

33. TECHNOLOGY TRANSFER: REPORTING REQUIREMENTS FOR FEDERALLY SPONSORED INVENTIONS NEED REVISION, GAO/RCED-99-242, at 15-16 (U.S. General Accounting Office 1999).

34. Peter Mikhail, *Hopkins v. CellPro: An Illustration That Patenting and Exclusive Licensing of Fundamental Science Is Not Always in the Public Interest*, 13 HARVARD J.L. TECH. 375, 385 (2000).

$1 billion since it was introduced, although sales fell to $100 million in 2003 from a high of $250 million in 1998.[40]

A public meeting was held at NIH on May 25, 2004, to discuss the petition on the patents on Norvir® owned by Abbott Laboratories. Norman Latker, James Love, and former Senator Birch Bayh, one of the principal co-sponsors of Bayh-Dole, as well as a number of other people from universities and the private sector, spoke on the issue.[41]

In a decision dated July 29, 2004 and released on August 4, 2004, Dr. Elias Zerhouni, the Director of NIH, determined that NIH did "not have information that leads it to believe that the exercise of march-in rights might be warranted."[42] NIH found that the record established that Abbott had met the standard for achieving practical application by its manufacture, practice and operation of Norvir®, by the drug's availability and use by patients with HIV/AIDS since 1996, along with Abbott's active marketing. With respect to drug pricing, NIH felt "that the extraordinary remedy of march-in is not an appropriate means of controlling prices . . . [which should be] left for Congress to address legislatively." Further, any anti-competitive behavior by Abbott should be addressed by the FTC. Essential Inventions responded on August 4, 2004 disagreeing with NIH's decision: "The plain language of the Bayh-Dole Act says that government-funded inventions should be made 'available to public on reasonable terms.'"[43]

The other petition related to latanoprost, a drug for the treatment of ocular hypertension and glaucoma sold under the trade name of Xalatan®, invented by Columbia University under a grant from the National Eye Institute, and exclusively licensed to Pharmacia Corporation, now owned by Pfizer (U.S. Patent No. 4,599,353).[44]

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40. Associated Press, *U.S. Won't Override AIDS Drug Patents*, U.S.A. TODAY, Aug. 4, 2004, *available at* http://www.usatoday.com/news/washington/2004-08-04-aids-drug_x.htm (last visited September 1, 2005).

41. Press Release, Essential Inventions, Inc., Essential Inventions Responds to NIH Refusal to Authorize Generic Versions of Overpriced AIDS Drug (Aug. 4, 2004), *available at* http://www.essentialinventions.org/drug/nih05252004 (last visited September 4, 2005) [hereinafter Press Release].

42. In the Case of NORVIR® Manufactured by Abbott Laboratories, Inc. (National Institutes of Health July 29, 2004) (determination) *available at* http://OTT.od.nih.gov/Reports/March-In-Norvir.pdf (last visited September 1, 2005).

43. Essential Inventions Responds to NIH Refusal to Authorize Generic Versions of Overpriced AIDS Drug (August 4, 2004), *available at* http://www.essentialinventions.org/drug/august42004pressrelease.htm (last visited September 4,

university or nonprofit organization. Under the law, the university need only take "effective steps," not achieve practical application.[47]

If a university is not directly engaged in the development of its invention, an agency should inquire as to what steps the university is planning on taking to commercialize the invention in a reasonable time. Since this involves future action and an undefined time period, it is not clear how an agency would evaluate this.[48] On the other hand, if the university has licensed a company to make, use and sell the invention, it may be considered as having taken effective steps even if no sales of the invention have yet to occur, assuming that the licensee is making some efforts to commercialize the invention.[49]

"Practical application," as defined, requires the benefits of the invention be "available to the public on reasonable terms." With respect to a university patent owner, reasonableness would apply only to its licensing terms and to neither the price nor the availability of the licensed product.[50] Further, in any license agreement, the price of the licensed product is left to the discretion of the licensee.[51] Furthermore, if the license agreement were to specify a minimum sales price, this might constitute a violation of the antitrust laws. The typical license agreement includes a "due diligence" clause, so if the licensee is not adequately achieving commercialization, the university can terminate the license and seek other licensees.

With Norvir®, Abbott Laboratories, not a university, was the contractor and so was directly responsible for commercialization of that invention. Since there was no license, there was no issue of "reasonable terms," and the dramatic price increase in Norvir® and the substantial funding of the research by NIH were not relevant.[52]

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47. 35 U.S.C. § 203(1)(a) (2000).

