Reasonable Pricing - A New Twist for March-In Rights under the Bayh-Dole Act

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In 1980, the Bayh-Dole[3] Act gave universities and small businesses the right to own their inventions made with federal funding. Prior to this time, the only existing statutes required certain agencies to own inventions arising from 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 will far more likely be developed and so made available to the public. To achieve this, ownership is left with the innovators, rather than 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.

Although there was spirited opposition to Bayh-Dole when it was debated in Congress, a broad political consensus[4] developed ultimately around the notion that market forces would do a better job of commercializing government-funded technology than federal agencies could.

The Act has been enormously effective. As the Economist, Technology Quarterly, concluded, the Act is "the most inspired piece of legislation to be enacted over the past half-century."[5]

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[3] This is the popular name of the law, which takes its name from the principal sponsors in the Senate: Birch Bayh and Robert Dole.

[4] S. 414, which resulted in the Bayh-Dole Act, passed 99-0.

[5] Dec. 12, 2002.

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 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 and start-up companies. As noted by the Economist that since 1980, American universities have witnessed a ten-fold increase in their patents, created more than 2,200 companies to exploit their technology producing 260,000 new jobs and have contributed $40 billion annually to the American economy.[6]

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 which the opponents maintain that the taxpayers have already paid for.[7] There have 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[8] asserts that march-in rights were clearly intended to combat the price of drugs invented by universities with federal funds and

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[6] Id.

[7] This criticism is remarkably similar to the views of some opponents of Bayh-Dole. See Admiral Hyman Rickover (※In 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.※), The University and Small Business Patent Procedures Act, Hearings before the Senate Committee on Judiciary, 96th Cong., 1st sess., 1979, at 157.

[8] Peter Arno and 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).

identified to be excessive.[9] It is the purpose of this article to analyze this assertion and its consequences.

History of March-In Rights

A. 1947 Attorney General Report

March-in rights were discussed in the 1947 Attorney General's Report and Recommendations to the President[10] as part of an appropriate government patent policy which was being developed to accompany the expansion of government research and development program after World War II as recommended by the presidential science adviser, Vannevar Bush.[11] The Attorney General's Report recommended that the Government generally should own inventions made by contractors but in special circumstances, the contractor may be permitted to own 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

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[9] Arno and Davis presented similar arguments in an op-ed article in the Washington Post on March 27, 2002 entitled "Paying Twice for the Same Drugs." This was rebutted by Birch Bayh and Robert Dole in another op-ed article in the Washington Post on April 11, 2002 "Our Law Helps Patients Get New Drugs Sooner," that

> "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."

[10] Report and Recommendations of the Attorney General to the President, "Investigation of Government Patent Practices and Policies" (1947). The 3-volume report was initiated by a letter dated February 5, 1943 from President Franklin Delano Roosevelt to Attorney General Francis Biddle. President Roosevelt felt there was a need for a uniform Government policy on the ownership of inventions made by Government employees and contractors.

[11] Vannevar Bush, ▒Science: The Endless Frontier,▒ Report to the President on a Program for Postwar Scientific Research (July 1945).

does not place the invention in adequate commercial use within a designated period.[12]

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 Kennedy (1963)[13] and Nixon (1971)[14]. These were implemented in the Federal Procurement Regulations[15] and various agency procurement regulations.[16]

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 (1) the contractor or grantee who has been permitted to own[17] the invention, its licensee or assignee has not taken effective steps within three years after the patent issues to bring the invention to the point of practical application[18] or (2) has made the invention available

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[12] Recommendation 2(d), 1 Rep. Atty. Gen. 76 and 110, n.10.

[13] 28 Fed. Reg. 10,943 (Oct. 12, 1963).

[14] 36 Fed. Reg. 16,887 (Aug. 26, 1971).

[15] Section 1-9.107-3(b) of the Federal Procurement Regulations, 38 Fed. Reg. 23782 (Sept. 4, 1973) as revised by 40 Fed. Reg. 19814 (May 7, 1975). The standard patent rights clause is now in 37 CFR 401.14 and 48 CFR 52.227-11.

[16] Compare with a march-in like provision in 9(h) of the Federal Nonnuclear Act of 1974, 42 U.S.C. 5908(h)(6). This section 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.

