DRAFT

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

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In 1980, the Bayh-Dole 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. ~~This law was developed with bipartisan support and~~ The principal sponsors were Senators Robert Dole, a Republican from Kansas and Birch Bayh, a Democrat from Indiana. In a memorandum[3] in 1983 and Executive Order 12591[4] in 1987, President Reagan ~~applied~~ extended this law to large business contractors.

Universities have been very successful in commercializing their inventions. Bayh-Dole is generally credited for contributing to the dramatic increase over the last 20 years in the number of university inventions, patents, ~~licenses and royalties~~ reported granted, royalty bearing licenses negotiated, collaborative agreements and new start ups. F.N.

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[3] Memorandum on Government Patent Policy, 1983 Pub. Papers 248, 252 (Feb. 18, 1983).

[4] 3 CFR § 220 (1988), reprinted in 15 U.S.C. 3710 app. at 1374-75 (1988).

[5] 35 U.S.C. 202(c)(4).

[6] 35 U.S.C. 203.

[7] Several authors have suggested that the Government will never exercise these rights. See Bar-Shalom and Cook-Deegan, "Patents and Innovation in Cancer Therapeutics: Lessons from CellPro," 80 The Milbank Quarterly 637, 661 (2002) 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,

In general, these march-in rights permit the

Under Bayh-Dole, the Government has certain rights including a paid-up license[5] and march-in rights.[6] Although the Government has never[7] exercised march-in rights under this law, there have been several petitions to the Department of Health and Human Services (HHS).

On March 3, 1997, HHS was asked by CellPro, Inc. to march-in against Johns Hopkins University and its licensees of three stem cell patents. The matter was referred to NIH, which funded the research. NIH concluded that march-in proceedings were not warranted and denied the petition on August 8, 1997.[8]

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An article by Peter S. Arno and Michael H. Davis[9] asserts that march-in rights should be used to combat the high price of drugs invented by universities with federal

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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 before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at 160.

[5] 35 U.S.C. 202(c)(4).

[6] 35 U.S.C. 203.

[8] 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.7 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).

[9] 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).

[10] The authors 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."

funding.[10] On January 29, 2004, James Love and Sean Flynn filed two petitions to HHS on behalf of Essential Inventions, Inc. relying on this theory. These petitions are still pending.[11] But before examining this theory, we should first consider the history of march-in rights.

History

March-in rights existed prior to Bayh-Dole and were described in the Presidential Memoranda and Statements of Government Patent Policy by Kennedy (1963)[12] and Nixon (1971)[13]. These were implemented in the Federal Procurement Regulations[14] and various agency procurement regulations. In addition, they were mentioned in the Attorney General's Report in 1947.[15] That Report recommended 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

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[11] A public meeting was held at NIH on May 25, 2004 to discuss the petition on the patents owned by Abbott Laboratories on Norvir, which is useful in the treatment of AIDS. Statements were made by Mr. Latker, Mr. Love and former Senator Bayh and a number of other people.

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

[13] 36 Fed. Reg. 16,887 (Aug. 26, 1971).

[14] 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.

[15] Report and Recommendations of the Attorney General to the President, "Investigation of Government Patent Practices and Policies" (1947).

[16] Recommendation 2(d), Volume 1 of the Attorney General Report, Chapter Four, page 76.

Prior to Bayh-Dole, there was little[20] activity in march-in rights. At most, the focus was on whether a particular invention funded by the Government was being used.

Institutional Patent Agreements

The Bayh-Dole Act relies heavily on Institutional Patent Agreements (IPA) which were used by NIH beginning in 1986 and NSF in 1973 to handle inventions for universities with an approved patent policy. Under the IPA, the university had the automatic rights to any invention made with NIH or NSF funds and did not have to request rights under a deferred determination policy. Bayh-Dole can be considered a codification[21] of the IPA, which was authorized for all agencies in 1978. The model IPA was developed by the University Patent Policy Ad Hoc Subcommittee[22] of the Committee on Government Patent Policy of the Federal Council of Science and Technology after receiving comments from many agencies and universities. However, implementation of the IPA was postponed for 120 days at the request of Senator Gaylord Nelson on March 17, 1978, who held hearings.[23] The IPA regulation became effective on July 18, 1978.[24]

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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.

21 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.

22 Chaired by Norman Latker and included John Raubitschek as a member.

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

24 Hearings, n.24 at 1014.

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:

> "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]

It is of interest that the model IPA contained a requirement that the royalties "be limited to what is reasonable under the circumstances or within the industry involved."[26] Thus, the focus of reasonable terms was on the licensing by the universities and not the price of the licensed product. Further, it was done under a specific clause and not as part of march-in.