48. Under both the Presidential Memoranda, the time period was three years from the issue date of the patent. *See* Kennedy Memorandum, *supra* note 10, and Nixon Memorandum, *supra* note 10. A mere statement that a patent is available for licensing may not be sufficient.

49. *See* Cellpro Determination, *supra* note 35.

50. But in the CellPro march-in case, NIH interestingly concluded that practical application had been achieved because the licensee was manufacturing, practicing and operating the licensed product. *See* McGarey & Levey, *supra* note 36, at 1101. Of course, in view of the substantial sales of Xalatan®, the benefits of this invention would have been reasonably available to the public under this approach.

51. The model IPA contained a requirement that royalties "be limited to what is reasonable under the circumstances or within the industry involved." Thus, the focus of reasonable terms was on the licensing by the universities and not the price of the licensed product.

never any doubt that this meant the control of profits, prices, and competitive conditions."[58]

Support for this surprising conclusion that "reasonable terms" means "reasonable prices" is found in unrelated testimony during the Bayh-Dole hearings, and in other Government patent policy bills that did not become law, as well as in a number of non-patent regulatory cases.[59] Even if "reasonable terms" is interpreted to include price that does not necessarily mean that patented drugs funded by the Government must be sold at reasonable prices.

If Congress meant to add a reasonable pricing requirement, it would have explicitly set one forth in the law, or at least described it in the accompanying reports.[60] That a new policy could arise out of silence would truly be remarkable. There was no discussion of the shift from the "practical application" language in the Presidential Memoranda and benefits being reasonably available to the public, to benefits being available on reasonable terms under 35 U.S.C. § 203.

On the other hand, there was much debate during the Bayh-Dole hearings on whether there should be a recoupment provision to address any windfall profits that a university may make out of research funded by the Government.[61] There was a recoupment provision in S. 414 as passed by the Senate but it did not become law.[62] Further, the pre-1984 limitation on the length of an exclusive license term in Bayh-Dole meant that other companies would have access to the patented technology after five years from the first commercial sale or eight years from the date of license.[63]

After convincing themselves that they have made their case, Arno and Davis criticize Bayh-Dole and the Department of Commerce's implementing regulation in 37 C.F.R 401 for leaving the enforcement of reasonable prices up to the agencies.[64] Finally, Arno and Davis accuse the GAO of committing the "fatal error of

58. *Id.* at 662.

59. Compare this with Arno and Davis' opinion of NIH's "unbelievable" complaints that price review is beyond its ability notwithstanding the "countless" cases and "host of" statutes to the contrary. *See* Arno & Davis, *supra* note 6, at 651-52.

60. Admiral Rickover in his testimony on Bayh-Dole never suggested a reasonable pricing requirement as a condition for allowing universities to retain title to their inventions made with government funds. Rather, he proposed to give universities and small businesses an automatic five-year exclusive license after which the invention would fall into the public domain, thereby obviating the need for march-in and recoupment. *University Hearing, supra* note 5, at 161-62.

61. S. Rep. 96-480, *supra* note 2, at 25-26.

of use. According to the legislative history,[71] this section was "intended to continue existing practice and the [House Judiciary] Committee intends that agencies continue to use the march-in provisions in a restrained and judicious manner as in the past."[72]

Although H.R. 6933 ultimately incorporated S. 414, the discussion by the House Judiciary Committee is considered relevant to 35 U.S.C. § 203 because of the similarity in language and the fact that it is included in the legislative history of Bayh-Dole. Thus, it does not appear that Congress intended that there be any change in the application of march-in rights by the agencies, which prior to that time focused on the non-utilization or non-working of federally funded patented inventions, as is evident from the previous discussion of the history under the Presidential Memoranda and the IPAs.[73]

The authors recognize that 35 U.S.C. § 203 includes the language "available on reasonable terms," but one has to understand the context of the phrase in the statute. As previously mentioned with respect to the history of march-in and the two recent petitions to HHS, that term relates only to licensing. Thus, a university licensing its invention to a drug company that sells the patented product to the public is fulfilling its responsibility under Bayh-Dole of making the benefits of the invention available to the public on reasonable terms.

