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This Article discusses drug pricing in the context of federally funded inventions. It examines the "march-in" provision of the Bayh-Dole Act, a federal statute that governs inventions supported in whole or in part by federal funding. It discusses technology-transfer activity as a whole and the often-conflicting roles of the government, academia, and industry. The Article discusses the mechanisms of the Bayh-Dole Act and examines its legislative history. It notes that the Act has had a powerful price-control clause since its enactment in 1980 that mandates that inventions resulting from federally funded research must be sold at reasonable prices. The Article concludes that the solution to high drug prices does not involve new legislation but already exists in the unused, unenforced march-in provision of the Bayh-Dole Act.

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† Professor of Law, Cleveland State University College of Law; Registered to Practice Before the U.S. Patent & Trademark Office in Patent Matters. J.D. 1975, Hofstra Law School; LL.M 1979, Harvard Law School. I would like to thank Dr. Arno for teaching me about co-authorship. Having co-authored less than a handful of pieces at the time Peter and I started this collaboration, I thought of co-authorship as a convenient way to share the work; as time passed, I came to think of it as a way to share the blame; as even more time passed and the work was completed, I finally realized that it was really a way to share the pain, for which I apologize. I must also express my sincere appreciation to C.S.U. law library's Marie Rehmar, one of the world's two greatest reference law librarians. This Article owes much of its completion to two generous grants from the Cleveland-Marshall Fund, for whose patience I am most grateful.

I. INTRODUCTION

It is widely believed that advances in drug development and biomedical technology over the next few decades will revolutionize the delivery of health care, reduce mortality and morbidity, and improve the quality of life for individuals afflicted by many life-threatening conditions.[1] An apparent nirvana of high technology seems within reach, and yet the dark shadow of exploitation and a growing disparity of access lurks, threatening a loss of democratic control over the necessities of life through corporate domination of economic and political freedoms. Increasingly, the combined efforts of government, industry, and academia are advancing free trade in both domestic and international fora. However, the immediate, financial fruits of these achievements appear, for the most part, to adduce to private participants. The relationships among these players have an enormous impact on the costs of health care, the health of the American public, the nation's competitive position in the global economy, and the integrity, quality, and independence of science. In light of the controversies, the evolving approach to these public-private relationships in health-related research demands scrutiny.[2]

1. RUTH E. BROWN ET AL., THE VALUE OF PHARMACEUTICALS: AN ASSESSMENT OF FUTURE COSTS FOR SELECTED CONDITIONS 3 (1991).

2. It is difficult to call such often one-sided relationships partnerships. Not only is there little question that the real winners here are private entities, but the government, when reviewing the results, reports these private gains in what can only be characterized as a contentedly sanguine manner:

> Two major beneficiaries of this federal spending have been universities and U.S.-based corporations. The universities benefited because the government was

The failure of the Clinton health plan, the apparently growing domination of medical care by what are effectively legally immune health maintenance organizations (HMOs),[3] and the stranglehold over pharmaceuticals by the drug industry, have led to feelings of frustration, impatience, and anger over unmanageable and unaffordable health care in the United States.[4] Complaints about the high cost of medical care have settled, to a substantial extent, on the costs of pharmaceuticals, which have grown faster than other components of health care in recent years. Even the medical establishment, long a conservative force, has begun to ask why drug prices are so high[5] and why there is no way to regulate them, as is done in so many foreign countries.[6] Many drugs, of course, are produced through joint public and private efforts, and though it would seem logical to use this as a leverage point to regulate drug prices,[7] the critics remain so silent on that point that it seems almost conspiratorial.[8]

In fact, as this Article will show, a leverage point is available through an existing statutory remedy in the Bayh-Dole Act.

willing to underwrite basic research that may not lead to the creation of new and profitable products or services in the near term. The corporations benefited from the products and services they were able to develop for the government itself as well as from the "spin-off" process, whereby the results of government-sponsored research could be used to develop products and services for the private sector.

U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-98-06, TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES 2 (1998) [hereinafter ADMINISTRATION OF THE BAYH-DOLE ACT].

3. *See* Pegram v. Herdrich, 120 S. Ct. 2143, 2147 (2000); N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 658-62, 668 (1995). In *Pegram*, the United States Supreme Court affirmed a lower court's holding that ERISA preempted claims against an HMO and that the HMO could not be sued under ERISA for breach of fiduciary duty. *Pegram*, 120 S. Ct. at 2158.

