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[4] in 1983 and Executive Order 12591[5] in 1987, President Reagan applied 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. According to figures published by the Association of University Technology Managers (AUTM), the total license revenue for all universities has been over $1 billion for the fiscal years 2000-2.

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

[5] 3 CFR § 220 (1988), reprinted in 15 USC 3710 app. at 1374-75 (1988).

Under Bayh-Dole, the Government has certain rights including a paid-up license[6] and march-in rights.[7] Although the Government has never[8] 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.[9]

An article by Peter S. Arno and Michael H. Davis[10] submits that march-in rights should be used to combat the high price of drugs invented by universities with federal

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[6] 35 USC 202(c)(4).

[7] 35 USC 203.

[8] 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 Public Contract Law Journal 645 (1998).

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[11] 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

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funding.[11] 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.[12] But before examining this claim, 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 Memorandum and Statement 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. In addition, they were mentioned in the Attorney General's Report in 1947.[16] 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.[17]

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[18] the invention, its licensee or assignee has not taken effective steps within three years after the patent

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collaborator has not successfully commercialized the invention as a product."

[12] 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.

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

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

[15] Section 1-9.107-3(b) of the Federal Procurement Regulations, 38 Fed. Reg. 23782 (September 4, 1973) as revised by 40 Fed. Reg. 19814 (May 7, 1975).

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

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

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

[19] As defined in section 4(g), "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 and under such conditions as to establish that the invention is being worked and that its benefits are reasonably

issues to bring the invention to the point of practical application[19] 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."

The march-in rights in section 1(f) of the Nixon Memorandum are very similar[20] to those in the Kennedy Memorandum except that the utilization 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 latter change probably arose because of the new emphasis on exclusive licensing by the Government. 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 licensing and not to the availability or price of a patented invention arising from federally funded research.[21]

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available to the public."

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

[21] 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." The University Patent Policy Ad HoC Subcommittee of the Committee on Government Patent Policy of the Federal Council of Science and Technology issued a report in 1976 which recommended in section 8 that any agency IPA contain a restriction that royalty charges be limited to what is reasonable under the circumstances or within the industry involved.

[22] Prior to Bayh-Dole, there was some activity with march-in rights. See Hearings on S. 1215, Subcommittee on Science, Technology and Space of the Committee on Commerce, Science, and Transportation, 96th Cong., 1st sess. (1979), p. 366, Dale Church of DoD responding to Senator Stevenson 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

Prior to Bayh-Dole, there was not much[22] activity in march-in rights. At most, the focus was on whether a particular invention funded by the Government was being used.

Bayh-Dole

March-in rights under Bayh-Dole are provided for university and small business inventions made with federal funding in 35 USC 203 and for inventions by large businesses in 35 USC 210(c). The funding agency may take action if the contractor or grantee or assignee[23] has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application in a field of use.[24] "Practical application" is defined in 35 USC 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."[25] 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.[26]

Any decision to exercise march-in is appealable to the Court of Federal Claims

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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 University of Pittsburgh Law Review 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 Public Contract Law Journal 63, 95 (2003) which refers to two march-ins by the predecessor to the Department of Energy in 1974.

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

[24] There are three other bases for exercising march-in rights. 35 USC 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 USC 204.

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

[26] 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.

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.[27] 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.[28] The regulation allows an agency to initiate a march-in proceeding "[w]henever it receives information that it believes might warrant the exercise of march-in rights."[29] 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.[30] However, before initiating a proceeding, the agency is required first to notify the contractor and request its comments.[31]

According to the legislative history[32] 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."

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 to 35 USC 203. Under (a)(1) of the provision, an agency could terminate the contractor's title or exclusive rights or

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[27] See S. Rep. 96-480, at 34 ("'Marchin' is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or outside parties, although it is expected that in most cases complaints from third parties will be the basis for the initiation of agency action.").

[28] 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.8 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.")

[29] 37 CFR 401.6(b).

[30] 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 USC 202 amounts to the kind of guidelines that would render the agencies' actions reviewable.

[31] Id.

[32] S.Rep. 96-480, 96th Cong, 1st sess., pg 33.

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,[33] 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 USC 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-use of federally funded patented inventions as is evident from the previous discussion of the history under the Presidential Memoranda. 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. Further, one of the stated objectives of Bayh-Dole is to "protect the public against nonuse or unreasonable use." 35 USC 200. It does not say "unreasonable prices."[34]

Recent Petitions by Essential Inventions, Inc.

It may be instructive to apply 35 USC 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). 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 one 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. This is considered unreasonable in view of the taxpayer support of the research at Columbia University of over $4 million.

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[33] House Report No 96-1307, Part 1, House Judiciary Committee, September 9, 1980, Legislative History of PL 96-517, Congressional News 6460, 6474.

[34] Arno and Davis, n.10 at 683, argued that "unreasonable use" includes unreasonable prices.

But, how does this relate to march-in? Clearly, the benefits of this drug are available to the public in view of the substantial sales. The fact that the price may be high compared to the manufacturing costs or is less outside of the United States has no relevance to 35 USC 203(1)(a). Rather, Columbia University (the contractor) has complied with this statute because by licensing Pfizer which is utilizing the invention, it took effective[35] steps to achieve practical application. The reference to "reasonable terms" in the definition of "practical application" in 35 USC 201(f) relates to the licensing terms of the contractor and not the price charged by the licensee.[36] In view of the large amount of sales, the royalty terms are presumed to be reasonable, especially in the absence of any evidence to the contrary. Licensors generally do not control the price of the licensed product but if they did, such provisions may violate the antitrust laws.

With Norvir, Abbott Laboratories is the contractor and there is no licensee. In the absence of a license, there is no issue of reasonable terms as explained above. However, the petition considers the recent dramatic price increase[37] as being "unreasonable" in view of the substantial[38] funding of the research by NIH. However, since Norvir is available to the public from Abbott either directly or through other companies which purchase it from Abbott, there does not appear to be any basis to conduct a march-in rights proceeding under 35 USC 203(1)(a).[39] By manufacturing and selling Norvir, Abbott took 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.

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."[40] The authors further suggest that under Bayh-Dole, the contractor

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[35] There is no requirement that practical application must be achieved.

[36] Under IPAs on which Bayh-Dole was based, universities were required to charge reasonable royalties. See n.20.

[37] 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.

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

[39] But see 35 USC 203(1)(b), the march-in for health.

[40] Arno and Davis, n.10 at 651.

may have the burden to show that it charged a reasonable price.[41] This could be made part of its development or marketing plan.[42]

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,"[43] but yet they conclude that "there was never any doubt that this meant the control of profits, prices and competitive positions."[44] Support for this surprising[45] 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" may include price.

Then after convincing themselves they have made their case, the authors criticize Bayh-Dole and the Department of Commerce implementing regulation in 37 CFR 401 for leaving the enforcement of reasonable prices up to the agencies.[46] Finally, the authors accuse GAO as committing the "fatal error of confusing march-in rights with simple working requirements."[47] 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,[48] which 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

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[41] Id. at 653.

[42] There is no requirement in Bayh-Dole for contractors to have such a plan although there is one for Federal laboratories in 35 USC 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.10 at 635 n.12, 666 and 667 n.227. The amendment was not adopted.

[43] Arno and Davis, n.10 at 649.

[44] Id. at 662.

[45] 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.

[46] Arno and Davis, n.10 at 648-49.

[47] Arno and Davis, n.10 at 676, n.273.

[48] 35 USC 200.

funding.

We recognize that the Presidential Memoranda and 35 USC 203 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[49] 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 USC 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."[50] Furthermore, that would make any[51] patent license granted by a Government contractor or grantee subject to attack, which would discourage or inhibit the commercialization of Government-funded technology.[52] At one time, NIH had a reasonable pricing[53] requirement in its CRADAs by withdrew it in 1995 after participation in CRADAs by industry had dropped substantially.

Conclusion

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[49] A university generally is not permitted to assign its invention. See 35 USC 202(c)(7)(A).

[50] See testimony by Bernadine Healy, Director of NIH, on Feb. 24, 1993 that NIH is not equipped, either by its expertise or its legislative mandate, to analyze private sector product pricing decisions. See Arno and Davis, n.10 at 670, n.245, citing Daily Rep. for Executives (BNA), No. 9 (Feb. 25, 1993).

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

[52] This could be especially damaging for biotech inventions. See McCabe, n.8 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 Marquette Intellectual Property Law Review 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."

[53] Arno and Davis suggest that march-in rights apply to CRADAs although they are not funding agreements as defined by Bayh-Dole. See Arno & Davis, n.10 at 645. However, CRADAs have their own march-in rights provision in 15 USC 3710a(1)(B) and (C)) although it is more limited than 35 USC 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 B(i).

It is our opinion that there is no reasonable price requirement under 35 USC 203(1)(a)(1) considering the words of this section, the statutory 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.[54] 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 USC 203(1)(a)(2), the Government license in 35 USC 202(c)(4) and eminent domain in 28 USC 1498(a).[55] In addition, NIH asserted co-inventorship in AZT which contributed to reducing the cost for this important AIDS drug sold by Burroughs Welcome even though the claim of co-ownership was not sustained in court.[56]

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[54] See Alstadt, n.22 at 81.

[55] See McGarey and Levey, n.9 at 1116.

[56] See Lacey et al., "Technology Transfer Laws Governing Federally Funded Research and Development," 19 Pepp. L.R. 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).

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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.

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[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."

[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.

commercial use within a designated period.[16]

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."

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.

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

[17] The Memorandum 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), "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 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] 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

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.23 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, this 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.23 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."

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."

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.

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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.

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

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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.

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 discussion of the shift from the "practical application" language in the Presidential

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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.

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.[53] There was a recoupment provision in S. 414 as passed by the Senate passed but it did not become law.[54] 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, 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.[55] Finally, the authors accuse GAO as committing the "fatal error of confusing march-in rights with simple working requirements."[56] 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 promote the utilization of federally funded inventions and to minimize the costs of administering the technology transfer policies.[57] As pointed out by Justice Brennan, "a thing may be within the letter of the law but not within the purpose of the law."[58] 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

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53 S.Rep. 96-480, n.31, at 25-6.

54 Section 204 Return of Government Investment.

55 Arno and Davis, n.9 at 648-49.

56 Arno and Davis, n.9 at 676, n.273.

57 35 U.S.C. 200.

58 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).

59 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.")

objectives of Bayh-Dole is to "protect the public against nonuse or unreasonable[59] use." 35 U.S.C. 200. It does not say "unreasonable prices."[60]

We recognize that 35 U.S.C. 203 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 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."[61] Furthermore, that would make any[62] patent license granted by a Government contractor or grantee subject to attack, which

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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 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.

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

[61] 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.

[62] 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).

63 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

would discourage or inhibit the commercialization of Government-funded technology.[63] 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.[64] Around this time, NIH also had a reasonable pricing clause in all its CRADAs.[65] 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.[66]

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.[67] 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,

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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.").

64 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.

65 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.

66 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.

67 See Alstadt, n.20 at 81.

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).[68] 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.[69] 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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68 See McGarey and Levey, n.8 at 1113-15.

69 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.

NEXT

From: Carole and Norman Latker <Latkerc@bellatlantic.net>
To: <njl@browdyneimark.com>
Date: 4/21/04 11:29AM
Subject: [Fwd: RE: Latest round on Bayh-Dole]

-------- Original Message --------
Subject: RE: Latest round on Bayh-Dole
Date: Tue, 20 Apr 2004 16:02:15 -0400
From: "Adler, Reid" <Reid.Adler@venterscience.org>
To: <jallen@nttc.edu>, <armbrecht@iriinc.org>,
<alfred.berkeley@cos.com>, <Louis_Berneman@nttc.edu>,
<hwbremer@warf.org>, <RLD1@msn.com>, <kofaley@venable.com>,
<henry.fradkin@comcast.net>, <Larry_Gilbert@nttc.edu>,
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<rriddell@promaxrealtors.com>, <jas@purdue.edu>, <Larry_Udell@nttc.edu>,
<John_Weete@nttc.edu>, <Deborah_Wince-Smith@nttc.edu>,
<rich.wolf@caltech.edu>, <smsheehan@mail.wvu.edu>

As another historical footnote, I had the same discussion with Prof. Davis back in 1989-1990 when NIH was developing its technology transfer policies to implement the FTTA. At that time, Joe Allen, Deborah Wince-Smith and Lita Nelson were also in that loop. Health and energy permitting, we should probably look forward to having the same discussion in 2020!

Reid A.

From: jallen@nttc.edu [mailto:jallen@nttc.edu]
Sent: Tuesday, April 20, 2004 12:20 PM
To: Adler, Reid; armbrecht@iriinc.org; alfred.berkeley@cos.com;
Louis_Berneman@nttc.edu; hwbremer@warf.org; RLD1@msn.com;
kofaley@venable.com; henry.fradkin@comcast.net; Larry_Gilbert@nttc.edu;
randolph.j.guschl@usa.dupont.com; P_Harsche@fccc.edu; whendee@mcw.edu;
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Jay_Rappaport@nttc.edu; robinlr@umich.edu; niels@leland.stanford.edu; BAReres@venable.com; rriddell@promaxrealtors.com; jas@purdue.edu; Larry_Udell@nttc.edu; John_Weete@nttc.edu; Deborah_Wince-Smith@nttc.edu; rich.wolf@caltech.edu; smsheehan@mail.wvu.edu
Subject: Latest round on Bayh-Dole

Thought you might be interested in my recent e-mail exchange with Prof. Davis, co-author with Prof. Arno of a Washington Post op-ed piece in 2001 "Paying Twice for the Same Drug," alleging that NIH is remiss in enforcing Bayh-Dole with regard to march-in rights on resulting drug prices. This is the philosophical underpinning of the recent petition to NIH. I quoted Senators Bayh and Dole's subsequent rebuttal that Davis and Arno misinterpreted the law in my recent letter to NIH .

----- Forwarded by Joe Allen/NTTC on 04/20/2004 11:57 AM -----

Joe Allen/NTTC

04/20/2004 11:54 AM

To

"Michael H. Davis" <michael.davis@law.csuohio.edu>

cc

Subject

Re: [Fwd: [Ip-health] Nat'l Tech Transfer Ctr on March-in]Link <Notes://852565E10051B0C4/DABA975B9FB113EB852564B5001283EA/BAAF80607A44A4F785256E7B005E74C3>

Thanks for your e-mail. When the Bayh-Dole Act states 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," as Senators Bayh and Dole wrote in reply to your article in the Washington Post several years ago, it was not their intent that this phrase would include the ability of the Government to oversee prices of resulting products.

While drug pricing is a serious issue, attempting to read into the law an intent missing in the words of the statute and the accompanying legislative history, would be a mistake.

"Michael H. Davis" <michael.davis@law.csuohio.edu>

04/19/2004 01:11 PM

To

jallen@nttc.edu

cc

Subject

[Fwd: [Ip-health] Nat'l Tech Transfer Ctr on March-in]

Dear Mr. Allen:

I found your statement puzzlilng. Can you tell me whether or not the Bayh-Dole Act does mandate that Bayh-Dole inventions must be offered to the public "on reasonable terms?"

M. Davis

-------- Original Message --------

Subject:

[Ip-health] Nat'l Tech Transfer Ctr on March-in

Date:

Mon, 19 Apr 2004 12:27:39 -0400

From:

Sean Flynn <sean.flynn@cptech.org> <mailto:sean.flynn@cptech.org>

Organization:

http://www.cptech.org <http://www.cptech.org/>

To:

ip-health@lists.essential.org <mailto:ip-health@lists.essential.org>

March 31, 2004

Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852

Dear Dr. Rohrbaugh:

I recently became aware of a petition addressed to you by Mr. James Love, President of Essential Inventions, Inc. requesting that the National Institutes of Health exercise the march-in rights provision of the Bayh-Dole Act to lower the price of several drugs developed from NIH extramural research.