[17] The Kennedy Memorandum, n.13, refers to principal or exclusive rights and not ownership because of the required Government irrevocable paid-up license for Government purposes throughout the world.

[18] As defined in section 4(g) of the Kennedy Memorandum, n.13, "to the point of practical application" means 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

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. As in the Attorney General 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."

The Nixon Memorandum

The march-in rights in section 1(f) of the Nixon Memorandum are very similar[19] to those in the Kennedy Memorandum 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 are reasonable under the circumstances if the invention was not being developed.

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

C. Institutional Patent Agreements

Institutional Patent Agreements (IPAs) were first used by National Institutes of Health (NIH) beginning in 1968 and later by 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[20] in the Bayh-Dole Act come from IPAs, Bayh-Dole can be considered a codification of the IPA. Under both these 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

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and under such conditions as to establish that the invention is being worked and that its benefits are reasonably available to the public."

[19] The definition of "to the point of practical application" was unchanged.

[20] 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 research purposes, (4) requirement that any patent application contain a reference to the federal support which resulted in the invention and (5) a paid-up license to the Government.

conditions required by the Presidential Memoranda including march-in rights and the requirement to license on "reasonable terms."

A model IPA containing these conditions was later developed for government-wide use by the University Patent Policy Ad Hoc Subcommittee[21] of the Committee on Government Patent Policy of the Federal Council of Science and Technology after receiving comments from many agencies and universities. Implementation of the model IPA was postponed for 120 days at the request of Senator Gaylord Nelson on March 17, 1978, who held hearings[22] but became effective on July 18, 1978.[23]

Use of March-In Prior to 1980

Before Bayh-Dole, there was little[24] activity in march-in rights. At most, the focus was on whether a particular invention funded by the Government was being used. During the Nelson hearings, march-in rights were discussed. In particular, Donald R. Dunner, 1st Vice President of the American Patent Law Association, indicated that:

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[21] Chaired by Norman Latker and included John Raubitschek, then patent counsel for NSF, as a member.

[22] Hearings before the Subcommittee on Monopoly and Anticompetitive Activities of the Senate Select Committee on Small Business, 95th Cong., 2nd sess., 1978, at 4.

[23] Id. at 1014.

[24] See Hearings on S. 1215, Subcommittee on Science, Technology and Space of the Committee on Commerce, Science, and Transportation, 96th Cong., 1st sess., 1979 at 366, where Dale Church of the Department of Defense responded to Senator Stevenson's question: "Has the Department exercised march-in rights?" "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 those the patents were not being utilized. As to one of the patents, it was found that MIT was using it and was allowed to exclusive title. In the case of the other, we found that MIT was not efficiently using it, and they did provide for the complainant to use the patent." See also, n.121 of Alstadt, "The 1980 Patent Rights Statute: A Key to Alternate Energy Sources," 43 U. Pitt. L. Rev. 73, 95 (1981) which discusses march-in activity at NIH, NSF and the Air Force and n.245 of Sidebottom, "Intellectual Property in Federal Government Contracts: The Past, The Present and One Possible Future," 33 Pub. Cont. L.J. 63, 95 (2003) which refers to two march-ins by the predecessor to the Department of Energy in 1974.

"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."[25]

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 or grantee or assignee[26] has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application in a field of use.[27] 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 "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

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[25] Hearings, n.22 at 577.

[26] It is interesting that § 203 does not mention "licensee" as did the Nixon Memorandum and so does not directly consider the commercialization activities of the contractor's licensee.

[27] There are three other bases for exercising march-in rights. 35 U.S.C. 203(1)(b)-(d). Two relate to health, safety or public use and so are similar to the Nixon Memorandum except that they come into play only if the contractor, grantee, assignee or licensee cannot reasonably alleviate or satisfy such needs. The third basis relates to a breach of the "domestic manufacturing" requirement in 35 U.S.C. 204.

or Government regulations available to the public on reasonable terms."[28] Section 203 not only authorizes the funding agency to require the contractor or grantee, 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 grant a license.[29]

According to the legislative history[30] of Bayh-Dole, "[t]he 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."

Any decision to exercise march-in is appealable 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.[31]

The Bayh-Dole regulation in 37 CFR 401.6 sets forth a detailed multi-step process although the agency can terminate the proceedings at any time.[32] The regulation allows an agency to initiate a march-in proceeding "[w]henever it receives information

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[28] This definition differs from the one in the Kennedy and Nixon Memoranda, which say merely "that its benefits are reasonably accessible to the public."