Although we disagree with the interpretation of 35 U.S.C. § 203 by Arno and Davis, Congress could decide to amend Bayh-Dole to impose a reasonable pricing requirement. However, we would not recommend such a change because of the difficulty in determining what is "reasonable."[74] Furthermore, that would make any patent license granted by a Government contractor or grantee subject to attack,[75] which would discourage or inhibit the commercialization of

71. H.R. REP. NO. 96-1307, pt.1 (1980) *reprinted in* 1980 U.S.C.C.A.N. 6460, 6474.

72. *Id.* at 6474.

73. *See* Koons Buick Pontiac GMC, Inc. v. Nigh, 125 S. Ct. 460, 468 (2004), *citing* Church of Scientology of Cal. v. IRS, 484 U.S. 9, 17-18 (1987), where the Supreme Court focused on the lack of Congressional intent to significantly change the meaning of a clause by referring to a Sherlock Holmes story. ("All in all, we think this is a case where common sense suggests, by analogy to Arthur Conan Doyle's 'dog that didn't bark . . . .'"). It is remarkable that there is no discussion in the legislative history of Bayh-Dole about a reasonable pricing requirement.

74. See testimony of Dr. Bernadine Healy, Director of NIH, on Feb. 24, 1993 that NIH is not equipped, either by its expertise or its legislative mandate, to analyze private sector product pricing decisions. Arno & Davis, *supra* note 6, at 670 n.245. Such a determination would be further complicated by when it is done because of the long time and large funds it takes to get to

CONCLUSION

There is no reasonable pricing requirement under 35 U.S.C. § 203(1)(a)(1), considering the language of this section, the legislative history, and the prior history and practice of march-in rights. Rather, this provision is to assure that the contractor utilizes or commercializes the funded invention.[81]

However, that does not mean that the price charged for a drug invented with Government funding is never of concern to the funding agency. There are other mechanisms to address this concern, including the health march-in authority of 35 U.S.C. § 203(1)(a)(2), the Government license in 35 U.S.C. § 202(c)(4), and eminent domain in 28 U.S.C. § 1498(a).[82] In addition, NIH asserted co-inventorship in AZT, which contributed to reducing the cost for this important AIDS drug, sold by Burroughs Wellcome, even though the claim of co-ownership was not sustained in court.[83] Finally, discriminatory pricing of drugs, whether or not invented with Government funds, may fall within the responsibility of the Federal Trade Commission if it can be found to be anti-competitive behavior in violation of antitrust laws.[84]

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81. *See* Alstadt, *supra* note 20, at 81.

82. *See* McGarey & Levey, *supra* note 36, at 1113-15.

83. *See* Lacy et al., *Technology Transfer Laws Governing Federally Funded Research and Development*, 19 PEPP. L. REV. 1, 2 (1991), and Ackiron, *The Human Genome Initiative and the Impact of Genetic Testing and Screening Technologies: Note and Comment: Patents for Critical Pharmaceuticals: The AZT Case*, 17 AM. J.L. & MED. 145 (1991). Dr. Healy explained that the licensing of AZT by NIH was to lower Burroughs Wellcome's price, which went from $8,000-10,000 to $2,000. *The National Institutes of Health and its Role in Creating U.S. High-Technology Industry Growth and Jobs: Hearing before the Subcommittee on Regulation, Business Opportunities, and Energy of the House Committee on Small Business*, 102d Cong. 23


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Act.[76]

It is of interest that NIH had a reasonable pricing policy several years ago. In October 1991, NIH put a reasonable pricing clause in an exclusive patent license with Bristol-Myers-Squibb for the use of ddI, a new AIDS drug.[77] Around this time, NIH also had a reasonable pricing clause in all of its cooperative research and development agreements (CRADAs).[78] Dr. Harold Varmus, the Director of NIH, withdrew the reasonable pricing requirement in its CRADAs in 1995 after convening panels of scientists and administrators in government, industry, universities, and patient advocacy groups to review this policy.[79] In a recent report to Congress, NIH acknowledges that "[t]he cost of prescription drugs is a legitimate public concern that exists whether or not a drug was developed from a technology arising from federally funded research . . . [but NIH] has neither the mandate nor the authority to be the arbiter of drug affordability."[80]

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76. This could be especially damaging for biotech inventions. *See* McCabe, *supra* note 31, at 648. However, a contrary view is taken by Mary Eberle, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 MARQ. INTELL. PROP. L. REV. 155, 171 (1999) ("I argue, by contrast, that a march-in under one of the four circumstances enumerated in the Act would not harm technology transfer.").