While the subject of delivering affordable health care is certainly a serious issue, the provisions of the Bayh-Dole Act do not provide for governmental actions such as those requested by Essential Inventions. Indeed, such actions were never contemplated by the Congress and are not reflected in the legislative history of the law.

The interpretation of the intent of Congress in passing this landmark legislation reflected in Mr. Love's petition is, therefore, entirely fanciful.

While serving former Senator Birch Bayh on the Senate Judiciary Committee, I staffed the hearings and wrote the report of the Senate Judiciary Committee on the bill. I also served for many years as the Director of Technology Commercialization at the U.S. Department of Commerce. There I oversaw the implementation of the regulations for Bayh-Dole and chaired the Interagency Committee on Technology Transfer which developed guidelines for utilizing the Federal Technology Transfer Act, under whose authorities NIH develops many of its intramural partnerships with U.S. industry.

Regrettably, Mr. Love and several others making the same case mix up the legislative history of the Bayh-Dole Act with hearings on rival legislation that was not enacted. The only legislative history with any bearing on the law are the hearings of the U.S. Senate Judiciary Committee in the 96th Congress on S. 414, the University and Small Business Patent Procedures Act (commonly called Bayh-Dole), the report

of the Senate Judiciary Committee on the same, and the Senate debates on S. 414.

Fortunately, we do have an unambiguous opinion from Senators Birch Bayh and Robert Dole themselves on the topic at hand. The Washington Post ran an article by Professors Peter Arno and Michael Davis on March 27, 2002, Paying Twice for the Same Drugs, making the same arguments as Mr. Love. They wrote:

Bayh-Dole is a provision of U.S. patent law that states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price. If it is not, then the government can insist that the drug be licensed to more reasonable manufacturers, and, if refused, license it to third parties that will make the drug available at a reasonable cost.

A joint letter by Senators Bayh and Dole on April 11, 2002, to The Washington Post effectively refutes this argument. Here is the complete text of what the authors of the law said was their intent with regard to fair pricing of resulting products:

As co-authors of the Bayh-Dole Act of 1980, we must comment on the March 27 op-ed article by Peter Arno and Michael Davis about this law.

Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector. The purpose of our act was to spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner.

For every $1 spent in government research on a project, at least $10 of industry development will be needed to bring a product to market. Moreover, the rare government-funded inventions that become products are typically five to seven years away from being commercial products when private industry gets involved. This is because almost all universities and government labs are conducting early-stage research.

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. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.

The article also mischaracterized the rights retained by government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a 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. (Emphasis added).

The law we passed is about encouraging a partnership that spurs advances

to help Americans. We are proud to say it's working.

Birch Bayh/Bob Dole

In their typically succinct manner, the authors of the law effectively rebut the argument now before you.

The Bayh-Dole Act has become a linchpin of our economy. While not perfect, the U.S. record of commercializing new products and services funded by the Government is the envy of the world. The Economist Technology Quarterly said: "Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980." Any legislative or administrative actions undertaken to alter this Act must be done very carefully.

We have already witnessed well-intended Congressional attempts to impose fair pricing clauses on NIH intramural research partnerships. These efforts failed. Technology transfer cannot be a vehicle for trying to control prices. Rather than allowing Government to dictate drug prices, companies simply walked away from partnering with NIH. Wisely recognizing its mistake, Congress rescinded the fair pricing requirement. NIH's subsequent success in building effective partnerships with industry is well documented, and is a great benefit to the public.

President Johnson asked in 1968 how many NIH owned inventions had been commercialized. The answer was none. At that time there were no incentives for industry to undertake the risk and expense inherent in developing such early stage inventions. We should reflect that because of the Bayh-Dole Act, many life saving drugs and therapies are now available for those in need. By altering this delicately balanced law, we may well discover that publicly funded inventions go back to gathering dust on the shelves. Before Bayh-Dole such discoveries were not available at any price.

Sincerely,

Joseph P. Allen
President
National Technology Transfer Center

Ip-health mailing list
Ip-health@lists.essential.org <mailto:Ip-health@lists.essential.org>
http://lists.essential.org/mailman/listinfo/ip-health

Dad

CC: "Carole and Norman Latker" <Latkerc@bellatlantic.net>

THE WASHINGTON POST

THE FEDERAL PAGE

House Panel Scolds NIH Chief, HHS

Members Threaten To Pursue New Ethics Legislation

By RICK WEISS
Washington Post Staff Writer

Angered by recent revelations that some high-level scientists at the National Institutes of Health are enjoying lucrative consulting arrangements with drug and biotech companies—and unsatisfied with a blue-ribbon panel's recommendations for rectifying the problem—members of a House subcommittee yesterday told NIH Director Elias A. Zerhouni they were losing patience with him and his superiors at the Department of Health and Human Services.

The lawmakers warned they might take action if more comprehensive reforms are not instituted soon.

"It is clear from the cases we have reviewed that some NIH scientists are either very close to the line or have crossed the line" of ethical conduct, Rep. James C. Greenwood (R-Pa.), chairman of the Energy and Commerce subcommittee on oversight and investigations, said at a hearing unusual for its level of open hostility toward some of the government's most prestigious—and best-paid—scientists. "If we are serious about upholding the highest ethical standards at the NIH, then NIH scientists should not even be close to the line."

Greenwood was especially critical of the legal staff at HHS, whose "delays and obstinacy," he said, had slowed the subcommittee's efforts to determine whether NIH scientists are engaged in outside activities that might conflict with their government responsibilities. He and others noted with evident frustration that HHS declined to have the department's general counsel testify at a follow-up hearing scheduled for Tuesday.

"This investigation has been slow-rolled and stonewalled," Rep. John D. Dingell (D-Mich.) fumed in a statement. Dingell led perhaps the most memorable standoff between Congress and the scientific establishment in the late 1980s—a fiery investigation into allegations of scientific misconduct that focused on Nobel laureate David Baltimore, who is now president of the California Institute of Technology.

Yesterday's hearing had Zerhouni and the two co-chairs of his blue-ribbon panel facing four hours of often withering criticism from both Republicans and Democrats. Even some lawmakers not on the subcommittee showed up for the fray, including Health Committee Chairman Michael Bilirakis (R-Fla.) and Energy and Commerce Committee Chairman Joe Barton (R-Tex.).

"We have found NIH to be less than cooperative, and that's going to change," Barton said. "They can cooperate cooperatively, or we will make them cooperate coercively."

At issue are long-standing policies, some of them government-wide and others specific to NIH, that allow scientists—with agency approval but in some cases without public disclosure—to earn outside income from drug, biotech and other companies.

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He defended the blue-ribbon panel's recommendations, which include forbidding certain kinds of remuneration (such as company stock, which can make scientists more beholden to a company's long-term interests) and limiting the amount of outside income and the number of hours spent on outside work.

"We should be more transparent, more vigilant about oversight, and we need to tighten the rules," Zerhouni testified. "But it would be a mistake to ban all compensated activities with outside organizations. Such an action would be bad for science, unfair to employees, and ultimately hinder our efforts to improve the nation's health."

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Greenwood outlined the many ways in which members of Congress in recent decades have limited their own access to outside income and gifts. "If this kind of reform was good enough for Congress, why isn't it good enough for the National Institutes of Health?" he asked.

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Over all, pharmaceutical and health companies contributed nearly $30 million to political campaigns in the 2002 election cycle, the group reports.

Researcher Lucy Shackelford contributed to this report.



Director Elias A. Zerhouni defended recommendations from a panel on ethics reforms for NIH personnel.



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TELEFAX CONTROL SHEET

SENT TO: Joe Allen

DATE SENT: 5/13/04

SUBJECT: B-D

No. of pages (including this cover sheet):

FROM: Norm Latker

Remarks:

More bad news. The L.A. Times already identified the consulting problem as being created by Bayh-Dole, it's not even a FITA problem.

CONFIDENTIALITY NOTE

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THE WASHINGTON POST
5/13/04

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Members Threaten To Pursue New Ethics Legislation

By RICK WEISS
Washington Post Staff Writer

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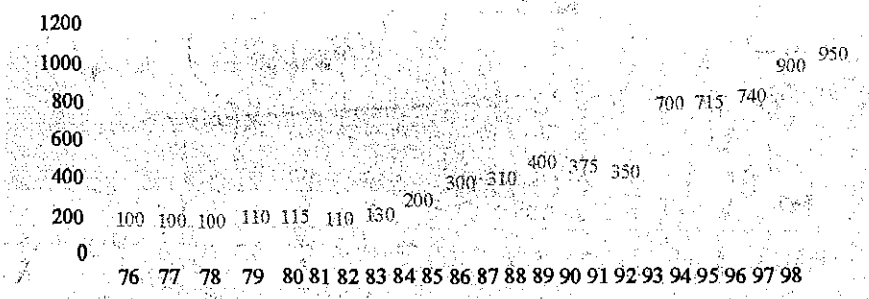

ered to have been almost directly spawned because of or as the result of the Bayh-Dole Act is the Federal Technology Transfer Act of 1986 (FTTA). That act was introduced as an amendment to the Stevenson-Wydler Act of 1980 which had been intended to promote the utilization of technology generated in government laboratories, but was singularly unsuccessful in accomplishing that goal.

The FTTA was largely a response to the increasingly tough international competition facing the United States and the prevalent complaint that "the US wins Nobel Prizes while other countries walk off with the market." The designers of the FTTA built the act under certain fundamental principles:

> The federal government will continue to underwrite the cost of much important basic research in scientifically promising areas that takes place in the United States.
>
> Transferring this research from the laboratory to the marketplace is primarily the job of the private sector, with which the federal government should not compete.
>
> The federal government can encourage the private sector to undertake this by judicious reliance on market-oriented incentives and protection of proprietary interests.

The principles enumerated were first tested through experience with the Bayh-Dole Act and the FTTA responded to the lessons learned from that law, perhaps the most important of which was its success in promoting university-industry cooperation.

The FTTA is, clearly, a direct highly beneficial legacy of the Bayh-Dole Act, as has been additional legislation designed to expand the use of the results of research carried out within government-owned government operated laboratories by expanding the licensing opportunities for those laboratories.

Commentary

The growth of technology transfer has taken place over the last 30 years in an environment that slowly progressed from hostile to favorable. That progression was given major impetus by the passage of the Bayh-Dole Act. During that period we have seen a dramatic change in the attitude of the Justice Department and the interpretation of the anti-trust laws where patents and anti-trust are no longer viewed as antithetical. We have seen a move toward a favorable statutory basis under which we have much greater freedom to operate. We have had an active effort by various administrations to obtain equitable treatment for U.S. citizens in foreign venues, both in trade and intellectual property pursuits. We have had numerous and far-reaching changes in the patent laws of those foreign venues for example the Patent Cooperation Treaty which provided greater opportunities for technology transfer to

NEXT

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BURTON'S RARE COINS

Religion commentary

Additional Titles

RE-INVENTING MORALS

By Graham Strachan
October 10, 2002
NewsWithViews.com

One of the Big Lies of modern times concerns the notion that morals are a 'social construct' largely traceable to the Christian religion, and in particular the Ten Commandments. For readers who've forgotten, and those who never knew, the Ten Commandments say it is wrong to murder, steal, lie, falsify corporate accounts, and have sex with interns in the White House when your wife's not around. Little wonder then, that the globalist Left and Right are both working hard to have the Commandments 'disappeared', along with the morals they supposedly gave rise to.

But according to Biblical legend, the Ten Commandments date from the time of the exodus of the Jews from Egypt, thought to be around 1500 BC. If morals indeed date from

that time, what went before? - bearing in mind that human civilisation dates from the Neolithic Revolution around 8000 BC. That's a long time for the world to be operating in a moral vacuum, and in fact it didn't. The law code of Lipit-Ishtar, which dates from ancient Sumerian times - perhaps 4000 BC - has an unmistakeable moral foundation. Morals long predated Moses and the burning bush. The Ten Commandments merely codified moral rules which had, even then, existed from time immemorial.

Let's be clear on what morals are: morals are rules of conduct in a social context, in their most visible form consisting of bans on certain specific types of behaviour. Contrary to popular belief, they are not confined to matters of sex, in fact sex is the least of their concerns. Their chief concern is to outlaw murder, rape, assault, lying and the failure to honour promises, behaviours which tend to make social living impossible. They are strictly a human thing: there are no morals in the wild. In fact morals ARE the defining difference between the wild state - in which the strong are free to kill and dominate the weak - and civilisation, in which the weak have as much right to exist as the strong. Morals define civilisation. Buildings, parliaments, law courts, universities and other institutions of societal governance do not make a 'civilisation' unless the people in them are acting morally. If they cease to act morally, 'civilisation' becomes simply a jungle with buildings.

If morals antidated the Ten Commandments,

where did they come from, and who or what initially decided what was, and what was not, moral behaviour? The claim by the globalist Left that morals are a social 'construct' suggests they were consciously thought up by human agency somewhere back in time and deliberately imposed. The authority of God may have been added later, they will say, but that's how morals began. The implication is that if one 'social construct' works, another 'social construct' can readliy be substituted for it which will work equally as well if not better.

However, as Professor Frederick Hayek explained at length in his 'Law, Legislation and Liberty', the idea that humans deliberately constructed their own society, together with its rules of moral/social behaviour, contradicts everything known about the origins of civilisation. Anthropology has shown that human societies evolved, the social behaviour patterns later called 'morals' evolving along with them. Societies that adopted cooperative moral/social behaviour gained a distinct evolutionary advantage over those that did not, and prospered while the others disintegrated and disappeared. We are here today because our distant ancestors happened to act morally.

The belief that human society is, or even could be, the product of deliberate human design, and that morals were consciously thought up and legislated, is an important ingredient in the ideology of the socialist Left, who want to replace existing morality with another mortality constructed by themselves.

But as Hayek pointed out, it has never yet been demonstrated that one can simply do away with the moral rules that built a civilisation and replace them with another set concocted in a 'think tank', at least not without risking social disintegration and collapse.

The evolutionary origin of morals presents other problems for the social engineers of the globalist Left. First of all, if moral rules evolved by natural selection, the resultant rules are likely to be those best suited to the human condition; improving on them would be difficult if not impossible. Secondly, since the most successful societies would have been those whose members had a natural propensity for moral/social behaviour, the tendency to act morally may well be encoded in the genes of the most civilised peoples, contradicting the notion that morals are 'nothing but' a social construct.

Thirdly, if the rules that evolved naturally were the same rules ultimately codified in the Ten Commandments – as a comparison between the Bible and the Codes of Lipit-Ishtar and Hammurabi suggests - then the scientific and religious explanations for the origin of morals are reconciled. People would have a powerful incentive to re-affirm existing morality, and to reject the 'new' morality being offered by the global socialists. One could no longer, for example, undermine the basis of traditional morality simply by declaring – as Nietzsche did – that God is dead.

Whether one accepts the religious or evolutionary explanation, there is a good reason to act morally. As Ayn Rand argued [The Voice of Reason (1988) p.17], man's ultimate survival 'qua man' - as a rational being in a civilised order - depends on it. It boils down to a question of whether one values civilisation or not. If the answer is 'yes', then adherence to the morality of civilisation is essential – and by that is meant the morality that evolved with civilisation and made civilisation possible: the time-tested variety, not the yet-to-be-proven variety being promoted by the globalist Left/Right.

The results of the new 'socially constructed' morality are already in evidence. As the world enters the 21st century it is witnessing a reversion to a jungle 'morality' in the centres of power - survival of the politically and economically fittest. Whoever can get control of the machinery of government and hold onto it by fair means or foul not only rules, but supposedly has a 'right' to rule. The 'moral' superiority of brute force and animal cunning is being exalted over reason and common decency. The result is a complex technological society controlled politically and economically by people with a 'morality' more suited to beasts than man, a frightening mix of sophisticated technology and primitive barbarism. It is time for all good people worldwide to demand a return to time-tested morality.