4. *See* Alan M. Garber & Paul M. Romer, *Evaluating the Federal Role in Financing Health-Related Research*, 93 PROC. NAT'L ACAD. SCI. 12,717, 12,717–24 (1996).

5. *See* Marcia Angell, *The Pharmaceutical Industry—To Whom Is It Accountable?*, 342 NEW ENG. J. MED. 1902, 1902-04 (2000).

6. Lucette Lagnado et al., *Dose of Reality*, WALL ST. J., Feb. 19, 1999, at A1; *Drug Pricing: Poor Prescription for Consumers and Taxpayers? Hearing Before the S. Comm. on Governmental Affairs*, 103d Cong. 11-14, 65-70 (1994) [hereinafter *1994 Drug Pricing Hearing*] (testimony and statement of Peter Arno, Ph.D., Assoc. Professor, Albert Einstein Coll. of Med.).

7. *See* 35 U.S.C.A. §§ 200-212 (West 1984 & Supp. 2000).

8. In the area of health care, there is some historical reason to resist labeling conspiracy theories as mere paranoia. *See* United States v. Kubrick, 444 U.S. 111, 128 n.4 (1979) (Stevens, J., dissenting) (suggesting that doctors are reluctant to inform patients that previous treatments provided by other doctors were performed negligently); Richard M. Markus, *Conspiracy of Silence*, 14 CLEV.-MARSHALL L. REV. 520, 521-22 (1965) (discussing the "conspiracy of silence" that exists in medical malpractice cases, caused by medical professionals' unwillingness to testify against one another).

Traditionally, there has been little explicit articulation of industrial policy in the United States. However, an increasing climate of globalization and a competitive international marketplace have led many policy makers (including those in recent administrations) to support greater planning and collaboration between the public and private sectors.[9] This Article explores the recent evolution of policies designed to transfer technology between the public and private sectors—although it is more accurate to say that they are, for the most part, transfers from the public *to* the private sector—and the appropriate means by which to do so. One fundamental thematic question that runs throughout this Article is, do American taxpayers, who fund a substantial portion of health-related research and development (R&D), receive a fair return on their investment? In a capitalist economy, it is remarkable that, to speak of public taxpayer returns on health-related R&D, one must limit the discussion to nonmonetary returns because the taxpayers seldom, if ever, see a financial return.[10]

The purported goal of the public-private relationships discussed is to serve the public interest by developing and commercializing inventions made with federal funding through the transfer of technology, resources, personnel, and expertise among federal government agencies, industry, and academia. Some have argued that the public interest is best served by aggressive efforts to encourage industry to commercialize products developed by academic or government scientists.[11] They point to the benefits of effective new therapies, the creation of new jobs, and the enhancement of private

9. The "partnership" between the Clinton administration and private industry had become so great—in the areas of (1) the first Clinton administration's health plan; (2) the greater globalization marked by NAFTA, GATT, and the entry of China into the WTO; and (3) the use of national statutory trade policies to assist private industry—that some have called the administration a "traitor" to the traditional goals of the Democratic party. Walter A. McDougall, *Tale of Two Presidents*, N.Y. TIMES, June 22, 2000, at A30 (letter to the editor) ("Mr. Clinton has likewise served to consolidate the Reagan revolution by balancing the budget, reforming welfare and unleashing the private sector. That explains . . . why much of the American left considers Mr. Clinton a traitor.").

10. The federal government receives less than a 1% return in royalties on government inventions. *See infra* text accompanying notes 40-42.