77. *The National Institutes of Health and its Role in Creating U.S. High-Technology Industry Growth and Jobs: Hearing before the Subcomm. on Regulation, Business Opportunities, and Energy of the House Comm. on Small Business*, 102d Cong. 9 (1991). When then Congressman Wyden asked about objections to this policy at NIH, Dr. Healy explained that "we are not interested in price setting, but we are interested in using our leverage." *Id.* at 22. She repeated later that NIH should not be involved in price setting. *TPCC Report: Hearing before Subcomm. on Regulation, Business Opportunities, and Technology of House Comm. on Small Business*, 103rd Cong. 16 (1993).

78. Arno and Davis suggest that march-in rights apply to CRADAs although they are not funding agreements as defined by Bayh-Dole. *See* Arno & Davis, *supra* note 6, at 644-45. However, CRADAs have their own march-in rights provision in 15 U.S.C. § 3710a(b)(1)(B) and (C) (2000), although it is more limited than 35 U.S.C. § 203 (2000) and does not refer to "practical application." The only mention of reasonable terms is with respect to a license to be granted by the Government in § 3710a(b)(1)(B)(i). Similarly, there is a march-in like right in the licensing of a Government-owned invention provided in 35 U.S.C. § 209(f)(2) and (4) (2000) under which the Government may terminate the license.

79. National Institutes of Health, *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected* (July 2001), *available at* http://www.nih.gov/news/070101wyden.htm (last visited September 1, 2005).

80. National Institutes of Health, *Affordability of Inventions and Products*, at 4 (July 2004), *available at* http://ott.od.nih.gov/New Pages/211856ottrept.pdf, (last visited June 4, 2005).

course, all this criticism is misplaced, since there is no evidence that Congress intended there to be a reasonable pricing requirement in Bayh-Dole.

The authors submit that the interpretation taken by Arno and Davis is inconsistent with the intent of Bayh-Dole, especially since the Act was intended to promote the utilization of federally funded inventions and to minimize the costs of administering the technology transfer policies.[66] As pointed out by Justice Brennan, a thing may be within the letter of the law but not within the purpose of the law.[67] On the other hand, this would not be the case if agencies were responsible for ensuring reasonable prices for any patented invention, not just a drug, arising out of federal funding. Further, one of the stated objectives of Bayh-Dole, found in 35 U.S.C. § 200, is to "protect the public against nonuse or unreasonable use."[68] It neither provides for, nor mentions, "unreasonable prices."[69]

In H.R. 6933,[70] a companion bill to S. 414 which resulted in Bayh-Dole, there was a march-in rights provision—§ 387—which was similar in part to 35 U.S.C. § 203(1)(a). Under § 387(a)(1) of the provision, an agency could terminate the contractor's title or exclusive rights, or require the contractor to grant licenses if the contractor had not taken and was not expected to take timely and effective action to achieve practical application in one or more fields

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65. *Id.* at 676 n.273.

66. 35 U.S.C. § 200 (2000).

67. United Steelworkers of America v. Weber, 443 U.S. 193, 201 (1979), *citing* Holy Trinity Church v. U.S., 143 U.S. 457, 459 (1892) and *discussed in* Judge Ruggero J. Aldisert, *The Brennan Legacy: The Art of Judging*, 32 LOY. L.A. L. REV. 673, 682-83 (1999).

68. Thus, an agency may march-in for reasons other than non-use of an invention. *See* S. REP. 96-480, *supra* note 2 at 30 ("The agencies will have the power to exercise march-in rights to insure that no adverse effects result from retention of patent rights by these contractors."). As Dr. Betsy Ancker-Johnson, former Assistant Secretary of Commerce, explained, the purpose for march-in rights is to correct "should something go wrong" and if there is "any remote possibility of abuse." *See University Hearing*, *supra* note 5 at 153-54. Unfortunately, no guidance was given on how to determine what is an abuse and this may refer to the other march-ins in 35 U.S.C. § 203(a)(2)-(4) (2000). On the other hand, there may be a situation where a contractor is using an invention for itself but not making the benefits of the invention available to the public at all or on reasonable terms, which could include price. This might be a basis for march-in as mentioned by David Halperin, *The Bayh-Dole Act and March-in Rights*, at 6 (May 2001) *available at* http://www.essentialinventions.org/legal/norvir/halperinmarchin2001.pdf (last visited September 1, 2005), although we disagree with the "reasonable pricing" arguments he adopted from Arno and Davis.