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Home

Greg Ransom The Hayek Center for MultiDisciplinary Research gransomemail -at- cox.net

Who is Hayek?

Two Things About Hayek

Provided on this page are two things to know about Hayek.

1. **Lead role in the global revival of liberalism***

If you were to know only a single thing about Hayek, you might start with this Hayek is regarded as a key figure in the 20th century revival of liberalism. Th has led some folks to suggest that the works of Hayek are playing a role in our something like the role the works of Adam Smith and John Locke played in the own -- meaning that Hayek's ideas are at the forefront of the movement toward society based on freedom of association and exchange according to the rule of and away from the control of society from the center according to the whim of government. So the first thing to know about Hayek is that he has played a lea role in the current tide change away from statism and back to liberalism* -- regarded by many as a defining event of the 20th century.

2. **Co-originator of the Hayek-Hebb synaptic model**

A second thing to know? Like Locke, Hume, Kant and other great liberals of t early modern period, Hayek's transformed understanding of society is grounde a transformed understanding of the cognitive process and the basis of human learning. At the root of this transformation is a rejection of the 'myth of the giv which provides the starting point of both rationalist and empiricist theories of knowledge and human cognitive function. Hayek replaced the static 'givens' o classic foundationalism with an adaptive neurological account of human learni memory and categorization built upon simple facts about neurons and their interconnections. From these simple beginnings Hayek co-originated the Hayek Hebb synaptic connection model of mind, a construction which has transforme modern thinking about the mind and brain. The thing to remember? Hayek's v

in theoretical psychology represents a landmark in 20th century thinking about human learning and cognition, and challenges the central dogma of traditional foundational models of human knowing.

Book of the Year:

Hayek's Challenge:

The Intellectual Biography of F. A. Hayek
by Bruce Caldwell

Buy it at 30% discount from Barnes & Noble.

hayekcenter.org

Hayek by Decade

1890's	1900's	1910's	1920's	1930's	1940's
1950's	1960's	1970's	1980's	1990's	

*Americans bewildered by the way English speakers everywhere (other than l natives with little depth in their liberal arts education) use the English langua with regard to the term "liberal" might consult Gene Callahan's article on th historical use (and misuse) of the word "liberalism" or Ronal Reagan's explica of the twists political language has undergone in America, in his *Reason* maga interview "Inside Ronald Reagan". See also the *Stanford Encyclopedia of Philosophy* entry on "liberalism" and Ludwig Mises' book *Liberalism*. Anotl good source on the word "liberalism" and its meaning is an article by Amy Stu

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Interview with David Horowitz *by Nic*

David Horowitz, founder of Students for Academic Freedom and author of the Academic Bill of Rights, spoke at Tufts University on April 1st. Horowitz is a communist-turned conservative who had been a leader in the movement against academic bias.



David

Primary Source: Left-wing activism by students, professors, and administrators seems to be more prevalent than ever. At the same time, movements like Students for Academic Freedom seem to be attracting a huge interest and polls indicate Republicans are doing very well on college campuses in terms of both recruitment and involvement. Given these two seemingly conflicting trends, how would you rate the academic climate of today when it comes to intellectual diversity?

David Horowitz: Students for Academic Freedom is non-partisan. The intention is to restore educational values and fairness to institutions of higher learning. The fact of conservative and Republican students are second-class citizens a campuses, including Tufts. Part of the activism of conservative s due to their oppression by Left-wing faculty. The fact that a lot o conservative and can resist indoctrination doesn't make it okay f an educational institution like Tufts. Professors who attempt to t depriving both liberal and conservative students of the education You can't get a good education if they're only telling you half th paying $40,000 per year.

PS: What were your college years at Columbia like?

DH: Part of the reason I started this campaign was because of th at Columbia, even though it was in the McCarthy '50s. I, of cour In retrospect, I have come to appreciate the fact that my professo communist liberals, treated me with respect and did not use the c soapbox. Thus, I didn't even know what their politics were until books that they had written.

PS: Taking into consideration the importance of ideological dive you consider among the best in the United States today? How ha

NEXT

File

Nelson

STATEMENT

BY

DR. WILLARD MARCY

VICE PRESIDENT-INVENTION ADMINISTRATION PROGRAM

RESEARCH CORPORATION
405 LEXINGTON AVENUE
NEW YORK, N.Y. 10017

BEFORE

SUBCOMMITTEE ON MONOPOLY AND ANTICOMPETITIVE ACTIVITIES

SENATE SELECT COMMITTEE ON SMALL BUSINESS

JUNE 20, 1978

Mr. Chairman and Members of the Committee:

My name is Willard Marcy, I am Vice President-Invention Administration Program of Research Corporation. Research Corporation is a not-for-profit organization chartered by the State of New York. It is a private foundation which was created in 1912 by Frederick Gardner Cottrell, dedicated to the support of science and technology. Cottrell donated his own patent rights for industrial gas cleaning as the original endowment, thus setting in motion a cycle that would be endlessly repeated, using inventions which result from research as a source of funds for more research. This concept has evolved to the point where Research Corporation now has invention administration agreements with many universities and other nonprofit institutions, and devotes all of its income after expenses to support further research in college and university laboratories. In grants alone it has contributed over $60 million to scientific and educational institutions; in royalties shared with institutons it has distributed another $11 million. These two functions are carried out by two separate groups within the foundation, the Invention Administration Program and the Grants Program.

Research Corporation's share of any royalties received is used for its chartered purposes: administration of inventions for public benefit, and grants in support of research and

experimentation in the sciences and technology. Except for the President, who is a full-time employee of the foundation, members of its distinguished Board of Directors are uncompensated. No bonuses, commissions or other similar payments are made to officers or employees.

Research Corporation specifically waives any right of ownership in any patent or other rights which might result from research supported by any of its grants.

I am pleased to have the opportunity to bring to your attention the experience of Research Corporation with Institutional Patent Agreements (IPAs) and to provide you with insight on how Research Corporation has been able to work within the IPA requirements in evaluating, patenting and licensing inventions resulting from Federally-funded research at universities and colleges.

In general, the IPAs provide a constructive and worthwhile procedure enabling the speedy, effective and efficient transfer of university inventions from the concept stage to the marketplace for the public benefit. The number of such inventions is very limited, as it is the rare discovery that can clear the intervening thickets and barriers on the very rocky road to its successful marketing.

Research Corporation has been able to serve well the universities to which it contributes its assistance under the requirements of both HEW and NSF IPAs, as well as with respect to other inventions. The results of the past 10 years of experience under the IPAs are just now beginning to come in, but a number of inventions handled in this manner are now being licensed under arrangements for making them available to the public. The inventions processed by Research Corporation since the IPA requirements were published and put into use in 1968, together with other pertinent data, are included in Tables I - IV as an appendix to this statement. I will be glad to furnish additional information on any one or more of these, if desired.

I should like to turn now to the specific areas of interest noted in the invitation to present testimony at this hearing.

The first area involves universities and nonprofit organizations holding IPAs and the arrangements between these organizations and patent management organizations. For Research Corporation these are straightforward and fairly standard contractual agreements, although the terms may vary slightly from one to the other. Other witnesses may be able to give details concerning the arrangements with other patent management organizations; I will confine my remarks to those to which Research Corporation is a party.

Research Corporation's formal arrangements with educational and other nonprofit institutions date back to the 1930s when the first such agreement was made with the Massachusetts Institute of Techology. While Dr. Jones' testimony at the May 22 hearing of this Committee is correct in stating that MIT no longer uses an outside patent management organization, that institution did use Research Corporation exclusively from 1938 until 1963. A number of the inventions that are now producing income for MIT were evaluated, patented, and in some instances initially licensed by Research Corporation. Vitamin A and the computer memory core were among those mentioned by Dr. Jones; semi-synthetic penicillin, and peroxides syntheses are also in this category.

Princeton University was the second institution to develop an arrangement with Research Corporation, and this agreement is still in effect today.

Over the years Research Corporation's contributed invention administration services have gradually been in greater demand until today there are 274 agreements in effect with universities and other nonprofit institutions, primarily in the United States, with a few in Canada and other countries. Research Corporation also handles inventions on a case by case basis for other universities.

Research Corporation's agreements are "open-ended" in permitting the institutions to request Research Corporation's services or those of other persons or organizations, or to develop the inventions on their own. The institution, entirely within its discretion, forwards such invention disclosures as it chooses to Research Corporation for evaluation and possible patenting at no cost to the institution. Likewise, Research Corporation is under no obligation to accept for patenting and licensing any invention disclosure it evaluates on behalf of an institution.

However, if Research Corporation does offer to accept an invention for patenting and licensing and the institution agrees to this course of action, the invention rights, including patent rights, are assigned to Research Corporation with a provision for sharing of any resulting royalties among the institution, the inventor and Research Corporation.

Research Corporation is then obligated to provide further services, as defined in the agreement, relating to patenting, licensing, administration of licenses, and distribution of any royalties. Research Corporation must report on its activities to the institution and make the required royalty distribution annually. The institution has the right to audit Research Corporation's books and examine its files as they relate to activities under the agreement with the institution.

Research Corporation assumes all costs, except certain special expenses, such as those relating to litigation to assert or defend the validity of the patent (as in infringement proceedings). If, after discussion, the institution concurs, these special expenses are divided between the institution and Research Corporation. If the institution does not agree to share these expenses, Research Corporation has the right to proceed at its sole expense. In any event, except for this special situation, which occurs rarely, any income received is shared with the inventor(s) and the institution.

In general there are two standard agreements with Research Corporation, copies of which are appended herewith. That identified as Form I, provides that Research Corporation distribute directly to the inventor(s) their share of the gross royalties received, generally 15%, with the institution and Research Corporation sharing equally the remaining 85%, i.e., 42.5% of gross royalty receipts each. In the agreement identified as Form II, Research Corporation distributes to the institution a 57.5% share of the gross royalties received, and retains 42.5%. Under this arrangement, the university may share its income with the inventor(s) in accordance with its own patent policy, but Research Corporation has no control over any such distribution.

Variations on the sharing arrangement exist. The most frequent variation provides for the HEW formula to be used in determining the inventor(s) shares; that is, the inventor(s) receive 50% of the first $3,000 of cumulative gross royalties, 25% of the next $10,000 and 15% of all over $13,000. In practically all cases under this situation, the university's share is proportionately less, while Research Corporation's share remains the same. Other variations of the sharing formula are minor and rare.

Research Corporation's share of royalties is used for making grants for support of scientific research in colleges and universities, and for the operating programs of the foundation.

In cases where a university or nonprofit organization has arrangements with other patent management organizations, as well as Research Coporation, the decision as to which such organization to use is entirely within the institution's discretion. The Research Corporation agreement does not require that the institution give the right of first refusal to Research Corporation. We understand that in some instances an institution will send an invention disclosure to one patent management organization, and then, if the invention is turned down, to a second one. We also know of cases where two organizations have been asked to perform an evaluation simultaneously, but this is rare.

I shall turn now to the second matter on which Research Corporation is requested to testify -- that concerning the royalty sharing arrangements in the agreement between Research Corporation and the University of Rochester. That agreement, an early version of the Form I type discussed earlier, and unlike later versions, specified that Research Corporation may unilaterally deduct certain special expenses before distribution of royalties -- a right, however, that it does not exercise. However, these royalty distribution arrangements for the inventor(s)' and institution's shares, reflect the institution's patent policy, not Research Corporation's. Research Corporation controls only the 42.5% of the gross royalties which it retains. If the institution's policy is to pay more than 15% of gross royalties to its inventors, Research Corporation does not object -- but, again this is a decision of the univeristy, not Research Corporation.

It may be of interest to the Committee to recount how the "standard" 15% was arrived at. In the original agreement between Research Corporation and MIT, mentioned earlier, MIT determined the inventor(s)' share was to total 2-1/2% of the gross royalties. Due to strong protests from some inventors, this was raised in several steps over the years to 15%. Since this seemed generally acceptable, Research Corporation concluded that this level would be suggested for future agreements. This formula for sharing has been almost universally adopted by educational and

other nonprofit institutions as being fair and equitable to all parties.

As an additional incentive, it has been suggested by some inventors that they should have a higher share of first royalty income received, with their share being reduced as royalties increase, reaching a steady state at some specified level of total royalty income. This line of reasoning is exemplified by the downward-sliding scale provided in the HEW IPAs.

The inventor royalty sharing arrangement within the university community, although set individually by each university, is remarkably standard and is further standardized by IPAs. In industry, on the other hand, company-employed inventors share infrequently in any royalty income or profit derived from inventions they make. Government employee inventors receive nothing above their salaries for any inventions they make within the scope of their employment, although there have been discussions recently within some agencies about the possibility of changing this situation.

Just why these different arrangements have evolved may be of interest to this Committee, and I would be pleased to discuss this, if time were available. Some of the philosophy and history behind these divergent attitudes is given in two papers I have written and which are appended to my formal remarks. The first

of these papers was delivered at a symposium on patent rewards for inventors held at a meeting of the American Institute of Chemical Engineers in 1971. The other, discussing the terms of an ideal university patent policy, was delivered in March 1978 at a symposium on patent policy held at a national meeting of the American Chemical Society.

Let me turn now to the third matter stated in the letter of invitation to testify. This involves the terms of agreements Research Corporation has with industrial firms for screening new chemical entities developed at universities for therapeutic, pesticidal, herbicidal or similar activity. These agreements reflect a new service being provided by Research Corporation to expedite the identification of materials useful for protecting the health and contributing to the welfare of the public. The rationale behind such agreements is that university chemists, including pharmaceutical chemists and biochemists, are expert in synthesizing new chemical compounds, but do not have available to them the necessary facilities for testing these materials for biological activity. This is true regardless of whether the support is Federal, institutional or private. Industry, on the other hand, while having excellent testing facilities, does not have easy access to the many compounds being synthesized in university laboratories. Research Corporation's role is conceived as one of facilitating communications between the two groups, each of which has what the other wants and needs.

The screening agreements set forth in formal fashion the protection of the rights and a stipulation of the obligations of the parties in interest. A crucial right that needs protection in this situation is the patent right. Obtaining patent rights is made more complex by the Patent Office requirement that a utility for new compounds must be disclosed in any patent application filed to protect the materials themselves and their method of manufacture (if this is also new). In addition, it is important to disclose and claim any significant uses of such materials at the time of filing a patent application in order to obtain and retain rights to such uses.

Basically, the screening agreement provides a mechanism by which Research Corporation agrees to offer samples of products, compounds or substances to a particular company for screening within the stated field of the agreement, which may be medical, agricultural chemical or some other specified field. The company has the option of accepting or rejecting any such sample for screening within a stated period of time; if it accepts the sample, the company must submit it to screening promptly.

The company further agrees to report the results of screening promptly to Research Corporation so that it will be in a position to evaluate the results and take appropriate steps to obtain patent protection where such appears to be justified.

In return for the screening work, which is carried out at the sole cost of the company, it receives an option to a license under reasonable terms and conditions, the details of which are to be negotiated between Research Corporation and the company. The specific terms of the option may vary, with some industrial concerns preferring that the option be prescribed in detail in the screening agreement, while others prefer to leave this to be resolved at the time they indicate an interest in the products that they have screened. Any license that Research Corporation may grant is administered under the invention administration patent agreement with the participating institution in conformance with any pertinent Federal agency regulations.

In order to implement its industrial screening agreements, Research Corporation has also entered into screening agreements with several institutions with which it has invention administration agreements. These institutional screening agreements supplement the invention administration agreements by providing for the submission of samples to the industrial screener by faculty members or others associated with the institution. The inventors and the institutions agree to assign the patent rights to Research Corporation for administration under the invention administration agreement in the event that the results of the screening lead Research Corporation to seek patent protection on the inventions relating to the sample. This affords Research

Corporation the right to grant an option to the company in return for the screening work.