[29] 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.

[30] S. Rep. 96-480, 96th Cong., 1st Sess., 1979 at 33-34.

[31] Id. at 34.

[32] 37 CFR 401.6(j). Thus, one author has concluded that the procedures have a built-in asymmetry which discourages march-in. See Bar-Shalom et al.,"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.")

that it believes might warrant the exercise of march-in rights."[33] Since the regulation provides no criteria for the initiation of a proceeding, an agency appears to have unlimited discretion on whether or not to initiate one.[34] However, before initiating a proceeding, the agency is required first to notify the contractor and request its comments.[35]

Since 1980, the government has not[36] exercised march-in rights. This might[37] be an indication that march-in is ineffective especially since GAO pointed out that agencies do not seek commercialization reports from contractors and so do not know if inventions are being commercialized.[38] Nevertheless, there have been three petitions to the Department of Health and Human Services (HHS) in recent years.

On March 3, 1997, HHS was asked by CellPro, Inc. to march-in against Johns Hopkins University and its exclusive licensee Baxter Healthcare Corporation on four patents covering an antibody useful

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[33] 37 CFR 401.6(b).

[34] 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 and Davis, n.8, at 689-90, n.366, suggested that an argument could be made that the detailed requirements in 35 U.S.C. 202 amounts to the kind of guidelines that would render the agencies' actions reviewable.

[35] 37 CFR 401.6(b).

[36] Several authors have suggested that the Government will never exercise these rights. See Bar-Shalom et al., n.32 and 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 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. The University and Small Business Patent Procedures Act Hearings, n.7 at 160.

[37] To the contrary, Mr. Dunner has suggested 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 n.25.

[38] GAO Report ▒Technoloy Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision▒ (GAO/RCED-99-242), pages 15-16.

for the treatment of cancer (U.S. Patents 4,965,204, 4,714,680, 5,035,994 and 5,130,144). 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 8, 1997[39] because Baxter Healthcare Corporation, an exclusive licensee, had taken steps to make its product available to the public on reasonable terms by obtaining European approval and filing for FDA approval. He also noted that it would be inappropriate for NIH "to provide for CellPro more favorable commercial terms that it can otherwise obtain from the Court or from the patent owners."[40] This matter was complicated by the pending patent infringement suit by Hopkins against CellPro filed in 1994 and included appeals to the Federal Circuit, which ultimately sustained the validity and infringement of the Hopkins' patents.[41]

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.[42] Both petitions were referred to NIH which 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 6,232,333). There were other Abbott patents (U.S. Patents 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.

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[39] http://www.nih.gov/news/pr/aug97/nihb-01.htm.

[40] For a description and analysis of the Cellpro case by two NIH attorneys, see McGarey and Levey, "Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition," 14 Berkeley Tech. L.J. 1095 (1999). There has been some criticism of the Cellpro decision. See Bar-Shalom et al. and McCabe, n.36 and also Mikhail, Hopkins v. CellPro: An Illustration That Patent Licensing of Fundamental Science Is Not Always in the Public Interest," 13 Harvard J.L. Tech. 375 (2000).

[41] Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342 (1998).

[42] See http://www.essentialinventions.org. 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.

The petition appears to have been a reaction to Abbott's increasing the U.S. retail price of Norvir 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 $1 billion since it was introduced although sales fell to $100 million in 2003 from a high of $250 million in 1998.[43]

A public meeting was held at NIH on May 25, 2004 to discuss the petition on the patents owned by Abbott Laboratories on Norvir. Statements were made by Norman Latker, James Love and former Senator Birch Bayh, one of the principle co-sponsors of Bayh-Dole and a number of other people from universities and the private sector.[44]

In a decision dated July 29, 2004 and released on August 4, 2004,[45] 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 is warranted." NIH found that the record establishes that Abbott has met the standard for achieving practical application by its manufacture, practice and operation of Norvir and the drug's availability and use by patients with HIV/AIDS since 1996 and is being actively marketed by Abbott. 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.'"[46]

The other petition related to latanoprost, a drug for the treatment for ocular hypertension and glaucoma sold under the trade name of Xalatan and 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 4,599,353).[47] Pfizer owns at least three other U.S. patents

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[43] N.Y. Times, "U.S. Won't Override AIDS Drug Patents" (Aug. 5, 2004).