The Bayh-Dole Act

March-in rights under Bayh-Dole are provided for university and small business inventions made with federal funding in 35 U.S.C. 203 and for inventions by large

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25 Id. at 577.

26 See 3.E. of the change to 41 CFR 101-1.4 contained in the Hearings n.24 at 1916. See also IX(c) of the IPA "Royalties shall not normally be in excess of accepted trade practice. Id. at 1926. Similarly, the NIH IPA required in section VI(e) that: "Any license granted . . . under any patent application or patent on a subject invention shall include adequate safeguards against unreasonable royalty and repressive practices. Royalties shall not, in any event, be in excess of normal trade practice. . . ." The NSF IPA required in section VI(e) that "Royalties shall not normally be in excess of accepted trade practice."

businesses in 35 U.S.C. 210(c). The funding agency may take action if the contractor or grantee or assignee[27] has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application in a field of use.[28] "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 or Government regulations available to the public on reasonable terms."[29] 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.[30]

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 complex 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 that it believes

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[27] 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.

[28] 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.

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

[30] The granting of any license 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.

[31] See S.Rep. 96-480, 96th Cong, 1st Sess., 1979 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., n.7 at 667 ("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.")

[33] 37 CFR 401.6(b).

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]

According to the legislative history[36] 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." (Bunner)

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,[37] 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."

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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 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.

? the Attorney-General would

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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 (S.Ct. 1985). However, Arno and Davis, n.10, 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] Id.

[36] S.Rep. 96-480, n.31, at 33-34.

[37] 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.

37 CFR 401.6 ?

Recent Petitions by Essential Inventions, Inc.

It may be instructive to apply 35 U.S.C. 203(1)(a) to the fact situations in the two recent petitions by Essential Inventions for HHS to march-in. One petition relates to Xalatan, a drug for the treatment for glaucoma 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).[38] The other relates to Norvir, a drug for the treatment of AIDS invented by Abbott Laboratories under a contract from the National Institute for Allergy and Infectious Diseases (U.S. Patent 6,232,333).

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.

"Reasonable Terms" Relate to Licensing

A review of the statute will make it clear that price charged by a licensee 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[39] 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. Thus, a contractor does not have to achieve practical application, only take effective steps.

If a contractor is not engaging in any commercial activity, an agency would need to inquire as to what steps the contractor is planning on taking to commercialize in a

38 It is of interest that Arno and Davis mentioned this drug as one where there should have been price controls. See n.10 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.

39 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.

40 Under both Presidential Memoranda, the time period was three years from

reasonable time. Since this involves future action and an undefined time period,[40] it is not clear how an agency should evaluate this.[41] On the other hand, if the contractor has licensed a company to make, use and sell the invention, such a contractor 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. 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, which is what the university contractor is doing.[42] Further, in any license agreement, the price of the licensed product is left up to the discretion of the licensee[43] 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 is the contractor and there is no licensee. In the absence of any license, there is no issue of "reasonable terms" as explained above notwithstanding the recent dramatic price increase[44] and the substantial[45] 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 does not appear to be any basis to conduct a march-in rights proceeding under 35 U.S.C. 203(1)(a).[46] 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.

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the date patent issues.

41 A mere statement that a patent is available for licensing may not be sufficient.

42 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.8 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.

43 Under IPAs on which Bayh-Dole was based, universities were required to charge reasonable royalties. See n.26.

44 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.

45 A witness at the NIH public meeting on May 25, 2004 indicated that the funding was around $3.5 million.

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

Reasonable Pricing

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."[47] The authors further suggest that under Bayh-Dole, the contractor may have the burden to show that it charged a reasonable price.[48] This could be made part of its development or marketing plan.[49]

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,"[50] but yet they conclude that "there was never any doubt that this meant the control of profits, prices and competitive positions."[51]

Support for this surprising[52] conclusion is said to be found in unrelated testimony during the Bayh-Dole hearings and other Government patent policy bills which did not pass 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 the Government must be sold on reasonable prices. F.N Pfizer

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. That a new policy could arise out of silence would truly be remarkable. There was no mention of the shift from the "practical application" language in the Presidential Memoranda to benefits being reasonably available to the public to benefits being

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[47] Arno and Davis, n.9 at 651.

[48] Id. at 653.

[49] 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.9 at 635 n.12, 666 and 667 n.227. The amendment was not adopted.

[50] Arno and Davis, n.9 at 649.

[51] Id. at 662.