To date, Research Corporation has entered into screening agreements with 12 universities and two pharmaceutical companies: American Cyanamid Company, Lederle Laboratories Division, having a principal office in Pearl River, New York, and Sandoz, Ltd. with a principal office in Basle, Switzerland. Since the program is relatively new, it is too early to tell whether such activities will prove to be productive over a long period of time.

I should like now to comment briefly on some of the questions posed in the Chairman's opening remarks made at the May 22 hearings of this committee.

In order to make rational judgments on whether one Government patent policy, or another, is to prevail, it is extremely important to have an understanding of what it is that individual contracts or grants require the contractor or grantee to perform. We frequently see public statements that $X billion of Federal funds has or will be spent for research and development in colleges and universities. (In the FY 1979 Federal budget X = $3.6 billion, and most of this is supplied by NSF and HEW).

To estimate the number of patentable inventions which might result from Federal funds granted to colleges and universities requires a knowledge of the purpose for which the money is being spent. A large percentage of HEW funding is going into bricks, mortar and equipment to build or refurbish hospitals and medical centers connected with universities. None of this expenditure can be expected to result in inventions. Another significant percentage from both the Department of HEW and NSF is for educational fellowships, some of which are in the social sciences; inventions cannot be expected to result from this funding. Finally, a large percentage is commited to "big science" or "high technology" endeavors such as the fusion laboratory at Princeton, and at the National Center for Atmosphere Research and the Jet Propulsion Laboratory at the California Institute of Technology. Very few patentable inventions for civilian use will arise from this funding, as experience has shown.

What remains is roughly $2 billion available for university research which could reasonably lead to inventive concepts. Using a rough rule of thumb, based on our experience, about one invention disclosure should result from each million dollars spent for research. Thus, approximately 2000 invention disclosures might be expected annually from the expenditure of $2 billion. Research Corporation's experience, confirmed by that of others, has shown that only about one out of ten disclosures

results in patented inventions, and, therefore, only about 200 inventions annually would be subject to HEW and NSF patent regulations and IPAs. Of these, only about one-quarter to one-third are likely to be attractive commercially. And, of those making it to the marketplace, only one in ten may prove to be so widely useful as to command multimillion dollar sales annually. Thus, when one speaks of a Government funding level of, say, $3.5 billion dollars per year for research at universities and colleges, one can expect, at best, somewhere between 50 and 67 inventions which may get to the market, and but perhaps five to seven may reach multimillion dollar annual sales.

What this means is that only a very few university and college inventors would ever receive significant royalty income. It also means that only the rare invention, indeed, will result in even moderate sums for the support of further research at the institution, or to support the programs of Research Corporation or other nonprofit patent management organizations. A thorough review of past experience will bear out this proximate analysis.

With this analysis in mind and reflecting on the words in Article I, Section 8, providing for protection of intellectual property in our nation's Constitution ...."To promote the progress of science and the useful arts ...," I feel the various branches of our Government should encourage research and provide all possible means for bringing the fruits of Government-supported research

into broad use for public benefit. This is best done within the patent system which provides incentives and rewards for the scientists whose inventions provide such benefits. It should also be recognized that the entrepreneurial effort in licensing and developing inventive concepts to the manufacturing stage is essential if the public is to benefit. In my opinion, the use of IPAs for colleges and universities is a much needed step in that direction. Extension of the IPA approach to other granting agencies can only be constructive.

Before concluding my statement I should like to remark on the use of the word "monopoly" in conjunction with patent rights. Patents, per se, are not monopolistic. Patents are public documents conveying full disclosure of inventions and are publications in every sense of the word. Patents convey only the right to exclude others for a limited time from making, using and selling products or processes unless a license is obtained from the patent owner to practice the patent rights. Patent owners can and often do license others under their patents, thus setting up competitive situations. Patents encourage entrepreneurs to bring new products and processes to the public, and they may stimulate others to "invent around" the patent claims; this is especially true of patents covering widely accepted, profitable products. This stimulates and encourages research on competitive products. In accordance with the spirit as well as letter of the constitutional mandate, the possibility of a patent grant is a

stimulus to invention and its public disclosure, and yet its limited lifetime precludes undue or unwarranted reward. In addition to the safeguards inherent in the patents themselves, rights granted by patents have been subject to substantial control by the courts throught the 188 years the patent system has been in existence.

It is important to note that under present regulations the Government does not pay royalties on patents covering inventions conceived or developed in whole or in part with Federal financial support, regardless of the ownership of the patent rights.

In negotiating licenses where exclusivity is required in order to bring a product to market, Research Corporation determines the time limitation through mutual agreement with the licensee in each situation based on estimates of how long it will take to get products on the market, recoup the initial investment and make a reasonable return on the investment. While the length of exclusivity varies from case to case, a reasonable exclusivity period in the case of pharmaceuticals, pesticides and like materials is five years from date of first marketing. This is the time limit stated in the proposed Government-wide IPA. These marketable products often stem from HEW and NSF supported research, and since this standard is reasonable, I would support it.

Now, I would like to cover briefly a matter relating to Research Corporation which was addressed by Mr. Herz, General Counsel for NSF, at the May 22 hearing before this Committee. I have reference to the work done on a three-year grant to Research Corporation supported by both the NSF and the Experimental Technology Incentives Program of the National Bureau of Standards. This grant was to cover an experimental approach directed toward enhancing the patent awareness of university researchers and instructing them in how to recognize inventions when they occur, and, then, what to do with them in order to transfer the new technology for public use. The basic objective of this work was to find some way to search out and bring into public use more inventions than has heretofore been the case.

Two reports on this work (which was completed in November, 1977), are in preparation. One, which will be issued shortly, is an instruction manual designed for use by universities and colleges in setting up and operating their own invention administration offices. The other details the experimental procedures and analyzes the results of the three-year program. This second report will be available within about two months.

The field work was carried out at eight carefully selected institutions to try to delineate some of the most important factors preventing the recognition of inventions, patentable or not, which might be of value to the general public. Interim

summaries of the results have already been presented at various professional society meetings. It is contemplated that additional presentations will begin shortly and continue over the next few years. Various aspects of the work are planned for wide dissemination. On the basis of the results obtained, we fully expect that the number of invention disclosures per $1 million of funding, Federal or otherwise, can be doubled or tripled by using the techniques evolved in the experiment. A copy of a summary of the final qualitative results is appended to this statement. This summary was presented at an international meeting of representatives of National Research Development Organizations from 16 countries in Seattle just last Thursday, June 15, 1978.

Although there are many other facets of the subject of Government patent policy which could and should be addressed, I shall conclude my testimony at this point.

Personally, and on behalf of Research Corporation, I appreciate very much the Committee's kind attention, Mr. Chairman, and convey to each member my thanks for the opportunity to address this body. If anyone has questions for me, I shall be pleased to answer them to the best of my ability.

NEXT

On December 12, 1980, President Carter signed into law a piece of legislation which most of us refer to as the University and Small Business Patent Act of 1980.

News of this event reached me in Detroit within an hour of its occurrence. And suddenly, it was all over. A victory which at one time had seemed hopelessly beyond our grasp, which had eluded our most determined efforts for years, had now become an incredible reality. It was a time for celebration, and also for reflection. Were we together then, we would have recounted, laughingly, the hours of our despair, while toasting the heroes and roasting the villains of a truly epic struggle.

I am sure there were parties somewhere, in Washington perhaps, where a few of our number could add the warmth of comraderie to the joy of victory. Yet most of us, being removed from one another by a considerable distance, were obliged to rejoice in solitude, if not also in silence.

Today, for the first time since that happy event, we have an opportunity to rejoice together. I have not come here today to explore with you the problems which lie ahead, nor to discuss the proper distribution among ourselves of specific assignments. I have come, rather, to celebrate what has already been accomplished. It is time to luxuriate in the knowledge not merely that we have won, but that, by all that is holy, we deserved to win.

What was the darkest hour of the campaign? It was not, as some might conjecture, when we were farthest from victory. Indeed, our progress was remarkably steady, albeit agonizingly slow, so that we inched closer to victory each day. The darkest hour was marked instead by the severity of our casualities. The nadir was reached on December 12, 1978, exactly two years prior to the date of enactment. If only we had known!

It is a tradition among employes everywhere, and among federal employes especially, for a departing worker to be escorted to lunch on his final day by a coterie of his friends and office mates. Such occasions can range from the simply bittersweet to the hilarious. And sometimes, very rarely, they can be poignant beyond description. Norm Latker had been fired by Joe Califano and December 12, 1978 was his last day on the job. After 22 plus years of federal service he was being terminated without separation pay for alleged departures from official DHEW policy. I was working at Argonne Laboratories during this period but arranged to be in Washington on that final day. There were just three of us for lunch. Norm, myself, and Dave Eden, my former special assistant at Commerce who was then with the Department of Energy. Our purpose, Dave's and mine, was to assure Norm of our continuing commitment to the joint undertaking, and more especially to one another. It was not a sad meeting, though the situation itself was grim. We were sustained by the conviction that the Civil Service Commission would ultimately set aside Norm's dismissal as illegal, restoring him to his post with full back pay. This eventually transpired, except that Norm got no back pay since his income as a private patent attorney during the layoff period far exceeded what he would have earned as a civil servant.

It would have helped had we known then that Califano himself would soon be dismissed by the President and that the President would prove willing to sign into law a policy which Califano had dismissed Norm Latker for espousing.

Califano was indeed the arch villain of the entire affair, yet his excesses helped our cause tremendously, turning otherwise neutral parties to our side. Yet, he was not around at the beginning.

The very first battle took place in late 1974, immediately prior to the establishment of the Energy Research and Development Administration (ERDA). At issue was the patent policy which would guide the contract and grant activities of this new agency. President Ford was anxious to get started with his energy initiatives of which ERDA was to be the cornerstone. His eagerness, however, left him vulnerable to a handful in Congress who saw an opportunity to impose rigid patent policies upon the fledgling organization. We fought this opposition to a standstill, then turned the tide so that, in the end, ERDA's patent policy was a lot better than that found in many federal programs. We were aided in this endeavor by an extraordinary communication from the Executive to the Legislature. It may well be without parallel in our history. It said, in effect, that the administration had carved out a compromise with Senator Hart, the leader of the opposition, and that the President would veto any bill which departed from the text of that compromise in the slightest particular. The battle ended with a minor victory for our side: we had averted disaster and had actually gained a little ground.

We were beginning to recognize our friends and win new ones. These included Congressmen Craig Hosner, Don Fuqua, Mike McCormack, and Barry Goldwater, Jr. On the other side were the rest of the House and the whole of the Senate, or so it appeared. Our leading foes were Kastenmeier, Seiberling and Udall in the House, and Hart and Long in the Senate. We should also remember Bernie Nash, Senator Hart's aide, who was both tenacious and indefatigable in his opposition. He was a worthy adversary and fully deserving of our respect, and perhaps even some grudging admiration. Unlike Joe Califano, Bernie Nash made few mistakes and he pushed no one into our camp.

And what about the good guys. The inner circle consisted of about six members of the Executive Subcommittee of the Committee on Government Patent Policy. These six were charged with the task of organizing an active constituency from among those who shared our philosophy. Their efforts produced strong support and write-in campaigns from the American Bar Association, the National Small Business Association, the National Patent Council, the Chamber of Commerce, the National Association of Manufacturers, Aerospace Industries Association, and like groups. Norm Latker was chairman of a subcommittee dealing with university patent policy. It was his job to organize the university sector and he did so magnificently, extracting immediate pronouncements of support from the American Council on Education, and NACUBO (National Association of College and University Business Officers), from which organization your own has sprung. SUPA came later, but we soon found ourselves with a team of dedicated supporters at the cutting edge of technological advancement. There is always a first, even among equals, and the first one on my list must be Howard Bremer of

the Wisconsin Alumni Research Foundation. With him were:

Neils Reimers of Stanford

Larry Gilbert then of MIT, now of Boston University

Ray Woodrow of Princeton and later the first President of SUPA

Ray Snyder of Missouri

Al Gold then of Rockfeller University and more recently of NY Polytech

Bob Johnson of the University of Florida

Earl Freise then of Northwestern and now of N. Dakota

Clark McCartney of the University of Southern Cal

Tom Martin of Utah

Will Farnell of Minnesota

Ralph Davis of Purdue

Ed McCordy of Washington University (St. Louis)

Alan Moore of Case Western

Mark Owens of the University of California

Rodger Ditzel then of Iowa State, now of University of Cal

Ed Yates of Johns Hopkins

Dennis Barnes then of the University of Virginia, now science aide to Senator Schmidt

Bill Burke of Georgia

Tom Evans of Michigan Tech

Joe Warner of Yale

With the first battle over, we were stronger - far stronger - than we had ever been. Rather than dismantle our army, we decided to take the offensive. Together we wrote a patent policy that was as perfect as we could make it, one totally devoid of the shortcomings associated with political expediency. In short, we set out to educate the misinformed, the untutored and the suspicious, rather than mollify them. The bill that we wrote is known today as Thornton - not the Thornton Bill or the Thornton Act - just plain Thornton. The University and Small Business Patent Act is Thornton applied to universities and small businesses. The name Thornton comes, of course, from Ray Thornton who introduced our bill to a reluctant if not hostile House of Representatives. Ray is now President of Arkansas State University, from which vantage point he must certainly look back with pride upon what he has wrought. He must also be surprised, given the fact that the bill was never reported out of committee, nor indeed were hearings ever scheduled.

We learned during these years that, of all the persuasive arts, education is the slowest. And the education of politicians is slower yet. From a purely personal point of view, I was keenly aware that time was running out. As the inauguration of President Carter approached, there remained two unfinished peices of business.

First - to prevent the imposition of federal control on Recombinant DNA experimentation, and

Second - to legislate Thornton.

The completion of these projects would depend upon the organization I left behind. In fact, more was accomplished after I left than when I was present. My successor, Jordan Baruch, pulled a Joe Califano. He repudiated Thornton absolutely and irrevocably which made everybody work twice as hard for Thornton as they might have otherwise.

Almost a year after the Carter Administration had begun, Senator Gaylord Nelson announced that his Monopoly Subcommittee would begin a truly extraordinary set of hearings:

> "These hearings," Nelson said, "would examine efforts by a highly placed group of Commerce Department employees - most of them holdovers from the two previous administrations - who are trying to persuade Congress to repeal laws that now require certain agencies to take title to the benefits of research paid for by the public."
>
> "The Commerce Department group, known as the Government Patent Policy Committee, has been circulating a draft report among government agencies aimed at drumming up Congressional support for repeal of laws that prohibit granting exclusive marketing rights to companies which developed inventions with government financed research."
>
> "If this group of Commerce Department employees has its way, the government would end up giving away to a small number of companies the rights to every invention produced through government financed research."

In truth and in fact, this set of hearings was intended to be a pre-emptive strike against Thornton - to prevent a Thornton-type bill from being introduced in the Senate, and to send a message to members of the House.

The witness list included a lot of my old sparring partners, including Admiral Rickover, Representative Seiberling and Senator Long, together with some new players.

By some incredible coincidence, my name popped up a couple of dozen times during these hearings, even though I've been gone for almost a year.

Representative Seiberling observes at one point that "Assistant Secretary Ancker-Johnson was almost fanatic in opposition; she was the leading protagonist in doing everything she could to stymie compulsory licensing."

Senator Long accuses me of making the same old, tired, discredited claims to justify the giving away of government owned rights. Then he gets to the heart of the problem. He says;

> "In April, 1977, a bill was introduced in the other body (H.R.6249) and, I must confess, it is a beaut. This is what a real giveaway should be like. It gives everything away; it doesn't leave even a sliver of meat on the bone."
>
> "This proposed legislation is one of the most radical, far-reaching and blatant giveaways that I have seen in the many years that I have been a member of the United States Senate."

Coming from Senator oil-depletion-allowance Long, this is high praise indeed.