69. Arno & Davis, *supra* note 6 at 683, argued that "unreasonable use" includes unreasonable prices.

70. H.R. 6933, 96th Cong. (1980).

directly or through other companies that can purchase it from Abbott, there was no basis to conduct a march-in rights proceeding under 35 U.S.C. § 203(1)(a).[53] By manufacturing and selling Norvir®, Abbott has taken effective steps to achieve practical application. According to the petition, the sales of Norvir® through 2001 have totaled more than $1 billion and may reach $2 billion over the next ten years.

B. There is No Reasonable Pricing Requirement

Arno and Davis maintain that "[t]he requirement for 'practical application' seems clear to authorize the federal government to review the prices of drugs developed with public funding under Bayh-Dole terms and to mandate march-in when prices exceed a reasonable level."[54] Arno and Davis further suggest that under Bayh-Dole, the contractor may have the burden of showing that it charged a reasonable price.[55] This could be made part of its business development or marketing plan.[56]

As we have mentioned previously, there is very little legislative history on march-in rights and nothing relating to when they are to be used. Similarly, Arno and Davis acknowledge that there is no clear legislative history on the meaning of the phrase "available to the public on reasonable terms,"[57] yet they conclude that "[t]here was

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Essential Inventions, Inc., to Susan Creighton, Director, Bureau of Competition – Federal Trade Commission (January 29, 2004), *available at* http://www.essentialinventions.org/legal/norvir/ftcletter.pdf (last visited September 1, 2005). On May 19, 2004, Senators Charles Schumer, John McCain and Fritz Hollins asked the FTC to initiate an investigation into Abbott's sudden price increase for Norvir®. *See* Letter from Schumer et al., United States Senate, to Timothy J. Muris, Chairman, Federal Trade Commission (May 19, 2004), *available at* http://www.essentialinventions.org/legal/norvir/schmccholl2FTC051904.pdf (last visited September 1, 2005). The FTC later advised Abbott that it had no plans to investigate this complaint. *See* Associated Press, *supra* note 40. Dr. Jeffrey Leiden, president of Abbot, commented at the NIH public meeting on May 25, 2004, that the NIH funding of the invention was around $3.5 million. Jeffrey M. Leiden, *Abbot Laboratories Comments at NIH Public Meeting Regarding Norvir® and Bayh-Dole March-in Provisions* (May 25, 2004), *available at* http://www.essentialinventions/drug/nih05252004/leiden.pdf (last visited June 29, 2005).

53. *But see* 35 U.S.C. § 203(1)(b) (2000), the march-in for health and safety needs.

54. Arno & Davis, *supra* note 6, at 651.

55. *Id.* at 653.

56. There is no requirement in Bayh-Dole for contractors to have such a plan although there is one for Federal laboratories in 35 U.S.C. § 209 (2000). In 2000, Congressman Sanders offered an amendment to HHS appropriations bill H.R. 4577 that would apply the licensing requirements for Federal laboratories to universities. *See* discussion of Sanders' amendment in Arno & Davis, *supra* note 6, at 635 n.12, 666-67 n.227. The amendment was not adopted.

57. Arno & Davis, *supra* note 6, at 649.

and 6,429,226) relating to Xalatan®, none of which were made with federal funds and so are not subject to march-in. According to the petition, Pfizer sells Xalatan® in the United States for two to five times the price charged in Canada and Europe. The drug is said to cost as much as $65 for a four to six week supply, although the cost of the active ingredient is less than 1% of the sales price. By 2000, the sales of Xalatan® were over $500 million a year. The petition considered this unreasonable in view of over $4 million of taxpayer support for the research at Columbia University.

In a decision by Dr. Zerhouni dated September 17, 2004, the National Institutes of Health "determined that it will not initiate a march-in proceeding as it does not believe such a proceeding is warranted based on the available information and the statutory and regulatory framework."[45] The basis for the decision was that the record "demonstrates that Pfizer has met the standard for achieving practical application of the applicable patents by its manufacture, practice, and operation of latanoprost and the drug's availability and use by the public." With respect to the lower prices being charged in Canada and Europe, NIH "believes that the extraordinary remedy of march-in is not an appropriate means for controlling prices." Rather, NIH felt that the lower foreign prices should be "appropriately left for Congress to address legislatively."