[44] Testimony is available on Essential Invention's website, n.42.

[45] http://OTT.od.nih.gov/Reports/March-In-Norvir.pdf.

[46] See n.42.

[47] It is of interest that Arno and Davis mentioned this drug as one where there should have been price controls. See n.8

(5,296,504, 5,422,368 and 6,429,226) relating to Xalatan but none of them 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 2-5 times the price charged in Canada and Europe. The drug is said to cost as much as $65 for a 4-6 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 the taxpayer support of the research at Columbia University of over $4 million.

In a decision by Dr. Zerhouni dated September 17, 2004,[48] "[a]fter careful analysis of the Bayh-Dole Act and considering all the facts of the case as well as comments received, 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 available information and the statutory and regulatory framework." 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."

"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. As set forth in 35 U.S.C. 203(a)(1), the agency may initiate a proceeding if it determines that the contractor or assignee[49] 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. In most funding agreements, the contractor will be a university or nonprofit organization. Under

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at 689. An extensive history of this drug is provided by Garth and 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. Id. at A20.

[48] http://OTT.od.nih.gov/Reports/March-in-xalatan.pdf.

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

the law, the university does not have to achieve practical application, only take "effective steps."

If a university is not engaging in any development of its invention, an agency would need to inquire as to what steps the university is planning on taking to commercialize in a reasonable time. Since this involves future action and an undefined time period,[50] it is not clear how an agency should evaluate this.[51] 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 if the licensee is practicing or using the invention. See the CellPro decision.[52]

The fact that the definition for "practical application" also requires that the benefits of the invention must be "available to the public on reasonable terms" applies only to the licensing by the contractor, which is what a university would normally do.[53] Further, in any license agreement, the price of the licensed product is left up to the discretion of the licensee[54] and if the license were to specify a minimum sales price, this may constitute a violation of the antitrust laws. The typical license has a "due diligence" clause so that if the licensee is not performing adequately the commercialization, the university can terminate the license and seek other licensees.

With Norvir, Abbott Laboratories was the contractor instead of a university and so was responsible for commercialization of that

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[50] Under both Presidential Memoranda, the time period was three years from the issue date of the patent.

[51] A mere statement that a patent is available for licensing may not be sufficient.

[52] See n.39.

[53] We note that NIH handled this a little differently in the CellPro march-in case where NIH concluded that practical application had been achieved because the licensee was manufacturing, practicing and operating the licensed product. See McGarey and Levey, n.40 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.

[54] 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.

invention. There was no issue of "reasonable terms" as that term only applies if there is licensing as explained above notwithstanding the recent dramatic price increase[55] and the substantial[56] funding of the research by NIH. Further, since Norvir is available to the public from Abbott either directly or through other companies which can purchase it from Abbott, there is no basis to conduct a march-in rights proceeding under 35 U.S.C. 203(1)(a).[57] By manufacturing and selling Norvir, Abbott has taken effective steps to achieve practical application. According to the petition, the sales of Norvir through 2001 is more than $1 billion and may reach $2 billion over the next ten years.

There is No Reasonable Pricing Requirement

Arno and Davis maintain that "[t]he requirement for 'practical application' seems clearly to authorize the federal government to review the prices of drugs developed with public funding under Bay-Dole terms and to mandate march-in when prices exceed a reasonable level."[58] Arno and Davis further suggest that under Bayh-Dole, the contractor may have the burden to show that it charged a reasonable price.[59] This could be made part of its development or marketing plan.[60]

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[55] Essential Inventions, Inc. filed a complaint with the Federal Trade Commission on January 29, 2004 alleging that the 400% increase in price for Norvir on December 2003 violated the antitrust laws. The FTC later advised Abbott that it had no plans to investigate this complaint. See N.Y. Times article "U.S. Won't Override AIDS Drug Patents" (August 5, 2004). There was also a private antitrust suit filed in February 2004 against Abbott by an AIDS foundation, which was settled in July 2004.

[56] Dr. Jeffrey Leiden, president of Abbott, testified at the NIH public meeting on May 25, 2004 that the funding was around $3.5 million. See n.42.

[57] But see 35 U.S.C. 203(1)(b), the march-in for health.