[52] Compare this with the authors' 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.10 at 651-2.

available on reasonable terms in 35 U.S.C. 203(1)(a)

On the other hand, there was much discussion 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. There was a recoupment provision in S. 414 as passed by the Senate passed but it did not become law. 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 8 years.

Then after convincing themselves they have made their case, the authors 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.[53] Finally, the authors accuse GAO as committing the "fatal error of confusing march-in rights with simple working requirements."[54] 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 especially since that law was intended to minimize the costs of administration.[55] As pointed out by Justice Brennan, "a thing may be within the letter of the law but not within the purpose of the law."[56]
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 is to "protect the public

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[53] Arno and Davis, n.9 at 648-49.

[54] Arno and Davis, n.9 at 676, n.273.

[55] 35 U.S.C. 200.

56 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).

[57] Thus, an agency may march-in for other than non-use of an invention. See S. Rep. 96-480, n.31 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." The University and Small Business Patent Procedures Act, Hearings before the Senate Committee on Judiciary, 96th Cong., 1st Sess., 1979, at

against nonuse or unreasonable[57] use." 35 U.S.C. 200. It does not say "unreasonable prices."[58]

We recognize that 35 U.S.C. 203 (1)(a) mention "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 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 (1)(a) 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."[59] Furthermore, that would make any[60] patent license granted by a Government contractor or grantee subject to attack, which would discourage or inhibit the commercialization of Government-funded technology.[61]

153-54. Unfortunately, no guidance was given on how to determine what is an abuse and so 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 could be a basis for march-in as discussed by David Halperin in his May 2001 paper entitled "The Bayh-Dole Act and March-in Rights," available online at http://www.essentialinventions.org/legal/norvir/halperinmarchin2001.pdf although we disagree with the "reasonable pricing" arguments he adopted from Arno and Davis.

[58] Arno and Davis, n.9 at 683, argued that "unreasonable use" includes unreasonable prices.

[59] See testimony by 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.9 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.

[60] 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).

61 This could be especially damaging for biotech inventions. See McCabe, n.7 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.").

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 to treat AIDS.[62] Around this time, NIH also had a reasonable pricing clause in all its CRADAs.[63] Dr. Harold Varmus, the new Director at 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.[64]

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 of march-in rights. Rather, this provision is to assure that contractor utilizes or commercializes the funded invention.[65] However, that does not mean that the price charged for a drug invented with Government funding is never a 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).[66] In addition, NIH asserted co-inventorship in AZT which contributed to reducing the cost for this important AIDS

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62 Hearing before the Subcommittee on Regulation, Business Opportunities, and Energy of House Committee on Small Business, 102nd Cong., 1st Sess., 1991 at 9. When Congressman Wyden asked about objections to this policy at NIH, Dr. Bernadine Healy, the Director, explained that "we are not interested in price setting, 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.

63 Arno and Davis suggest that march-in rights apply to CRADAs although they are not funding agreements as defined by Bayh-Dole. See n.9 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.

64 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.

65 See Alstadt, n.20 at 81.

66 See McGarey and Levey, n.8 at 1113-15.

drug sold by Burroughs Wellcome even though the claim of co-ownership was not sustained in court.[67] Finally, discriminatory pricing of drugs, whether or not invented with Government funds, may fall within the responsibility of the Federal Trade Commission.

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67 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.

DRAFT

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

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(1)

In 1980, the Bayh-Dole 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.

Although there was spirited opposition to Bayh-Dole when it was brought before Congress ~~in 1980~~, a broad political consensus was ultimately built around the notion that market forces would do a ~~far~~ better job of disseminating government-sponsored inventions than bureaucracies ~~ever~~ could.

~~This~~ law ~~was developed with bipartisan support and the principal sponsors were Senators Robert Dole, a Republican from Kansas and Birch Bayh, a Democrat from Indiana~~. In a memorandum[3] in 1983 and Executive Order 12591[4] in 1987, President Reagan ~~applied~~ extended this law to large business contractors.

In practice, Bayh-Dole

~~It~~ has fostered a potent four-way partnership between researchers, their institutions, government and industry. That partnership has evolved into the most powerful engine of practical innovation in the world, producing innumerable advances that have extended life, improved its quality and reduced suffering for hundreds of millions of people.

The Act, in particular

Universities have been very successful in commercializing their inventions. ~~Bayh-Dole~~ is generally credited for contributing to the dramatic increase over the last 20 years in the number of university inventions, patents ~~licenses and royalties~~.

reported

granted, royalty bearing licenses negotiated, collaborative agreements and new start-ups. F.N. 1.c Economist Autm

Under Bayh-Dole, the Government has certain rights including a paid-up license[5] and march-in rights.[6] Although the Government has never[7] exercised march-in rights under this law, there have been several petitions to the Department of Health and Human Services (HHS).