A. "Reasonable Terms" Relate to Licensing

A review of the statute makes it clear that the price charged by a licensee for a patented product has no direct relevance to march-in rights. As set forth in 35 U.S.C. § 203(1)(a), the agency may initiate a proceeding if it determines that the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of an invention made under the contract.[46] In most funding agreements, the contractor will be a

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Jeff Gerth & Sheryl Gay Stolberg, *Drug Makers Reap Profits on Tax-Backed Research*, N.Y. TIMES, April 23, 2000, at A1. According to this article, when the patent application was filed in 1982, no drug company in the United States was interested in a license because of its unusual approach to treating glaucoma.

45. In the Case of Xalatan® Manufactured by Pfizer, Inc. (National Institutes of Health Sept. 17, 2004) (determination), *available at* http://OTT.od.nih.gov/Reports/March-in-xalatan.pdf (last visited August 31, 2005).

46. Under 35 U.S.C. § 202(c)(7) (2000), a university is not permitted to assign its invention without the approval of the agency except to a patent management organization.

reasonable terms by obtaining European approval and filing for FDA approval. Dr. Varmus also noted that it would be inappropriate for NIH "to procure for CellPro more favorable commercial terms that it can otherwise obtain from the Court or from the patent owners."[36] This matter was complicated by the pending patent infringement suit by Johns Hopkins University against CellPro filed in 1994, and included appeals to the Federal Circuit, which ultimately sustained the validity and infringement of the Hopkins patents.[37]

On January 29, 2004, James Love and Sean Flynn filed two march-in petitions to HHS on behalf of Essential Inventions, Inc., relying on the Arno-Davis "reasonable pricing" theory.[38] Both petitions were referred to NIH, which had funded the research resulting in the two patented inventions.

One petition related to ritonavir, a drug for the treatment of AIDS sold under the trade name of Norvir® and invented by Abbott Laboratories under a $3.5 million grant from the National Institute for Allergy and Infectious Diseases (NIAID) (U.S. Patent No. 6,232,333).[39] There were other Abbott patents (U.S. Patent Nos. 5,541,206, 5,635,523, 5,648,497, 5,674,882, 5,846,987 and 5,886,036) relating to specific formulations or delivery techniques for Norvir®, which may not have been invented under the NIAID grant.

The petition appears to have been a reaction to Abbott's increasing the U.S. retail price of Norvir® by 400% in December 2003, when it shifted from being a primary treatment agent to one used in small doses to boost the effects of other anti-AIDS medicines. Norvir® has been a very successful drug, with total sales of more than

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36. *Id.* For a description and analysis of the Cellpro case by two NIH attorneys, *see* Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 BERKELEY TECH. L.J. 1095 (1999). *See also* 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, 219-33 (2000). There has been some criticism of the CellPro decision. *See* Bar-Shalom & Cook-Deegan, *supra* note 27; McCabe, *supra* note 31; and Mikhail, *supra* note 34.

37. Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342 (Fed. Cir. 1998).

38. *See Essential Inventions, Inc. Legal Documents, available at* http://www.essentialinventions.org/legal (last visited September 1, 2005). Both petitions requested that HHS issue non-exclusive licenses on the same non-discriminatory terms but suggested that each patent owner receive a 5% royalty from the generic drug companies.

regulations available to the public on reasonable terms.[23]

Section 203 not only authorizes the funding agency to require the contractor or grantee, or its assignee or exclusive licensee, to grant a license to a responsible applicant but itself can grant a license if the ordered party refuses to do so.[24]

According to the legislative history of Bayh-Dole

> The Government may "march-in" if reasonable efforts are not being made to achieve practical application, for alleviation of health and safety needs, and in situations when use of the invention is required by Federal regulations. "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.[25]

Any decision to exercise march-in is subject to appeal to the Court of Federal Claims within 60 days. The agency's decision is held in abeyance until all appeals are exhausted. A decision not to exercise rights is not reviewable.[26]

The Bayh-Dole regulation in 37 C.F.R § 401.6 sets forth a detailed multi-step process, although the agency can terminate the proceedings at any time.[27] The regulation allows an agency to initiate a march-in proceeding "[w]henever [it] receives information that it believes might warrant the exercise of march-in rights."[28] Since the regulation provides no criteria for the initiation of a proceeding, an agency appears to have unlimited discretion on whether or not to

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23. This definition differs from those of the Kennedy and Nixon Memoranda, which say merely "that its benefits are reasonably accessible to the public."