Rickover then reveals how the ERDA patent lawyers have actually invited contractors to request waivers, all of which goes to show how right he was in denouncing our perfidy the first time around.

An economist I never heard of compares my views to "stale wine in old bottles." Both the Chairman of the Federal Trade Commission and the Assistant Attorney General for Antitrust conclude with dire predictions for the future of our economy, absent their careful scrutiny of the patent system in general, and government patent policy in particular.

Somehow, after listening to all these testimony, Senator Nelson changes his mind and decides that Thornton is perfect for universities and small businesses.

Meanwhile, back at DHEW, Joe Califano was working his magic. Not a single patent waiver was granted by HEW from the summer of 1977 until the fall of 1978.

Mounting pressures from the university community, among others, forced the breaking of the log-jam in late '78. The firing of Norm Latker was effected in retaliation.

One Waiver had actually occurred in the spring of 1977, shortly after Califano took office, but was cancelled illegally, only a month later. The invention in this case involved a CAT scanner. The contractor/assignee was a small business concern known as American Science and Engineering, Inc., or AS&E for short.

Three months ago, AS&E finally got its day in court. I should say the Receivor of what is left of AS&E got his day in court.

The government was found liable and the matter remanded for the assessment of damages, among other things. I don't know how much the damages will be, but every penny will come out of the taxpayers' pocket for conduct which Mr. Califano, a lawyer, should certainly have known to be unlawful. If you think that I have had difficulty in rationalizing Mr. Califano's conduct, listen to what the court has to say.

> "Dr. Richmond's decision may also have been prompted by a memorandum from Joseph Califano, then serving as Secretary of HEW, in which Califano notified Dr. Richmond that he had asked the HEW Inspector General to review the decision process which led to the grant of the AS&E exclusive license. Califano's memorandum was dated July 21, 1977, the same date that Dr. Richmond wrote his letter to AS&E purporting to cancel the license agreement. In his memorandum, Califano stated, "In view of my general concern with respect to the contract procurement process within the Department, I am interested in knowing how this decision was made." This language is difficult to reconcile with that which appeared in a letter Califano had written to the Speaker of the House, Thomas (Tip) O'Neill, less than one month earlier. In his letter to the Speaker, Califano stated, "I am pleased to report that the Department has now granted and returned a limited exclusive license under these inventions to AS&E as an incentive toward their commercial development." His letter to the Speaker concluded that "this matter has now been resolved in a manner which is fair and equitable to AS&E, the Department, the public and other manufacturers of CT Scanners."

Returning to the events which were occurring in the Senate around the time of Senator Nelson's Damascus-Road conversion, you will recall that Senators Bayh and Dole introduced the University and Small Business Patent Act, and began hearings thereon. At this set of hearings our side got a chance to testify and we did so with a vengeance. Our opponents began looking for opportunities to be out of the country rather than face public cross-examination - all except Rickover who never answers questions anyway. He deserves high marks for persistence if not for perspicacity.

The remainder of the story is well known to all of you. What you may not know are the names of the heroes whose roles were played behind the scenes.

I will not reveal the identities of the remaining members of the Executive Subcommittee, since I don't want anybody to get fired the next time we have a change of administration. You already know that Norm is one of these. Nor is there time for me to tell you the exact contributionsof those individuals whose names I feel compelled to mention today. It would take hours to do everyone justice. Instead, I will merely indicate the capacity in which each one came to be of significant service to our cause.

Joe Keyes - Association of American Medical Colleges

Shelly Steinback - American Council on Education

Eric Schellin - National Patent Council and National Small Business Assn.

Tom Arnold - Patent Attorney, Officer of Texas Bar Assn., the American Bar Assn., the Licensing Executive Society and the American Patent Law Society. Each of these groups supported our legislation.

Barry Leshowitz and Brenda Levenson - Aides to Senator Dole. Barry is now on the faculty of the University of Arizona. I'm not sure where Brenda is at the moment.

Ed Brenner - Former patent commissioner and President of the Association for the Advancement of Invention and Innovation.

Francis Browne - Patent Attorney and officer of ABA

Frank Cacciapaglia and Barry Grossman - Patent Office officials with responsibilities for Congressional liaison.

Dr. Gail Pesyna - House Science and Technology Committee staffer - now with DuPont.

Mike Superata - House Science and Technology Committee staffer - later with House Ways and Means.

Joe Allen - Aide to Senator Bayh - now Executive Director of Intellectual Property Owners, Inc., a non-profit association.

Darcia Bracken - Congressional Staffer to Ray Thornton. I believe that Darcia is now with NASA.

Julie McDonald - Administrative Assistant to Ray Thornton. Present whereabouts not known to my staff - though probably back in Arkansas from which she is fully expected to return as a Congresswoman in her own right. Let's hope so.

Lester Fettig- Headed up the Office of Federal Procurement Policy in the Carter Administration. Gave us more assistance than any other Carter appointee.

Julius Tabin - Patent Attorney to Salk Institute.

Rudy Vignone - Director of Governmental Relations, Goodyear Tire and Rubber Company.

Brendan Somerville - National Association of Manufacturers.

How's that for an impressive array of talent! Kind of makes you wonder sometimes why it took us so long. Could we have made it without them? Probably not, and even if we could, we wouldn't be there yet. So we really do owe them a debt of gratitude. And yet, having said that, let us not overlook one incontrovertible truth:

THEY could NEVER have made it without US!

You know, and I know, that it is we who did it, and I for one am damn proud of it!

NEXT

DRAFT

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

In 1980, the Bayh-Dole Act gave universities and small business 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.

Simply put, the legal philosophy of Bayh-Dole is this: if the government accords broad marketplace prerogatives to the developers of government-funded inventions, practice supports that such inventions are far more likely to be developed and disseminated to the public.

The law holds that intellectual property rights should be accorded in full to the innovators, rather than to the government agency that financed their research, and that developers should be free to leverage their property rights to their advantage in the market place as intended by the patent system.

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

The Act has been enormously successful. As the Economist Magazine put it recently, it is "the most inspired piece of legislation to be enacted in America over the past half-century." F.N. Economist

In practice, Bayh-Dole has fostered a potent four-way partnership between researchers, their institutions, government and industry. That partnership ahs evolved into a powerful engine of practical innovation, producing innumerable advances that have extended life, improved its quality and reduced suffering for hundreds of millions of people.

Universities in particular have been very successful in commercializing their inventions. The Act is generally credited for contributing to the dramatic increase over the last 20 years in the number of

university inventions reported, patents granted, royalty bearing licenses negotiated, collaborative agreements and new startups.

Since 1980, American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2,200 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute $40 billion annually to the American economy. Having seen the results, America's trading partners have been quick to follow suit. F.N. Economist

Notwithstanding the unquestioned success in meeting its objectives, opposition to the Act continues on the basis of variations on the thesis that the public should not be charged, or should be charged less, for goods based on inventions which the opponents maintain taxpayers have already paid for. The growing success of the Act has been accompanied by an increasing number of articles pressing this thesis as a solution to the rising cost of healthcare especially prescription drugs protected by patents. One such article by Peter S. Arno and Michael H. Davis gives a new variation on this old thesis by asserting that the march-in provisions of Bayh-

Dole attached as a condition of ownership were clearly intended to be used to combat the price of drugs invented by universities with federal funding identified by the public to be excessive. It is the purpose of this article to address the Arno/Davis article and its consequences.

THE HISTORY OF MARCH-IN RIGHTS

A. 1947 Attorney General Report

March-in Rights as a condition of ownership of a government-funded invention were first suggested in the 1947 Attorney General's Report and Recommendations to the President as part of an appropriate government patent policy which was being developed to cover the expanding government research and development program after World War II. That report recommended that "the contractor (or his assignee who might acquire ownership) 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.

B. 1963 and 1971 Presidential Memorandum and Statements

Thereafter, similar march-in rights provisions attached to contractor ownership were used in the Presidential Memoranda and Statements of Government Patent Policy by Kennedy (1963)[12] and Nixon (1971)[13]. These were implemented as part of the Federal Procurement Regulations[14] and various agency procurement regulations.

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 application if 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. The fourth paragraph of the Kennedy Memorandum made clear that the reason for

this march-in right was, as in the 1947 Attorney General's Recommendation, limited 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 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 if the patent owner was not pursuing practice of the invention. The authors note that the concept of "reasonable terms" as used in the Kennedy and Nixon memorandums was a condition attached to the licensing of inventions. There is no language in these memorandums directed to the availability or price of a patented invention arising from federally funded research.

C. 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 a contractural agreement to elect ownership to any invention made with NIH or NSF funds, eliminating the arduous task of justifying such ownership after identification of such invention. Bayh-Dole is considered a codification[21] of the IPA, which was authorized for agencies in 1978 and had a march-in provision similar to that of the 1947 Attorney General's recommendations. The model IPA was developed by the University Patent Policy Ad Hoc Subcommittee[22] of the Committee on General 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. The IPA regulation became effective on July 18, 1978.[24]

Prior to Bayh-Dole there was little 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:

> 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]

(MOVE CELL-PRO AND ESSENTIAL INVENTIONS HERE AS EXAMPLE OF HOW RIGHT DUNNER WAS)

NEXT

THE BAYH-DOLE ACT

A guide to the law
and implementing regulations

COGR
COUNCIL ON GOVERNMENTAL RELATIONS

NOVEMBER 30, 1993

Council on Governmental Relations

This document, which deals with the Bayh-Dole Act, is intended to inform the public about technology transfer at U.S. research universities. This Guide has a compendium piece, entitled "University Technology Transfer—Questions and Answers". Although each document fulfills its own purpose, they complement each other. When taken together they present a primer on the subject.

The Council on Governmental Relations is an organization which includes among its members over 135 research intensive universities. This booklet does not claim to be a manual of university technology transfer and licensing activities. Rather, it illustrates the philosophy and processes currently practiced in the university community.

In preparing the material, the COGR Subcommittee on Technology Transfer drew on the assisrance of many COGR universities. Their help is gratefully acknowledged. Reproduction for purposes of sale or profit is prohibited without the written consent of the Council on Governmental Relations. Otherwise, reproduction is encouraged.

THE BAYH-DOLE ACT

A guide to the law and implementing regulations

Abstract

Modern day technology transfer from universities to industry can be dated to the 1980 enactment of P.L. 96-517, the Bayh-Dole Act, and amendments included in P.L. 98-620, passed in 1984. This paper provides a summary of the legislation and the implementing regulations, and describes some of the results to date.

Introduction

Technology transfer—the transfer of research results from universities to the commercial sector—is closely linked to fundamental research activities in universities. The concept is said to have originated in a report, entitled "Science—The Endless Frontier" which Vannevar Bush wrote for the President of the U.S. in 1945. At that time, the success of the Manhattan Project had demonstrated the importance of university research to the national defense. Vannevar Bush, however, recognized the value of university research as a vehicle for enhancing the economy by increasing the flow of knowledge to be used by industry through support of basic science. His report became instrumental in providing a substantial and continuing increase in funding of research by the federal government. It srimulated the formation of the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Office of Naval Research (ONR). Due to the success of these and other agencies, the funding of basic research is now considered a vital role of the federal government.

In the 1960s and 1970s, there was much study and debate surrounding federal patent policy, which eventually resulted in legislative activity. A major concern was the apparent inability of the federal government to transfer its technologies. There was no government-wide policy regarding ownership of inventions made under federal funding and the diversity in policies among the various funding agencies resulted in a mea-

ger flow of government assisted inventions to the private sector. In 1980, the federal government had approximately 30,000 patents and only 5% of these led to new or improved products.

This problem was due, in large part, to restrictive government policies on licensing and a reluctance on the part of the agencies to permit rights to an invention to rest with the universities and other grantees/contractors that develop them.[1] The government would not relinquish ownership of federally funded inventions to the inventing organization. Instead, it would make such inventions available by non-exclusive license to anyone who wanted to practice them.

As a result, an organization had no exclusive right to manufacture and sell a resulting product. Understandably, companies were not interested in the development of early stage inventions, if, when products finally were ready to reach the market, competitors could acquire a license and could then manufacture and sell the same products. Government remained unsuccessful in attracting private industry to license government-owned patents, because what belongs to everyone, belongs to no one.

Late in 1980, legislators and the administration finally decided that the public would be served best by a policy which encouraged the utilization of inventions produced under federal funding and which promoted the participation of universities and small businesses in development and commercialization processes.

Bayh-Dole Act and Related Legislation

The Bayh-Dole Act and subsequent amendments provide the basis for current university technology transfer practices. The federal patent and licensing policy was shaped by four events which occurred between 1980 and 1985.

1. On December 12, 1980, P.L. 96-517, the Bayh-Dole Act was enacted into law. This statute contains several important provisions[2]:
   - A uniform federal patent policy was established.
   - Universities were encouraged to collaborate with commercial concerns to promote the utilization of inventions arising from federal funding.
   - It was clearly stated that universities may elect to retain title to inventions developed through government funding.
   - Universities must file patents on inventions they elect to own.
   - The government retains a non-exclusive license to practice the invention throughout the world.
   - The government retains march-in rights.
   - Preference in licensing must be given to small business.
   - Uniform guidelines for granting licenses were provided.
2. On February 10, 1982, the Office of Management and Budget issued policy guidance to federal agencies for implementing the Act. This guidance is known as OMB Circular A-124.[3] The government clarified the following provisions:
   - Standard patent rights clauses for use in federal funding agreements.
   - Reporting requirements for universities electing title.
   - Special federal rights in inventions.
3. On February 18, 1983, a Presidential Memorandum on "Government Patent Policy" was issued. It mandated broad application of the new government policy.[4] Two significant aspects are:
   - Federal agencies were directed to extend the statutory terms beyond universities and nonprofit organizations ro for-profit grantees/contractors as well.
   - The Federal Acquisition Regulations (FAR) were amended on March 30, 1984 to assure that all R&D agencies would implement the Bayh-Dole Act and the Presidential Memorandum.
4. On November 8, 1984, the original statute was amended. The new language, referred to as P.L. 98-620, provides further refinement[5]:

- The term limitation on exclusive licenses was deleted.
- The Secretary of Commerce was substituted for the Comptroller General as the responsible party to determine "exceptional circumstances" when contractor rights might be overruled.

In summary, the Bayh-Dole statute and subsequent amendments created incentives for the government, universities, industry and the small business sector, and herein may lie the reason for its success. It was not until 1987, however, that all these provisions—the Bayh-Dole Act, its statutory amendment, the OMB policy guidance and the Presidential Memorandum—were finalized in rulemaking, published by the Department of Commerce.[6] These rules specify the rights and obligations of all parties involved and constitute the operating manual of the modern technology transfer officer.

Current Regulations

Procedures implementing legislative and executive patent and licensing policy regarding "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms " are codified at 37 CFR Part 401. The Department of Commerce is designated as the federal agency to promote commercialization and to assume responsibility to maintain these rules.[7] As technology transfer takes place, the following regulations must be observed:

- The provisions apply to all inventions conceived or first actually reduced to practice in the performance of a project, whether fully or partially funded by a federal agency.
- The university has an obligation to disclose each new invention to the federal funding agency within two months after the inventor discloses it to the university.
- The decision whether or not to retain title to the invention must be made within two years after disclosing the invention to the agency. This time is shortened, if, due to publication of results, the one year U.S. statutory patent bar has been set in motion. Under those circumstances, the university must make an election at least sixty days before the end of the statutory period.