[58] Arno and Davis, n.8 at 651.

[59] Id. at 653.

[60] 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. In 2000, Congressman Sanders offered an amendment to HHS appropriations bill H.R. 4577 which would apply the licensing requirements for Federal laboratories to universities. See discussion of Sanders' amendment in Arno and Davis, n.8 at 635 n.12, 666 and 667 n.227. The amendment was not adopted.

As we have mentioned previously, there is very little legislative history on march-in rights and nothing relating to when it is to be used. Similarly, Arno and Davis acknowledge there is no clear legislative history on the meaning of "available to the public on reasonable terms,"[61] but yet they conclude that "there was never any doubt that this meant the control of profits, prices and competitive positions."[62]

Support for this surprising[63] conclusion is said to be found in unrelated testimony during the Bayh-Dole hearings and other Government patent policy bills which did not become law as supplemented by a number of non-patent regulatory cases to show the phrase "reasonable terms" means "reasonable prices." Even if "reasonable terms" are 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 set forth one explicitly in the law or at least described it in the accompanying reports.[64] 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 in 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.[65] There was a recoupment

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[61] Arno and Davis, n.8 at 649.

[62] Id. at 662.

[63] 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 n.8 at 651-2.

[64] 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 5 year exclusive license after which the invention would fall into the public domain, thereby obviating the need for march in and recoupment. See Hearings on the University and Small Business Patent Procedures Act, n.7 at 161-162.

[65] S. Rep. 96-480, n.30 at 25-6.

provision in S. 414 as passed by the Senate but it did not become law.[66] Further, the limitation on the length of an exclusive license term in Bayh-Dole until 1984 meant that other companies would have access to the patented technology after 5 years from first commercial sale or 8 years from date of license.

Then after convincing themselves they have made their case, Arno and Davis criticize Bayh-Dole and the Department of Commerce implementing regulation in 37 CFR Part 401 for leaving the enforcement of reasonable prices up to the agencies.[67] Finally, they accuse GAO of making the "fatal error of confusing march-in rights with simple working requirements."[68] Of course, all this criticism is misplaced since there is no evidence that Congress intended there to be a reasonable pricing requirement in Bayh-Dole.

We submit the interpretation taken by Arno and Davis is inconsistent with the intent of the Bayh-Dole as expressed in 35 U.S.C. 200 to promote the utilization of federally funded inventions, to protect the public against non-use or unreasonable[69] use and to minimize the costs of administering the technology transfer policies. It does not provide for nor say "unreasonable prices." Further, even if "available on reasonable terms" could be

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[66] Section 204 Return of Government Investment.

[67] Arno and Davis, n.8 at 648-49.

[68] Id. at 676, n.273.

[69] Thus, an agency may march-in for other than non-use of an invention. See S. Rep. 96-480, n.30 at 30 ("The agencies will have the power to exercise march-in rights to insure that no adverse affects result from retention of rights by these contractors.") As Dr. Ancker-Johnson, former Assistant Secretary of Commerce, explained that march-in rights is to correct "should something go wrong" and if there is "any remote possibility of abuse." See Hearings on the University and Small Business Patent Procedures Act, n.7 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). 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 on page 6 of his May 2001 paper entitled "The Bayh-Dole Act and March-in Rights," available at http://www.essentialinventions.org/legal/norvir/halperinmarchin2001.pdf although we disagree with the "reasonable pricing" arguments he adopted from Arno and Davis.

interpreted[70] as requiring reasonable prices, "a thing may be within the letter of the law but not within the purpose of the law" as pointed out by Justice Brennan,[71]

In H.R. 6933, a companion bill to S. 414 which resulted in Bayh-Dole, there was a march-in rights provision, section 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 has not taken and is not expected to take timely and effective action to achieve practical application in one or more fields of use. According to the legislative history,[72] 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."

Although H.R. 6933 was ultimately replaced by 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 that it is included in the legislative history of Bayh-Dole. Thus, it does not appear that Congress intended[73] 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.

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[70] Arno and Davis, n.8 at 683, argued that "unreasonable use" includes unreasonable prices.

[71] United Steelworkers of America v. Weber, 443 U.S. 193, 197 (1979), citing Holy Trinity Church v. United States, 143 U.S. 457, 459 (1892) and discussed in Aldisert, "The Brennan Legacy: The Art of Judging," 32 Loyola L.A. L. Rev. 673, 682-83 (1999).