11. Indeed, commercialization of products developed by academic or government scientists is the purported justification for the Bayh-Dole Act—at least insofar as it adopted a "title," as opposed to a "licensing," approach to government-developed patents—and the legislative history is replete with claims that granting title, as opposed to a mere license, to federal contractors would speed and enhance technological progress. *Government Patent Policy: Hearings Before the Subcomm. on Sci., Research & Tech. of the House Comm. on Sci. & Tech.*, 96th Cong. 4-5 (1979) [hereinafter *1979 Government Patent Policy Hearings*] (statement of Hon. Harrison H. Schmitt, U.S. Senator, N.M.); S. REP. NO. 96-480, at 16, 27-30 (1979).

industry. The critics of this view believe that industry is not sufficiently accountable for its use of publicly funded resources and that the taxpayer's return on investment has been inadequate.[12] To support this argument, these critics cite the high price of goods that are supported by government funds through direct grants, licensing arrangements, corporate tax credits, and allowances.[13] They also argue that R&D subsidies distort investment and consumption incentives and introduce interest group pressures that can obscure market signals.[14]

The premise of this Article is that these public-private relationships all too frequently rest on untested and unsupported assumptions and that, even accepting those assumptions on faith, the mechanisms established to police these public-private relationships have been either ignored or misunderstood.[15] However, some claim that without them, the results of some meritorious publicly funded and

12. Witness the recent Sanders Amendment to the House appropriations bill, which required that federally-funded inventions be subject to reasonable pricing requirements—or, more accurately, insisted that march-in rights created by the Bayh-Dole Act be enforced to assure the reasonable pricing of such drugs. 146 CONG. REC. H4231 (daily ed. June 13, 2000) (statement of Rep. Sanders). The text of the Sanders Amendment is as follows:

> None of the funds made available in this Act for the Department of Health and Human Services may be used to grant an exclusive or partially exclusive license pursuant to chapter 18 of title 35, United States Code, except in accordance with section 209 of such title (relating to the availability to the public of an invention and its benefits on reasonable terms).

Id.

13. *See Health Care Reform: Hearings Before the Subcomm. on Health & the Env't of the House Comm. on Energy & Commerce*, 103d Cong. 591-96 (1994) (testimony of Abbey S. Meyers, President, Nat'l Org. for Rare Disorders); James P. Love, *The Other Drug War: How Industry Exploits Pharm Subsidies*, AMERICAN PROSPECT, Summer 1993, at 121, 121-22; Linda Marsa, *Unhealthy Alliances*, OMNI, Feb. 1994, at 36, 38-42.

14. U.S. OFFICE OF TECH. ASSESSMENT, MULTINATIONALS AND THE U.S. TECHNOLOGY BASE: FINAL REPORT OF THE MULTINATIONALS PROJECT 12 (1994).

15. A recent federal report on the administration of the Bayh-Dole Act reveals that there have been no enforcement actions and states:

> Federal agencies' administration of the Bayh-Dole Act as it applies to research universities is decentralized. While the Department of Commerce has issued implementing regulations and provides coordination under limited circumstances, the act actually is administered by the agencies providing the funds. The agencies' activities consist largely of ensuring that the universities meet the reporting requirements and deadlines set out in the act and regulations. According to Commerce officials, no agency has yet taken back the title to any inventions because they were not being commercialized.

ADMINISTRATION OF THE BAYH-DOLE ACT, *supra* note 2, at 1-2; *see also infra* notes 294-313 and accompanying text (discussing the failure of the NIH to apply the appropriate criteria for government march-in rights to the *CellPro* litigation).

conducted research would remain unavailable to the public.[16] Nonetheless, this Article asserts that the delicate mechanisms established to ensure that the fruits of these public investments are not abused have gone unnoticed or, worse, have been concealed.[17]

II. HEALTH-RELATED FEDERAL RESEARCH AND DEVELOPMENT

The U.S. government plays a key role in various stages of health-related R&D. Along with conducting and funding research, its support of educational institutions and training of young scientists have fostered and developed the world's premier biomedical infrastructure. Government-funded basic research has been largely responsible for the emergence and growth of the biotechnology industry.[18] The funding goes beyond basic research, of course; if it did not, it would not yield so many patentable inventions, because patents are not available for pure research, but only for those applications of basic research that have reached the level of concrete and demonstrable utility.[19] However, industry habitually claims sole credit for actual commercialization.[20]

Notwithstanding these claims, the government's funding of health-related R&D is, in fact, substantial. In 1995, the last year that the government collected and published data on public expenditures for health-related R&D, these expenditures reached $15.8 billion and represented 44% of the nation's total spending on such R&D.[21] In contrast, industry's contribution to health-related R&D in that year

16. U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-95-52, TECHNOLOGY TRANSFER S: BENEFITS OF COOPERATIVE R&D AGREEMENTS 9-10 (1994) (providing an example of how a public-private research endeavor benefited children born with birth defects).