- Upon election of title, the university must file a patent application within one year, or prior to the end of any statutory period in which valid patent protection can be obtained in the United States. The university must, within ten months of the U.S. filing, notify the agency whether it will file foreign applications. If the university does not intend to file, the agency may then file on its own behalf.
- If the university elects to retain title, the federal government is provided a non-exclusive, irrevocable, paid-up license to practice the invention (or have it practiced on behalf of the U.S.) throughout the world.
- Any company that holds an exclusive license for sales in the United States, must substantially manufacture the product in the U.S. Waivers of this rule may be granted by the federal agency upon a showing that reasonable but unsuccessful efforts had been made to find a company that would manufacture in the U.S.
- As they proceed to license an invention, universities must give preference to a small business firm, provided the firm has the resources and capability for bringing the invention to practical application. However, if a large company has provided research support that led to the invention, that company may be awarded the license.
- Universities may not assign their rights to inventions to third parties, except to a patent management organization.
- Universities must share with the inventor any income collected on the invention. Any remaining income, after expenses, must be used to support scientific research or education.
- Agencies may decide, due to exceptional circumstances, that title is better vested in the federal agency. Such decision must be made up front and becomes part of the funding agreement with the university. The agency must file an "exceptional circumstances" determination with the Department of Commerce, which rules on its validity. These exceptional circumstances might pertain to national security or sensitive research projects.[8]
- In some circumstances, the government can require the university to grant a license to a third party. This might

occur if the invention was not brought to practical use within a reasonable time, if health or safety issues arose, if public use of the invention was in jeopardy, or if other legal requirements were not satisfied.[9]

Details of procedure and other rights and obligations not cited above, as well as further elucidation of those items discussed, can be found in 37 CFR 401 and 35 USC 200-212.

Results

Has Bayh-Dole been effective in promoting technology transfer by universities? What measures can verify its effectiveness; and how much data are available? Some compelling data exist:

- In 1980, there were approximately 25–30 universities engaged in technology transfer; by 1992, there were 200.[10]
- Between 1974–1984, 84 universities applied for 4,105 patents (2,944 subsequently issued); in 1992 alone, 139 universities received 1,557 patents.[11]
- During 1974–1984, 1,058 licenses were granted by universities; in the period of 1989–1990, 1,510 licenses were granted.[12]
- In 1986, 112 universities reported licensing income of $30 million; in the two year period of 1989 and 1990, 35 universities reported income of $113 million.[13]
- According to the General Accounting Office, industrial support of university research has risen from 4% in 1980 to 7% in 1990.[14]
- A 1993 survey including 98 universities further illustrates the growing activity and success in university technology transfer for fiscal years 1991 and 1992.[15]

Conclusions

These data lead clearly to the conclusion that the Bayh-Dole Act has promoted a substantial increase in technology transfer from universities to industry, and ultimately to the public, as products become generally available. The Act provided a secure base to which universities could link some of their key research projects. Certainty of title to inventions made under federal funding proved to be most significant. While allowing commercialization, title also protects a researcher's rights to use and continue to build on a specific line of inquiry. Implementation of uniform patent and licensing procedures became the second ingredient for success. This combination of factors led to a tremendous boost in university technology transfer activities.

As Vannevar Bush foresaw, striking economic benefits to U.S. business have been a critical spinoff from this effort. University research and technology transfer has spawned the biotechnology industry and led to advances in the medical, engineering, chemical, computing and software industries, among others. Transfer of technologies has led to the creation of new companies, thousands of jobs, cutting-edge educational opportunities and spinoff to service industries.

As one example of this spinoff, the licensing income in 1989 and 1990 of over $100 million for thirty-five universities can be extrapolated, on a 4% royalty basis, to over $2.5 billion in sales, supporting thousands of jobs. And, this is only part of the picture. One should also take into account the funds invested by industry in development and in supporting these sales. One must also recognize the investment in new start-up companies all across the U.S., from which products are forthcoming. Finally, one must remember that U.S. universities have invested tens of millions of dollars since 1980 in developing their productive technology transfer infrastructure.

Perhaps, most importantly, one must acknowledge how technology transfer, facilitated by the Bayh-Dole Act, has improved our lives. New drugs, medical treatments, building materials, consumer products and diagnostic devices are but a few of the products that started as an idea in a university research laboratory and now touch our lives daily. The Bayh-Dole Act permits universities to be effective in promoting technology transfer. We must all be mindful of the tenets from which the Act was derived, and must be vigilant in protecting the rights granted by the Act.

Footnotes

[1] The term university(ies) as used in the text applies to all grantees/contractors.

[2] P.L. 96-517, Patent and Trademark Amendments of 1980. This law amended Title 35 USC, by adding Chapter 18, Section 200-212.

[3] Office of Management and Budget (OMB) Circular A-124 was subsequently codified at 37 CFR Part 401.

[4] The Presidential Memorandum was incorporated into the text of Office of Management and Budget (OMB) Circular A-124 on March 24, 1984.

[5] P.L. 98-620 amended Chapter 18, of Title 35 USC.

[6] Final rules were published on March 18, 1987 (52 FR 8552) and subsequently codified at 37 CFR Part 401.1-401.16.

[7] The Secretary of Commerce delegated this authority under 35 USC 206 to the Assistant Secretary for Productivity, Technology and Innovation.

[8] Other circumstances, not clearly elucidated in the regulations, may be invoked by the government. Further detail can be found in 37 CFR Part 401.3; general appeal mechanisms are found in Part 401.4.

[9] Such conditions, including appropriate procedures, are described at 37 CFR Part 401.6.

[10] Informal survey of the Association of University Technology Managers (AUTM)

[11] Data for the 1974-1984 period are taken from a General Accounting Office (GAO) report, entitled "Patent Policy: Universities Research Efforts Under Public Law 96-517", dated April 1986.

[12] Data for the 1989-1990 period is contained in a General Accounting Office (GAO) report entitled "University Research - Controlling Inappropriate Access to Federally Funded Research Results", dated May 1992.

[13] The source for the 1986 data is a General Accounting Office (GAO) report, entitled "R&D Funding: Foreign Sponsorship of U.S. University Research", dated March 1988, Appendix I.

[14] See reference [12].

[15] The AUTM Licensing Survey: Fiscal Years 1991 and 1992. Association of University Technology Managers, Inc., dated October 1993.

Invention Disclosures: 1991-4,848:1992-5,645;

Total Patent Filings: 1991-1,922:1992-2,329;

Licenses: 1991-2,096:1992-2,632;

Royalties Received: 1991-$130M:1992-$171M.

NEXT

(1)

DRAFT

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

John H. Raubitschek[1]
Norman J. Latker[2]

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.

Simply put, the legal philosophy of Bayh-Dole is this: if the government accords broad marketplace prerogatives to the developers of government-funded inventions, such inventions are far more likely to be developed and disseminated to the public. In practice supports that

The law holds that intellectual property rights should be accorded in full to the innovators, rather than to the government agency that financed their research, and that developers should be free to leverage their property rights to their advantage in the market place as intended by the patent system.

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.

The Act has been enormously successful. As the Economist Magazine put it recently, it is "the most inspired piece of legislation to be enacted in America over the past half-century."

~~That may sound like hyperbole, but the impact of the Act has indeed been astounding — and overwhelmingly positive.~~

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~~ a 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.

2

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 stantops.

. Since 1980, American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2,200 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute $40 billion annually to the American economy. Having seen the results, America's trading partners have been quick to follow suit. ~~Odd then, that the Bayh Dole~~

F.N. ECON.

MIT Exam.

Notwithstanding, the unquestioned success in meeting its objectives, ~~opponents of the Act~~ opposition to the Act continues on the basis of variations on the thesis that the public should not be changed on changed less for goods based on inventions which the opponents maintain ~~were~~ taxpayers have already paid for. The growing success of the Act has been accompanied by an ~~increasing~~ increasing number of articles pressing this thesis. ~~One of these articles An article by Peter S. Arno and Michael H. Davis assents~~ One of ~~these~~ such articles by Peter S. Arno and Michael H. Davis

(3) GOENS ~~[illegible]~~ a new variation ~~[illegible]~~ on this old thesis by asserting that the March-in provisions of Bayh-Dole were clearly intended to be used to combat ~~the high~~ the price of drugs invented by universities with federal funding identified by the public to be excessive. It is the purpose of this article to address the Arnold/Davis article and its consequences.

The History of March-in Rights

1947 Attorney General's Report

March-in Rights as a condition of ownership of a government funded invention were first suggested ~~as part~~ in the 1947 Attorney General's Report and Recommendations to the President on an appropriate government patent policy considered ~~Necessitated~~ ~~Necessitated~~ 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]

B. 1963 and 1971 Presidential memorandums and statements

(4)

Thereafter, similar provisions were used

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~~ as part of the Federal Procurement Regulations[14] and various agency procurement regulations. In ~~addition, they were mentioned in the Attorney General's Report in 1947~~[15]

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 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 as in the 1947 Attorney General's Recommendation limited 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 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~~ The authors note 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 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]

NEXT

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status?

DH: There are very few colleges that have escaped this problem in the last two days. Between Bentley and Brandeis, Brandeis is institution. It has whole departments devoted to the training of th directed by Clinton cabinet member Robert Reich. It's a training Democrats. The other is called Peace Studies. The way to tell wh studies programs are legitimate academic inquiries into how to a whether or not the program has on its faculty a professor of milit thousand years war has been the normal state of mankind. Peace condition. For 5,000 years it has been created by one fact alone – coalition of powers or one power so great that it imposed peace was too powerful to challenge. To inquire about the nature of pe understand the nature of warfare. If you are going to organize a l program, which will be anti-military, then you organize a peace way Tufts and Brandeis have. Their very structure is an abuse of betrayal of the educational vision. Brandeis' mission statement is of scholars united by the search for knowledge. If you pre-comm is going to be, if military history and science is not a part of peac you even have begun the inquiry, you have reached a partisan co

PS: How will we know when the objective of Students for Acad achieved? Are you optimistic that SAF will achieve its goal?

DH: I think it's going to take years, and it might take decades. E in restoring fairness, intellectual diversity, inclusion and respect great gain for both the institution and students in general.

PS: Where has the Academic Bill of Rights been adopted?

DH: We started this campaign in September, and now have 133 campuses nationally. We have legislation moving in seven states Georgia Senate, and it is in process of being adopted by the univ Colorado. If students are as active as they seem to be at Tufts, in dozens of states and many universities that will have adopted the Rights. A large part of it is up to the students themselves.

PS: Beyond working with Students for Academic Freedom, wha wishing to bring intellectual diversity to his college have?

DH: SAF is about the process. Our effort is to get these institutic themselves to try to adopt reforms that will enhance the value of getting. The next step for students is to become aware of what's courses but should be, register complaints where necessary, and compensate for the one-sidedness of the faculty by seeking out tl them. There will be a lot of decent faculty members who will be to them with these complaints.
No student who hasn't read Frederick Hayek should consider the has created one of the most formidable perspectives on the most

confront us, including the issue of so-called social justice. Marx discredited figure, but every student is familiar with his writings. Ludwig von Mises both predicted the fall of communism, and ex socialism wouldn't work. The Left, which supported communisn the history, sociology, and political science departments of our s interest in suppressing these facts. The best way to do so is to no Hayek even exists, let alone require that he be read in class. Ever The Road to Serfdom and The Mirage of Social Justice.

PS: An explicit sex fair was recently held in the lobby of the can was accompanied by a demonstration of sex toys in a freshman c performances of the infamous Vagina Monologues, to name just were all co-sponsored by University departments and carried a d message. The University's involvement in these activities was cr groups including this magazine, and subsequently caught the atte newspapers and television stations. Where do you believe the lin when it comes to University sponsorship of events?

DH: The problem is that these departments will sponsor left-win that's all they will sponsor. That's wrong. One of the tenets of th Rights is that there should be a fair distribution of resources for c speeches. While I think it is a travesty to use the University in th unnecessary considering the wealth of sexual information availal personally view the Vagina Monologues as ideological trash, the every right to hold these events, ludicrous as they may seem to o injustice to the community at Tufts, which is much larger than th sponsoring this, that they don't have equal access to University r to see Tufts students ask for a budget for events like this [The Va is known to all the students at Tufts who pay for it, and have an e these funds, for conservative or other events, whether directly rel

PS: You have talked about how the killing of a friend of yours b was a turning point for you in beginning to doubt the radical lefti subscribed to. Could you detail what later influences further cont transformation to conservativism?

DH: Frederick Hayek was one of them. It wasn't just the murder the Left reacted to it. The Left defends its own murderers. You c throughout the country and not come across my books. The Left justice for itself, that's why it has committed so many crimes ove social system has a way of dealing with injustices, and while it n what is in life?—at least it's there. There's a book called In Deni John Earl Haynes which documents professors in the fields of so communism. It's called In Denial because they [the professors] a facts, and are still defending the Soviet system.
It's taken 50 years and still, HBO just ran a Pulitzer Prize-winnir as sophisticated as a comic book. It was called Angels of Americ spy for the Soviets look like an angel. Instead of being laughed o considered probably the most significant drama in the American 20 years. That's the kind of perversity to which ideological mon

the left enjoys will lead. There is no one to challenge them in the and those who would are so miniscule in number, it becomes inti thankless to carry out this task. As a result, the intellectual level the liberal arts is at an all time low.

PS: Liberals seem to have an overwhelming advantage over con their ideas. Americans are subjected to liberal attitudes daily, wh form of MTV, The New York Times, schools, or Hollywood, to any exposure to conservatism, most Americans need to take a pr can conservatives do to change this, and how important is it that

DH: I have a big problem with calling leftists liberals. These pec they were there wouldn't be a problem. They are illiberal. The o liberal about are hard drugs and sex. In everything else, they're c want to tax and regulate and create rules. Liberalism is a misnom use it the way we do is because the left dominates the high cultu the Left has been able to do this is because conservatives have le Party has paid no attention. Conservative students haven't focus with the intention to solve its problems. I know nothing about th I'll give you odds and bet you that the lion's share of funding fo conservatives. It's important for Tufts students to be aware of thi trustees, alumni, and donors.

I already have indications that the Tufts administration is a probl comparable leftist—written 20 books, been nominated for a boo contributor to MSNBC instead of FOX, and been well known as would have been flattered to have me. They would have generou and shown respect. They don't show respect for the conservative conservatives probably contribute half of the school's budget. I t reforming the University would be for the diversity program to i diversity as part of the diversity mandate. I hope students at Tuft take it to the trustees.

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OCM-MO-3: Dr. John W. Helmuth, July 1998

DOES THAT DOG HUNT?
Concentration of Economic Power and Independent Producers
by
Dr. John W. Helmuth

It is bad public policy and bad economics to allow concentration of power in the food industry.

The food chain is one of the worst of all industries to have substantial concentration of economic power. Because food is essential to survival, any concentration of economic power has the potential to result in exploitation of both farmers and consumers. Food security is also an essential element of national security. Concentration of economic power in the food industry can thus endanger consumers, producers, and national security.

In 1945, the Noble prize winning **economist Frederick Hayek** pointed out that a free enterprise, market economy is most efficient as long as the economic decisions about what to produce and how to produce are made by those closest to the economic circumstances of time and place. In other words when economic decisions are disbursed among many independent resource owners, in the aggregate, their decisions will result in the most efficient use of resources. **Hayek** went on to say that the more resources and economic decisions are concentrated in the hands of a few, whether they be government bureaucrats, as in the former Soviet Union, or powerful corporate executives of large companies with substantial market power, the less productive and the less efficient the economy will be. I know of no stronger economic argument for the preservation of individual livestock producers' decision-making and the preservation of efficient, competitive, public markets.

Dr. Harold Breimyer of the University of Missouri calls the current trends in American agriculture "industrial feudalism." To put this characterization in historical perspective, during the age of European feudalism, land was owned by feudal lords in massive estates. These feudal lords had absolute power over the workers (serfs). Today, mergers, acquisitions, and consolidation is concentrating sector after sector of our economy, not only in the food system, but throughout most sectors of the American economy. These giant corporations, Dr. Breimyer points out, are today's counterpart of feudal lords.

To tie this back to **Hayek**, when a family farmer makes a bad economic decision only a few people may be hurt--the family, maybe a bank, or local suppliers. But when a large corporation makes a bad economic decision thousands can be hurt, possibly an entire industry. A good example is the US automakers' decision to continue to build large, fuel-inefficient cars in the 1970's during the oil embargo. It took two decades for America to recover from that bad decision and to once again be competitive with Japanese and European automakers. Millions of American workers and consumers were harmed by that one bad decision.