[72] House Report No. 96-1307, Part 1, House Judiciary Committee, Sept. 9, 1980, Legislative History of PL 96-517, reprinted in 1980 U.S.C.C.A.N. 6460, 6474.

[73] See Koons Buick Pontiac GMC, Inc. v. Nigh, 125 S.Ct. 460, 468 (2004) 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 in Church of Scientology of Cal. v. IRS, 484 U.S. 9, 17-18 (1987)("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.

We recognize that 35 U.S.C. 203 mentions "available on reasonable terms" but one has to understand the context of the term 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 which 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[75] patent license granted by a Government contractor or grantee subject to attack, which would discourage or inhibit the commercialization of Government-funded technology, one of the primary purposes of the Act.[76]

It is of interest that NIH had a reasonable pricing policy over 10 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 to treat AIDS.[77] Around this time, NIH also had a

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[74] See testimony by Dr. Bernadine Healy on Feb. 24, 1993 that NIH is not equipped, either by its expertise or its legislative mandate, to analyze private sector product pricing decisions. See Arno and Davis, n.8 at 670, n.245, citing Daily Rep. for Executives (BNA), No. 9 (Feb. 25, 1993). Such a determination would be further complicated by when it is done because of the long time and money it takes to get to get a drug to market.

[75] Although 35 U.S.C. 203 applies only to nonprofit organizations and small business firms, it was expanded to large businesses by 35 U.S.C. 210(c).

[76] This could be especially damaging for biotech inventions. See McCabe, n.36 at 645. However, a contrary view is taken by Eberle, "March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research," 3 Marq.Intell.Prop. L.Rev.155 (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] Hearing before the Subcommittee on Regulation, Business Opportunities, and Energy of House Committee on Small Business, 102nd Cong., 1st sess., 1991 at 9. When then Congressman Wyden asked about objections to this policy at NIH, Dr. Healy, the Director, explained that "we are not interested in price setting,

reasonable pricing clause in all its 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 authority to be the arbiter of drug affordability."[80]

Conclusion

It is our opinion that there is no reasonable price requirement under 35 U.S.C. 203(1)(a)(1) considering the words of this section, the legislative history and the prior history and practice[81] of march-in rights. Rather, this provision is to assure

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but we are interested in using our leverage." Hearing, id. at 22. She repeated later that NIH should not be involved in price setting. Hearing before Subcommittee on Regulation, Business Opportunities, and Technology of House Committee on Small Business, 103rd Cong., 1st sess., 1993 at 16.

[78] Arno and Davis suggest that march-in rights apply to CRADAs although they are not funding agreements as defined by Bayh-Dole. See n.8 at 645. However, CRADAs have their own march-in rights provision in 15 U.S.C. 3710a(b)(1)(B) and (C) although it is more limited than 35 U.S.C. 203 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) under which the Government may terminate the license.

[79] See C.6 of the NIH Response to the Conference Report Request in the FY 2001 DHHS Appropriation for a Plan to Ensure Taxpayers' Interests are Protected (July 2001), available online at http://www.nih.gov/news/070101wyden.htm.

[80] NIH Report to Congress on "Affordability of Inventions and Products" (July 2004), available at http://ott.od.nih.gov/NewPages/211856ottrept.pdf, pg. 4.

[81] NIH's interpretation of the march-in rights statute would be entitled to deference by the courts when it is administering that statute especially with respect to any ambiguity in the statute. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-843 (1984).

that contractor utilizes or commercializes the funded invention.[82] 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 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).[83] 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.[84] Finally, discriminatory pricing of drugs, whether or not invented with Government funds, may fall within the responsibility of the Federal Trade Commission.[85]

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[82] See Alstadt, n.24 at 81.

[83] See McGarey and Levey, n.40 at 1113-15.

[84] See Lacey 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. and Med. 145 (1991). Dr. Healy explained that the licensing of AZT by NIH was to lower Burroughs-Wellcome's price, which went from $8-10,000 to $2,000. Hearing before the Subcommittee on Regulation, Business Opportunities, and Energy of House Committee on Small Business, 102nd Cong., 1st sess., 1991 at 23.

[85] See NIH decision on the Norvir march-in petition, n.45.