24. Licensing by the Government would be unusual since it is not the patent owner. If there were royalties, it is assumed that they would belong to the patentee or exclusive licensee.

25. S. REP. NO. 96-480, *supra* note 2 at 33-34.

26. *Id.* at 34.

27. 37 C.F.R § 401.6(h) (2004). Thus, one author has concluded that the procedures have a built-in asymmetry which discourages march-in. *See* Avital Bar-Shalom and Robert Cook-Deegan, *Patents and Innovation in Cancer Therapeutics: Lessons from CellPro*, 80 THE MILBANK QUARTERLY 637, 667 (2002):

> The procedures stipulated in Bayh-Dole also have a built-in asymmetry that discourages march-ins. If an agency decides not to march in, the case is over. If it does decide to march in, the party whose patent is subject to compulsory licensing can contest the decision, which compels the agency to defend its action against a party with a strong financial stake.

28. 37 CFR § 401.6(b) (2004).

NSF IPAs, as in Bayh-Dole, the university had a contractual right to elect ownership to any invention, thereby eliminating the arduous task of justifying ownership after identification of an invention. Each IPA contained all the conditions required by the Presidential Memoranda, including march-in rights and the requirement to license on "reasonable terms."

After receiving comments from many agencies and universities, a model IPA containing these conditions was later developed for government-wide use by the University Patent Policy Ad Hoc Subcommittee of the Committee on Government Patent Policy of the Federal Council of Science and Technology.[17] Implementation of the model IPA was postponed for 120 days at the request of Senator Gaylord Nelson on March 17, 1978, who held hearings,[18] and sought to receive recommendations by July 18, 1978.[19]

D. Use of March-In Prior to 1980

Before Bayh-Dole, there was little activity regarding march-in rights.[20] At most, the focus was on whether a particular invention funded by the Government was being used. The absence of march-in rights was discussed during the Nelson hearings. In particular, Donald R. Dunner, the first Vice President of the American Patent Law Association, indicated that:

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17. The Subcommittee was chaired by Norman Latker and included John Raubitschek, then patent counsel for NSF, as a member.

18. *Government Patent Policies: Institutional Patent Agreements: Hearings before the Subcommittee on Monopoly and Anticompetitive Activities of the Senate Select Committee on Small Business*, 95th Cong. 4 (1978), [hereinafter *IPA Hearings*].

19. *Id.* at 1004.

20. *See Patent Policy: Hearings on S. 1215 Before the Senate Subcomm. on Science, Technology and Space of the Comm. on Commerce, Science, and Transportation*, 96th Cong. 366 (1979), where Dale Church of the Department of Defense responded to Senator Stevenson's question, "Has the Department exercised march-in rights?", by remarking, "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." *See also* Lynn J. Alstadt, *The 1980 Patent Rights Statute: A Key to Alternate Energy Sources*, 43 U. PITT. L. REV. 73, 95 n.121 (1981), which discusses march-in activity at NIH, NSF and the Air Force, and Diane M. Sidebottom, *Intellectual Property in Federal Government Contracts: The Past, The Present and One Possible Future*, 33 PUB. CONT. L.J. 63, 95 n.245 (2003), which refers to two march-ins by the predecessor to the Department of Energy in 1974. But these may have related to "waived" inventions. *See* Federal Nonnuclear Act, *supra* note 11.

The Attorney General's Report recommended that, generally, the Government should own inventions made by contractors, but that in special circumstances the contractor may be permitted to own its inventions, provided that "[t]he contractor (or his assignee) shall be required to offer nonexclusive licenses at a reasonable royalty to all applicants" if the contractor or assignee does not place the invention in adequate commercial use within a designated period.[9]

B. 1963 and 1971 Presidential Memoranda and Statements

Thereafter, similar provisions attached to contractor ownership of inventions were described in the Presidential Memoranda and Statements of Government Patent Policy by Presidents Kennedy (1963) and Nixon (1971).[10] These were implemented in the Federal Procurement Regulations and various agency procurement regulations.[11]

1. The Kennedy Memorandum

According to section 1(f) of the Kennedy Memorandum, the government shall have the right to require the granting of a nonexclusive royalty-free license to an applicant if the contractor or grantee who has been permitted to own the invention, or its licensee or assignee, (1) has not taken effective steps within three years after the patent issues to bring the invention to the point of practical

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8. Vannevar Bush, *Science: The Endless Frontier*, (U.S. GOV'T PRINTING OFFICE July 1945), *available at* http://www.nsf.gov/od/lpa/nsf50/vbush1945.htm (last visited May 31, 2005) (report to the President on a program for postwar scientific research).