Today's increasing concentration of market power in the hands of fewer, larger companies violates the conditions necessary for a market economy to work. By definition, successful market capitalism must rest on a dispersion of resource ownership among many market buyers and sellers, all of whom may have some market power (bargaining power), but no one of which has any significant degree of market power. These ground rules of market capitalism are being violated today in America.

Livestock industry concentration is freezing out the independent farmers.

In today's livestock industry the trends are very clear. The squeeze on independent livestock operations is being brought about exactly as it was done in the poultry industry--by closing out markets. This is key to what has happened to public, competitive, capitalistic livestock markets, including cattle and other agricultural markets.

As concentration has increased the large corporations have closed out the competitive public markets. What is meant by closing out markets?

The nemesis of those with market power over price is the free, public, capitalistic, competitive, auction market. To have to bid competitively, in a public, capitalistic market, to buy livestock is the last thing a packer wants to do. This is the packer's motivation behind the move to more and more direct contracting of livestock. As packers control larger captive supplies and use more forward contracts and more marketing agreements, they are less and less likely to have to bid competitively in the public, capitalistic markets.

They are closing out the markets by avoiding them at all costs. By not using them unless they absolutely have to. Why buy in public if one can strike a deal in secret? As this phenomenon continues over the years, public, capitalist markets become thinner and thinner and usually end up essentially being residual markets where the lowest quality livestock, the culls, are disposed of.

An analogy is useful in understanding the effects of packers closing out the public markets. Consider what happens when a large buyer does not use a public market. Assume that the US Air Force decides to build a new Air Force Base in Indianapolis, Indiana. Now, what might we expect to happen to home prices in Indianapolis? They will most likely go up as new people move into the area to work at the Air Force base. New home buyers in the area are likely

to bid up the price of homes, reflecting the demand for housing. But, suppose for a moment that the Air Force--the government--decides to prevent home prices from increasing by avoiding the public market for houses. Suppose they try to do this by telling the sellers of houses that anyone working at the Air Force Base who wants to buy a home will only pay the average Indianapolis home price from last year, before the base announcement was made. Sounds absurd. Sounds absolutely impossible. Indianapolis would never stand for such an absurd attempt to close out the public market for houses. But this is exactly what the meat packers are currently doing in the cattle markets.

In my opinion, that dog don't hunt.

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NEXT

The Evolution of Modern Technology Transfer

By Norman J. Latker

In 1885, after Louis Pasteur saved a boy with rabies, patients flocked from all parts of the world to his office, but it was too small to receive them. The next year, before the Academy of Sciences, Pasteur declared, "There is a need for prophylactic measures against rabies. An anti-rabies vaccine should be created." The request from the father of microbiology resulted in an extensive, international public subscription generating a fantastic burst of generosity that built the Pasteur Institute as a clinic for rabies treatment, a research center for infectious disease and a teaching center, with Pasteur as director.

But, in subsequent years, as the early and fundamental discoveries in the life sciences evolved, it became clear that the resources necessary to bring them to practical life exceeded what their investigators could provide through their own efforts.

Indeed, Professor and Inventor Frederick Cottrell recognized "...a number of meritorious patents given to the public absolutely freely have never come upon the market chiefly because what is everybody's business is nobody's business." This observation led Cottrell to donate his patents and their royalty return from his electrostatic precipitator to fund the creation of the Research Corporation in 1913 to serve as the technology transfer agent for investigators isolated from the commercial marketplace.

In 1925, Professor Harry Steenbock made a similar donation of his vitamin D patents to fund the creation of the Wisconsin Alumni Research Foundation limited to serve as the technology transfer agent only for investigators at the University of Wisconsin at Madison. These targeted services were intended to provide greater attention to reported inventions than previously provided by universities.

During these early years of the century, the services of Research Corporation and WARF were clearly limited by their resources. The majority of investigators were left to determine on their own whether to pursue moving their discoveries into practical life.

The huge increase in funding of research and development by the federal agencies proposed by presidential science adviser Vannevar Bush following World War II brought with it the establishment of a patchwork of different policies covering the ownership of inventions resulting from this funding. Outside the Department of Defense, the policies were heavily weighted in favor of government ownership, resulting in either dedication to the public or nonexclusive licensing of the government's patent rights.

By the 1960s, it was clear to the science management at the National Institutes of Health that the department's

title policy was an impediment to industry development of the life-science inventions resulting from NIH funding.

The problem was dramatized by increasing numbers of invention-ownership disputes involving inventions assigned without notice to NIH to industrial developers by NIH-grantee investigators motivated, as was Pasteur, to see their direct application to practical life.

Professor Carl Heidelberger and the University of Wisconsin, after being publicly accused by Sen. Russell Long's staff of confiscating ownership of 5FU, a breakthrough cancer chemotherapy drug, and licensing it to an industry developer, successfully convinced the department that minimal government funds were involved in its conception.

Professor Robert Guthrie, a department grantee and the inventor of the then preferred test for PKU (Phenylketonuria) being marketed by an industrial developer under license, after being publicly pilloried for confiscating the invention, assigned ownership to the department.

These cases had a further chilling effect on industry involvement as they suggested that any amount of government funding touching an industry invention could result in a similar claim of right by the government.

Thereafter, in 1968, the Government Accounting Office added additional urgency to resolving the problem, by reporting that, due to department patent policy, inventions resulting from all of NIH's medicinal chemistry grants could not find the necessary industry support to continue development.

Finally, in 1969, responding to increasing internal pressure, the department changed its patent policy and established a uniform institutional patent agreement that left ownership to grantee institutions that agreed to staff a technology transfer office to manage and license these rights when they requested an agreement. The conditions attached to these agreements reflected the accepted practices of Research Corporation and WARF. The National Science Foundation followed with similar changes in 1972. Thereafter, HEW (DHEW? Department of Health, Education and Welfare?) and NSF staff responsible for IPA policy joined together in a long series of interagency discussions aimed to establish the IPA policy throughout the government agencies.

In 1974, the newly established IPA holders formed the Society of Patent Administrators to enhance outreach to industry so as to overcome industry's continuing resistance to development of government-funded inventions because they were not made in the companies' laboratories.

In that same year, members of the society found their political legs by assisting in preventing the inclusion in legislation creating the Energy Research and Development Agency of a requirement for government ownership of

inventions resulting from its funding.

By 1976, 75 IPAs had been negotiated and executed with institutions that received well more than 50 percent of the annual DHEW extramural funding, and GSA (General Services Administration?) regulations expanding the IPA policy to the rest of the government agencies, otherwise covered by statute, were accepted by the interagency Federal Council for Science and Technology and published.

Also in 1976, NIH Director Donald Frederickson agreed, with the consent of the FCST, to permit the University of California and Stanford to administer the Cohen-Boyer gene-splicing patent under their IPAs. Stanford's nonexclusive licensing of Cohen-Boyer to dozens of commercial concerns sparked the start of the biotech industry.

Notwithstanding the clear record of increasing licensing by IPA holders, DHEW Secretary Joe Califano instituted a 1977 "reassessment" of the department IPA policy that stopped further invention processing on the ground that the introduction of new technology into the marketplace was escalating the price of health care, which required department oversight. Legislation was introduced in the Senate to provide the department with this oversight authority at the same time.

Simultaneously, Sen. Gaylord Nelson of Wisconsin initiated hearings to discuss the legality of IPAs and the GSA regulations expanding their use to all government agencies.

The Califano and Nelson actions served as the flashpoint for organizations having IPAs to pursue legislation to assure continuance of the 1969 department policies and their further expansion by the GSA regulations to other federal agencies having conflicting policies. Led by the University of Wisconsin, Stanford University, the University of California and Purdue, the IPA community, over a period of two years, was so successful in making their views known to the Congress that Bayh-Dole passed the Senate by a vote of 91-4.

Some suggest that the primary purpose for Bayh-Dole is the production of income for those who participate in the conception and delivery of inventions to the marketplace. I do not believe that was the primary motivation of the act's architects. Income, which was a distant possibility at the time of enactment, was viewed only as a collateral benefit of success. The act is structured so as to assist investigators in their pursuit of direct application of their discoveries to practical life up to the point of either success or definitive failure.

As such, investigators intuitively understand that the act provides to them the possibility of their advancing mankind, as Pasteur did, which explains their growing enthusiasm to participate.

NEXT

Don't Mess with Success

People will know you're serious when you produce
Muhammad Ali

On August 4, 2004 the National Institutes of Health rejected a petition seeking to use the authorities of the Bayh-Dole Act to force Abbott Laboratories to lower the price of Norvir, an important part of the AIDS "cocktail" used by many patients. Since Abbott had discovered Norvir at least in part with NIH funds, was the agency correct legally and as a policy matter to reject the petition?

The answer is yes and yes.

The research alliances between our universities, federal laboratories and U.S. industry are essential to our economic growth. However, it must be realized that commercializing federally funded inventions is a high-risk endeavor. By allowing the Government to come in years later and second-guess product pricing would destroy the system.

While little known in the popular press, the Bayh-Dole Act of 1980 has been an essential part of the American economic renaissance. As **The Economist Technology Quarterly** said on September 14, 2002:

> Possibly the most inspired piece of legislation to be enacted in America over the past half century was the Bayh-Dole Act of 1980... More than anything, this single policy measure helped reverse America's precipitous slide into industrial irrelevance.

Before its enactment, few inventions were commercialized from the billions of dollars invested in federal R&D at our research universities. The reason was that they were warehoused in Washington and typically offered to industry non-exclusively. Industry was not interested without strong patent protections to justify their significant development risks. A study in the Johnson Administration was unable to find a single instance where any drug had been developed when the government owned the patent.

Bayh-Dole provided incentives for universities and small companies to nurture inventions they make with federal funds. University inventors must receive a share of royalties, the remainder must be invested in research. Preferences are given in licensing to small companies and those who will develop the resulting products in the United States.

The basis for the petition to NIH was a misreading of the rights of the funding agencies. A great fear when Bayh-Dole was debated in Congress was that companies might license university discoveries to stop their development when the discovery might threaten a company's existing products. Therefore, agencies were given the right to "march-in" if a

licensee was not making good faith efforts to move the product toward market. Because the universities are serving as stewards of the public interest, additional language required them to make their licenses available on "reasonable terms" for subsequent commercial development.

Through a misreading of the law and its legislative history (the hearings, Committee report and floor debate leading to enactment) a public interest group developed a theory that somehow the university's requirement to license on "reasonable terms" provides the federal agencies the right to make sure that resulting products are available at reasonable prices. Despite a joint letter to **The Washington Post** by Senators Bayh and Dole decrying such a misreading of their bill, a petition was filed to NIH asking the agency to "march-in" and regulate the price of Norvir.

If Congress had intended for government to regulate prices of resulting discoveries, surely it would have given some guidance on how to define a fair price. Senators Bayh and Dole would have been poor legislators, indeed, if they had hidden such an intent for almost 25 years. Legislation is not archeology!

If further clarification was required, former Senator Bayh spoke at the NIH meeting considering the petition again clearly explaining how the law worked. Ultimately NIH agreed, rejecting the petition.

Trying to combine technology transfer legislation with product price controls would again doom federally funded inventions to the dustbin. As NIH reported to Congress, 75% of licensed university patents were little more than a proof of concept. The vast majority of such patents are licensed to small companies.

Thomas Edison said, invention is 1% inspiration and 99% perspiration. In the case of publicly funded R&D, government is typically funding the inspiration and industry the perspiration. **The Economist Technology Quarterly** rightly concluded about Bayh-Dole: "A goose that lays such golden eggs need nurturing, protecting and even cloning, not plucking for the pot."

To paraphrase the Champ, Bayh-Dole has produced, don't mess with it.

NEXT

NL.

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RE: Rochester amicus

- Comments: Norm – here are the headnotes from the District Court case. They might help clarify the court's reasoning.

Regards.
Howard

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H
Motions, Pleadings and Filings

United States District Court,
W.D. New York.

UNIVERSITY OF **ROCHESTER**, a New York Education Corporation, Plaintiff,
v.
G.D. **SEARLE** & CO., INC., a Delaware Corporation, et al., Defendants.

No. 00-CV-6161L.

March 5, 2003.

Patent holder brought infringement action against competitor over patent relating to new generation of pain relief medication that did not produce certain undesirable side effects, particularly stomach irritation. On competitor's motion for summary judgment, the District Court, Larimer, J., held that: (1) patent did not satisfy written description requirement, and (2) patent did not satisfy enablement requirement.

Motion granted.

West Headnotes

[1] **Patents** 112.5
291k112.5 Most Cited Cases

[1] **Patents** 323.2(5)
291k323.2(5) Most Cited Cases

A moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity that no reasonable jury could find otherwise; alternatively, a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable finder of fact could invalidate the patent. 35 U.S.C.A. § 282; Fed.Rules Civ.Proc.Rule 56, 28 U.S.C.A.

[2] **Patents** 314(5)
291k314(5) Most Cited Cases

[2] **Patents** 323.2(2)
291k323.2(2) Most Cited Cases

Whether a patent specification complies with the written description requirement is a question of fact; however, as in other areas of the law, if the court finds that there is no genuine issue of material fact as to this issue, summary judgment is appropriate. 35 U.S.C.A. § 112; Fed.Rules Civ.Proc.Rule 56, 28 U.S.C.A.

[3] **Patents** 118
291k118 Most Cited Cases

A court need not decide the meaning of all disputed patent claims if the construction of the claims would have no bearing on the invalidity analysis. 35 U.S.C.A. § 282.

[4] **Patents** 99
291k99 Most Cited Cases

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing; thus, an applicant complies with the written-description requirement by describing the invention, with all its claimed limitations, not that which makes it obvious, and by using such descriptive means as words, structures, figures, diagrams, formulas, et cetera, that set forth the claimed invention. 35 U.S.C.A. § 112.

[5] **Patents** 99
291k99 Most Cited Cases

Patent relating to method of pain treatment, by targeting cyclooxygenase activity over prostaglandin H synthase, did not satisfy written description requirement, even though inventor made some significant discoveries in the field and patent described compound, that was necessary to practice method, in terms of its function; patent did not set forth any procedure that would necessarily lead to discovery of such compound, and it did not identify

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any particular class of compounds that contained at least one suitable member, so only means provided for finding such compound was essentially trial and error process. 35 U.S.C.A. § 112.

[6] Patents 99
291k99 Most Cited Cases

It is not necessary to give a precise chemical formula, or a description of a chemical structure, in order to satisfy the patent law's written description requirement, when persons of ordinary skill in the art can ascertain what substance is being described by resort to the public depository where a specimen of that substance is kept. 35 U.S.C.A. § 112.

[7] Patents 99
291k99 Most Cited Cases

The enablement requirement demands that a patent specification enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation. 35 U.S.C.A. § 112.

[8] Patents 314(5)
291k314(5) Most Cited Cases

Whether a patent complies with the enablement requirement is a question of law, although the ultimate legal conclusion of enablement rests on factual underpinnings. 35 U.S.C.A. § 112.

[9] Patents 99
291k99 Most Cited Cases

Enablement is determined as of the effective filing date of the patent. 35 U.S.C.A. § 112.

[10] Patents 312(1.2)
291k312(1.2) Most Cited Cases

As with the written description requirement, the burden of showing invalidity due to nonenablement is on the party asserting the defense. 35 U.S.C.A. § 112.

[11] Patents 99
291k99 Most Cited Cases

Patent relating to method of pain treatment, by targeting cyclooxygenase activity over prostaglandin H synthase, did not satisfy enablement requirement; even though patent described assay for determining whether given compound possessed certain desired characteristics, and identified some broad categories of compounds that might work, those descriptions, without more precise guidelines, amounted to little more than direction for further research with no assurance of success. 35 U.S.C.A. § 112.