On March 3, 1997, HHS was asked by CellPro, Inc. to march-in against Johns Hopkins University and its licensees of three stem cell patents. The matter was referred to NIH, which funded the research. NIH concluded that march-in proceedings were not warranted and denied the petition on August 8, 1997.[8]

(2)

move the language of the B-D

An article by Peter S. Arno and Michael H. Davis[9] asserts that march-in rights should be used to combat the high price of drugs invented by universities with federal funding.[10] On January 29, 2004, James Love and Sean Flynn filed two petitions to HHS on behalf of Essential Inventions, Inc. relying on this theory. These petitions are still pending.[11] But before examining this theory, we should first consider the history of march-in rights.

move

History

as a condition of ownership a government funded inventor

March-in Rights were first suggested as part in the 1947 Attorney General's Report and Recommendations to the President on an appropriate government patent policy considered necessary by the expanding government research and development program after WWII.

That Report recommended 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.[16]

Thereafter, similar provisions were used as part of

March-in rights existed prior to Bayh-Dole and were described in the Presidential Memoranda and Statements of Government Patent Policy by Kennedy (1963)[12] and Nixon (1971)[13]. These were implemented in the Federal Procurement Regulations[14] and various agency procurement regulations. In addition, they were mentioned in the Attorney General's Report in 1947.[15]

(3)

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 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. There was also a march-in right in section 1(g) if the invention is required for public use by Government regulations or as may be necessary to fulfill health needs or other public purposes stipulated in the contract or grant. However, the required licensing could be royalty-free or on terms that are reasonable in the circumstances. As stated in the fourth paragraph of the Kennedy Memorandum, the reason for march-in rights was to "guard against failure to practice the invention."

as in the 1947 Attorney General's Recommendation limited

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 working 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. The health march-in right in section 1(g) was expanded to refer to safety. It is interesting that the concept of "reasonable terms" is used in the Presidential Memoranda with respect to the required licensing and not to the availability or price of a patented invention arising from federally funded research.

if the patent owner was not pursuing practice of the invention

Prior to Bayh-Dole, there was little[20] activity in march-in rights. At most, the focus was on whether a particular invention funded by the Government was being used.

Institutional Patent Agreements

The Bayh-Dole Act relies heavily on Institutional Patent Agreements (IPA) which were used by NIH beginning in 1986 and NSF in 1973 to handle inventions for universities with an approved patent policy. Under the IPA, the university had ~~the automatic rights~~ to any invention made with NIH or NSF funds ~~and did not have to request rights under a deferred determination policy~~. Bayh-Dole can be considered a codification[21] of the IPA, which was authorized for all agencies in 1978. The model IPA was developed by the University Patent Policy Ad Hoc Subcommittee[22] of the Committee on Government Patent Policy of the Federal Council of Science and Technology after receiving comments from many agencies and universities. However, implementation of the IPA was postponed for 120 days at the request of Senator Gaylord Nelson on March 17, 1978, who held hearings.[23] The IPA regulation became effective on July 18, 1978.[24]

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:

> "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]

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INNOVATION'S GOLDEN GOOSE

The reforms that unleashed American innovation in the 1980s, and were emulated widely around the world, are under attack at home

REMEMBER the technological malaise that befell America in the late 1970s? Japan was busy snuffing out Pittsburgh's steel mills, driving Detroit off the road, and beginning its assault on Silicon Valley. Only a decade later, things were very different. Japanese industry was in retreat. An exhausted Soviet empire threw in the towel. Europe sat up and started investing heavily in America. Why the sudden reversal of fortunes? Across America, there had been a flowering of innovation unlike anything seen before.

Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.

Before Bayh-Dole, the fruits of research supported by government agencies had belonged strictly to the federal government. Nobody could exploit such research without tedious negotiations with the federal agency concerned. Worse, companies found it nigh impossible to acquire exclusive rights to a government-owned patent. And without that, few firms were willing to invest millions more of their own money to turn a raw research idea into a marketable product.

The result was that inventions and discoveries made in American universities, teaching hospitals, national laboratories and non-profit institutions sat in warehouses gathering dust. Of the 28,000 patents that the American government owned in 1980, fewer than 5% had been licensed to industry. Although taxpayers were footing the bill for 60% of all academic research, they were getting hardly anything in return.

The Bayh-Dole act did two big things at a stroke. It transferred ownership of an invention or discovery from the government agency that had helped to pay for it to the academic institution that had carried out the actual research. And it ensured that the researchers involved got a piece of the action.

Overnight, universities across America became hotbeds of innovation, as