9. RECOMMENDATIONS, *supra* note 7, vol. 1 at 76, 110.

10. Memorandum of October 10, 1963, 28 Fed. Reg. 10,943 (Oct. 12, 1963) [hereinafter Kennedy Memorandum]. Memorandum of August 23, 1971, 36 Fed. Reg. 16,887 (Aug. 26, 1971) [hereinafter Nixon Memorandum].

11. Federal Procurement Regulations § 1-9.107-3(b), 38 Fed. Reg. 23,782 (Sept. 4, 1973), *revised by* 40 Fed. Reg. 19,814 (May 7, 1975) (codified at 37 C.F.R. § 401.14 and 48 C.F.R. § 52.227-11). *Compare with* Federal Nonnuclear Act of 1974 § 9(h), 42 U.S.C. § 5908(h)(6) (2000) (repealed). A march-in like provision which allowed the head of the agency to terminate a waiver of title or grant of an exclusive license if the recipient has not taken effective steps necessary to accomplish substantial utilization of the invention. Section 9 was later repealed by Bayh-Dole.) See discussion of march-in by the Department of Energy in GAO letter to Senator Bayh dated July 17, 1979, *reprinted in University Hearing*, *supra* note 5, at 52-56. According to DOE as reported by GAO, march-in was intended to address contractor windfall profits but has not been utilized although available for more than 10 years because the problems are illusionary and not actual. *Id.* at 56.

was debated in Congress, a broad political consensus ultimately developed around the notion that market forces would do a better job of commercializing government-funded technology than federal agencies could.[2]

The Act has been enormously effective. As *The Economist: Science Technology Quarterly* concluded, the Act is "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century."[3] In operation, Bayh-Dole fostered a potent four-way partnership between researchers, their institutions, government, and industry. That partnership has created a powerful engine of practical innovation, producing many scientific advances that have extended human life, improved its quality and reduced suffering for millions of people.

Universities, in particular, have been very successful in commercializing their inventions. Bayh-Dole is generally credited for contributing to the dramatic increase over the last 25 years in the number of university inventions reported, patents granted, royalty-bearing licenses negotiated, collaborative research agreements signed, and start-up companies founded. As noted by *The Economist*, since 1980, American universities have witnessed a ten-fold increase in their patents and created more than 2,200 companies to exploit their technology, which in turn has produced 260,000 new jobs; they now contribute $40 billion annually to the American economy.[4]

Notwithstanding its unquestioned success, the Act has recently been criticized on the basis that the public should not be charged, or should be charged less, for goods based on inventions for which, the opponents maintain, the taxpayers have already paid.[5] There have

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2. S. 414, 96th Cong. (1980). The bill passed the Senate 91-4 and resulted in the Bayh-Dole Act, Pub. L. 96-517, 96th Cong., 94 Stat. 3015 (1980). The agencies' passive licensing approach resulted in less than 4% of government patents being licensed as of 1975 in comparison with 33% of university owned licensed patents. S. Rep. No. 96-480, at 2 (1979).

3. The Economist Newspaper and the Economist Group, *Innovation's Golden Goose,* THE ECONOMIST: SCIENCE TECHNOLOGY QUARTERLY (2002), *available at* http://www.economist.com/science/tq/displayStory.cfm?story_id=1476653 (last visited May 31, 2005).

4. *Id.*

5. This criticism is remarkably similar to the views of some opponents of Bayh-Dole. *See The University and Small Business Patent Procedures Act: Hearing on S. 414 before the Senate Comm. on the Judiciary*, 96th Cong. 157 (1979) (statement of Admiral Hyman Rickover) [hereinafter *University Hearing*]. Admiral Rickover states "[i]n my opinion, Government contractors—including small businesses and universities—should not be given title to inventions developed at Government expense . . . . These inventions are paid for by the public and therefore should be available for any citizen to use or not as he sees fit."