[12] Patents 99
291k99 Most Cited Cases

In the enablement inquiry, the factors that may be considered in determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. 35 U.S.C.A. § 112.

[13] Patents 99
291k99 Most Cited Cases

Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable; thus, tossing out the mere germ of an idea does not constitute enabling disclosure. 35 U.S.C.A. § 112.

[14] Patents 99
291k99 Most Cited Cases

While the need for some experimentation is by no means necessarily fatal to the validity of a patent due to lack of enablement, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. 35 U.S.C.A. § 112.

[15] Patents 99
291k99 Most Cited Cases

A patent need not disclose that which is already well known in the art in order to be enabling. 35 U.S.C.A. § 112.

[16] Patents 312(6)
291k312(6) Most Cited Cases

Declarations of experts failed to support patent holder's assertion that patent relating to new generation of pain relief medication met enablement requirement, since declarations were conclusory or failed to support conclusion that patent application

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would have enabled one of ordinary skill in art to practice invention claimed in patent without undue experimentation. 35 U.S.C.A. § 112.

Patents ⇐328(2)
291k328(2) Most Cited Cases

6,048,850. Invalid.

*218 David M. Lascell, Harter, Secrest and Emery, LLP, Rochester, NY, Carol E. Heckman, Harter, Secrest & Emery, LLP, Buffalo, NY, Gerald P. Dodson, Eric S. Walters, Morrison & Foerster, LLP, Palo Alto, CA, Erica D. Wilson, Win Hwango, Steven J. Keoninger, Kenneth A. Kuwayti, Cynthia L. Lopez, Marc J. Pernick, Kanika Radhakrishnan, Jennifer L. Piel, Cathryn M. Sadler, Bryan Ward, Rachel Williams, Emily A. Evans, Erik Jeffrey Olson, Morrison & Foerster, LLP, Palo Alto, CA, Harold A. Jurland, Eric J. Wared, Ward, Norris, Heller & Reidy, LLP, Rochester, NY, for University of Rochester.

Michael Wolford, Wolford & LeClair, LLP, Rochester, NY, Henry J. Renk, Nicholas M. Cannella, Robert L. Baechtold, Fitzpatrick, Cella, Harper, Scinto, New York City, David T. Pritikin, Richard F. O'Malley, Charles W. Douglas, Sidley Austin Brown and Wood, Chicago, IL, for G.D. Searle, Inc., Monsanto Co., Pharmacia Corp.

Paul J. Yesawich, III, Harris Beach LLP, Pittsford, NY, Gerald Sobel, Richard G. Greco, Kaye, Scholar, Fierman, Hays & Handler, LLP, New York City, Sylvia M. Becker, Kaye, Scholar, Fierman, Hays & Handler, LLP, Washington, DC, for Pfizer, Inc.

DECISION AND ORDER

LARIMER, District Judge.

Patent law often involves subject matter and legal principles that can be both complex and arcane. But there are some basic principles that should be evident even to the lay person.

An "inventor" or patentee is entitled to a patent to protect his work but only if he produces or has possession of something truly new and novel. The "invention" he claims must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The inventor must be able to describe the item to be patented with such clarity that the reader is assured that the inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection.

The patent at issue here does not do that. What the reader learns from this patent is a wish or plan or first step for obtaining a desired result. What he appreciates is that the patentee had a goal for achieving a certain end result. The reader can certainly appreciate the goal but establishing goals does not a patent make. The reader also learns that the patentee had not proceeded to do what was necessary to accomplish the desired end. In my view, such an "invention" is not really one at all. As the Court of Appeals for the Federal Circuit stated in a case involving similar issues, an inadequate patent description that merely identifies a plan to accomplish an intended result "is an attempt to preempt the future before it has arrived." *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed.Cir.1993). Such a patent fails to comply with the requirements of the federal statutes concerning issuance of patents and, therefore, must be held invalid.

***219 BACKGROUND**

The patent at issue, United States Patent No. 6,048,850 ("the '850 patent") relates to a new generation of pain relief medication that does not produce certain undesirable side effects, particularly stomach irritation, associated with many other pain relievers such as aspirin, acetominophen, ibuprofen, etc. Specifically, the '850 patent claims a pharmaceutical "method for selectively inhibiting PGHS-2 activity in a human host" in which "the activity of PGHS-1 is not inhibited." '850 Patent, col. 71, lines 36-37, 43-44. PGHS-1 and PGHS-2 [FN1] are two enzymes produced by the human body. They play a role in the manufacture of hormones known as prostaglandins.

FN1. PGHS-1 and PGHS-2 are also sometimes referred to as Cox-1 and Cox-2. These terms are taken from the chemical names prostaglandin H synthase and cyclooxygenase.

Prostaglandins perform various functions; prostaglandins produced through the activity of PGHS-1, for example, are beneficial and help protect the stomach lining. PGHS-2, on the other hand, is associated with inflammatory stimuli. When those stimuli are present, production of PGHS-2 increases, which in turn leads to an increase in the

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RE: Amicus – Rochester Case

- Comments:

Norm
Here is the DNA piece on the case. Thought it might help you. Note the full text availability at the end of the article
Regards Howard

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Hyde Denies Hands-Off Policy. Rep. John Conyers Jr. (D-Mich.), the ranking minority member of the full committee, interrupted the discussion to ask former full committee chairman Rep. Henry J. Hyde (R-Ill.), whether it had not been the previous policy of the Judiciary Committee to refrain from acting on legislation that would interfere with ongoing litigation.

Hyde denied that there had been any such tradition, pointing out that the committee had often addressed issues related to abortion, which is continually subject to litigation. Furthermore, Hyde objected to the Berman amendment as "an attempt to codify moral rights," which are not generally recognized in American copyright law.

"Once this work of art is put into the stream of commerce, it seems to me the artist loses some degree of control," Hyde said.

Waters then offered an amendment that would create an exception to the bill's general exemption from infringement if the copyright owner sold or licensed copies that were edited for broadcast television or airline use. This amendment was shortly rejected by voice vote.

Finally, Berman offered what he called the "anti-profanity, anti-sex, and anti-violence amendment," which would limit the right to use skipping technology only for the purpose of shielding the viewer from such scenes.

Such a restriction, Berman said, would ensure that the bill "not provide a license to those commercial companies who make filters of a more unsavory nature," such as altering political messages or making movies more violent or more sexual.

Rep. Spencer T. Bachus III (R-Ala.) denounced Berman's amendments as "micromanaging parents" and evidence that Berman did not trust citizens to make decisions for themselves.

This amendment was also rejected by voice vote. The subcommittee then accepted by voice vote Smith's substitute bill. The bill was reported favorably out of subcommittee on a vote of 11 to 5.

BY ANANDASHANKAR MAZUMDAR

Patents/Invalidity

Federal Circuit Refuses to Rehear Case On Written Description Requirement

The U.S. Court of Appeals for the Federal Circuit on a vote of seven to five July 2 denied a petition to reconsider en banc a February panel decision that a university's patent on an arthritis treatment was invalid for failure to meet the Patent Act's written description requirement (*University of Rochester v. G.D. Searle & Co.*, Fed. Cir., No. 03-1304, 7/2/04).

The controversy over the panel's ruling that the Patent Act's written description requirement is separate from the statute's enablement requirement generated three dissenting opinions and two concurring opinions.

Panel Affirms Invalidity Ruling. The University of Rochester owns a method patent (6,048,850) for selectively inhibiting the activity of the COX-2 enzyme, while not adversely affecting the activity of the COX-1 enzyme.

The university sued G.D. Searle & Co., Pfizer Inc., and other drug manufacturers, alleging that their sale of the COX-2 inhibitor drugs Celebrex and Bextra for treatment of inflammation infringed the '850 patent. Judge David G. Larimer of the U.S. District Court for the Western District of New York granted the drug companies' motion for summary judgment of patent invalidity. 249 F. Supp.2d 216, 68 USPQ2d 1424 (W.D.N.Y. 2003) (65 PTCJ 427, 3/14/03).

The district court found that, although the '850 patent claims require the use of a "non-steroidal compound that selectively inhibits the activity of the PGHS-2 gene," the patent neither discloses any such compound nor provides any suggestion as to how such a compound could be made other than by trial-and-error research. Indeed, the court found no evidence that the inventors themselves knew of such a compound at the time their patent application was filed. The court accordingly concluded that the '850 patent claims were invalid under 35 U.S.C. § 112 for lack of written description.

The district court also found that the practice of the claimed methods would require "a person of ordinary skill in the art . . . to engage in under experimentation, with no assurance of success," and therefore, that the patent was invalid for lack of enablement.

A panel of the Federal Circuit affirmed, reasoning that the Section 112 written description requirement cannot be satisfied with generalized language that does not detail the identity of the invention. (67 PTCJ 338, 2/20/04).

Judge Alan D. Lourie rejected the university's contention that no written description requirement exists independent of the enablement requirement. Three separate requirements are contained in Section 112, the appellate court observed, pointing to the written description requirement, the enablement requirement, and the best mode requirement. Although there is often significant overlap between them, these three requirements are independent of each other, Judge Lourie insisted.

The university filed a petition for rehearing en banc.

Full Court Review Denied by Slim Majority. The petition for rehearing en banc was denied, with Chief Judge H. Robert Mayer, Judge Lourie, and Judges Paul R. Michel, Raymond C. Clevenger III, Alvin A. Schall, Timothy B. Dyk, and Sharon Prost casting the deciding votes.

Judge Pauline Newman, in a dissenting opinion, agreed with the earlier panel decision that the written description requirement must be fulfilled separately from the statute's enablement requirement. Judge Newman rejected assertions there has never been a separate written description requirement in the patent law. "It has always been necessary to disclose and describe what is patented," she wrote. The public purpose of patents would be seriously disserved by eliminating the description requirement entirely, she said.

However, Judge Newman faulted the en banc majority for refusing to resolve the "burgeoning conflict in pronouncements of this court" concerning those requirements. "The question has percolated enough; it is ripe for en banc resolution," she insisted.

Dissenting Judge Randall R. Rader, joined by Judges Arthur J. Gajarsa and Richard Linn, also advocated en banc review, but urged setting aside the "new judge-made doctrine" applied by the panel. Judge Rader maintained that the written description requirement was first applied in 1997 as a general disclosure require-

ment, rather than in its "traditional role" as a doctrine to prevent applicants from adding new inventions to an older disclosures, citing *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) (63 PTCJ 483, 4/5/02).

Judge Rader went on to trace "the confusion engendered by this new doctrine," pointing in particular to "firestorm" created by the Federal Circuit's "flip-flop" in *Enzo Biochem. Inc. v. Gen Probe Inc.*, 323 F.3d 956, 63 USPQ2d 1609 (Fed. Cir. 2002) (64 PTCJ 276, 7/19/02), where the court vacated its original decision invalidating claims to polypeptides that detect gonorrhea because the mere deposit of the claimed material did not satisfy the written description requirement. He attached a 15-page appendix summarizing the academic commentary on the *Eli Lilly* doctrine, noting that most of the articles were critical of that ruling.

In Judge Rader's view, the *Eli Lilly* doctrine "has no basis in the written description language of the original Patent Act," nor has the statute "changed in any way that justifies 'discovery' of a vast new validity doctrine over two hundred years after the 1793 Act." By imposing a "new free-standing validity requirement," Judge Rader charged, *Eli Lilly* subjects many patents in the field of biotechnology to serious and unavoidable validity challenges simply because the patent drafter may not have included lengthy nucleotide sequences that are often routinely available to those of ordinary skill in the art.

Because the panel decision does not resolve any of the confusion or provide a sound legal basis for the *Eli Lilly* doctrine, Judge Rader summed up, the court should have reviewed this case en banc.

In an additional dissenting opinion, Judge Linn, joined by Judges Rader and Gajarsa, similarly urged en banc review to overturn precedent establishing separate written description and enablement requirements. "There is simply no reason to interpret section 112 to require applicants to set forth the metes and bounds of the claimed invention in two separate places in the application," he wrote. "That is the function of the claims." While he agreed with Judge Rader that the "burden of *Lilly* and *Enzo*" has fallen on the biotech industry disproportionately, Judge Linn also asserted that "the new-found written description requirement will affect all fields of emerging technology."

Judges Lourie and Dyk filed concurring opinions, endorsing the majority's refusal to hear the case en banc. In Judge Lourie's view, there has always been a separate written description requirement in the patent law, and that requirement "poses no conflict with the role of the claims." The specification teaches an invention, and the claims define the right to exclude, Judge Lourie said.

He discounted the fact that the written description has only been relied upon in recent years as a ground of invalidity. Nor did he agree that the Federal Circuit's decisions, particularly *Eli Lilly*, have created a "heightened" written description requirement for biotechnology inventions. "Our precedent is clear and consistent and necessitates no revision of written description law," he concluded.

For his part, Judge Dyk stressed that his vote to deny en banc review "should not be taken as an endorsement of our existing written description jurisprudence." He conceded that there may come a time when en banc consideration of the proper written description standards will be appropriate. According to Judge Dyk, however, "this is neither the right time, nor the right case, in which to consider those difficult questions."

Gerald P. Dodson of Morrison & Foerster, Palo Alto, Calif., represented the University of Rochester. Gerald Sobel of Kay Scholer, New York, represented G.D. Searle & Co.

Full text at http://pub.bna.com/ptcj/031304.htm

Legislation/Trademarks

Senate Panel Considers Repeal of Law Against Enforcing Cuba-Confiscated Marks

Legislation (S. 2002 and H.R. 2494) should be enacted to repeal a law forbidding U.S. recognition of trademarks that are linked to businesses that were confiscated from their rightful owners by the Cuban government, a trademark expert and a global trade advocate told the Senate Judiciary Committee July 13. However, a former commissioner of the Patent and Trademark Office joined property rights defenders and several Florida lawmakers in calling for legislation (S. 2373 and H.R. 4225) that would "fix" a problem identified in the law by the World Trade Organization, while leaving intact its policy against enforcing confiscated marks without the permission of the original owners.

Rum Row Roils Relations. At issue during the hearing was Section 211 of the 1999 Omnibus Consolidated and Emergency Supplemental Appropriations Act (Pub. L. No. 105-277; 56 PTCJ 760, 10/22/98). That provision essentially prohibits U.S. courts from granting protection to or enforcing a trademark that is the same or substantially similar to a trademark used in connection with a confiscated business or assets, unless the original owner or "bona fide successor-in-interest" expressly agrees to the trademark's use. The legislation was specifically designed to protect trademarks belonging to businesses confiscated by the Cuban government after the 1959 Communist revolution.

Section 211 was tacked on to the budget bill after lobbying by rum-maker Bacardi Co., which bought the rights from the exiled Arechabala family to use the trademark "Havana Club" for its rum on the U.S. market. The Arechabala family owned the distillery producing Havana Club, but the distillery was seized by the Cuban government in 1960.

Meanwhile, the French spirits group Pernod Ricard challenged Bacardi's claim to the Havana Club mark on the ground that the Arechabala family abandoned the mark by failing to renew its registration in 1973. Pernod claimed that the mark was registered with the PTO in 1976 and later transferred to Havana Club Holding S.A., a joint venture that Pernod set up with Cuba in 1993.

In February 2000, the U.S. Court of Appeals for the Second Circuit upheld Bacardi's right to use the name. *Havana Club Holding S.A. v. Galleon S.A.*, 203 F.3d 116, 53 USPQ2d 1609 (2d Cir. 2000) (59 PTCJ 546, 2/11/00). The court agreed with a 1999 lower court ruling that Havana Club Holding had no right to use the mark in the United States. 62 F. Supp. 1085, 50 USPQ2d 1889 (S.D.N.Y. 1999) (57 PTCJ 544, 4/29/99). Both courts reasoned that Pernod's efforts to protect the Ha-

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