17. *See infra* text accompanying notes 294-315 (analyzing the *CellPro* litigation).

18. *See* LYNNE G. ZUCKER ET AL., INTELLECTUAL CAPITAL AND THE BIRTH OF U.S. BIOTECHNOLOGY ENTERPRISES 20 (Nat'l Bureau of Econ. Research, Working Paper No. 4653, 1994).

19. Nothing can be patented unless it first satisfies, among other elements, the demonstrable utility requirement of the Patent Act. *See* 35 U.S.C. § 101 (1994).

20. *See* Jeff Gerth & Sheryl Gay Stolberg, *Drug Makers Reap Profits on Tax-Backed Research*, N.Y. TIMES, Apr. 23, 2000, at A1; Peter G. Gosselin & Paul Jacobs, *DNA Device's Heredity Scrutinized by U.S.*, L.A. TIMES, May 14, 2000, at A1.

21. *See* NAT'L INSTS. OF HEALTH, FEDERAL OBLIGATIONS FOR HEALTH R&D, BY SOURCE OR PERFORMER: FISCAL YEARS 1985-1999, *available at* http://silk.nih.gov/public/cbz2zoz.@www.awards.sourfund.htm (last modified Nov. 30, 1999) [hereinafter NIH FEDERAL OBLIGATIONS]. It should be noted that there have been no figures published since 1995, the last year that the National Institutes of Health (NIH) collected this data. It may seem astonishing, or merely suspicious, but no government agency has maintained these statistics since that date. NAT'L INSTS. OF HEALTH, ESTIMATES OF NATIONAL SUPPORT FOR HEALTH R&D BY SOURCE OR PERFORMER, FY 1986-1995, *available at* http://grants.nih.gov/grants/award/trends96/pdfdocs/FEDTABLA.PDF.

was $18.6 billion, or 52% of the nation's total.[22] By projecting public and private R&D expenditures from 1986 through 1995, total national spending on health-related R&D in 1999 was an estimated $45.5 billion: $19.2 billion contributed by government (42% of the total), $24.8 billion contributed by industry (55% of the total), and the balance funded by private nonprofit sources (3% of the total).[23] However, these figures on health-related R&D exclude the phenomenally valuable tax credits and deductions that effectively constitute a public investment in these private enterprises.[24] Moreover, the shift to managed care has increased pressures to augment public funding and thus tip the balance even more toward public investment without any clear policing mechanisms.[25]

Because its taxes pay for them, the public has certain claims or rights, both moral and legal, to government-funded inventions. Public funding through the National Institutes of Health (NIH) is the most obvious and direct source of taxpayer support for health-related

22. NIH FEDERAL OBLIGATIONS, *supra* note 21.

23. We chose to use a linear extrapolation based on historical data to estimate expenditures for 1999 because the government stopped collecting comprehensive data in 1995. This seems to be a more reasonable approach than using either industry-generated data or estimates of specific sectors by the NIH. The NIH's most recent estimate of total federal spending on health-related R&D in 1999 is $17.2 billion. *See* NIH FEDERAL OBLIGATIONS, *supra* note 21. However, these figures do not include state and local government spending, which, in 1995, totaled $2.4 billion. The pharmaceutical industry's own estimate of its R&D for 1999 is $24 billion. *See* PHARM. RESEARCH & MFRS. OF AM. (PHRMA), THE PHARMACEUTICAL INDUSTRY'S R&D INVESTMENT, *available at* http://www.phrma.org/publications/backgrounders/development/invest.phtml (last updated Feb. 1, 2000).

24. Memorandum from Gary Guenther, Analyst in Business Taxation and Finance, to Joint Economic Committee 1-7 (Dec. 13, 1999) (on file with author) [hereinafter Guenther Memorandum] (finding that "net income in the drug industry was taxed relatively lightly between 1990 and 1996" and "that the drug industry realized significant tax savings from five tax provisions: the foreign tax credit, the possessions tax credit, the research and experimentation tax credit, the orphan drug tax credit, and the expensing of research expenditures").

25. One commentator described this phenomenon, highlighting the potential drawbacks of the shift to managed care:

> At the same time, a third force—the move toward managed care in the delivery of health care services—pushes in the other direction. This change in the market for health care services is desirable on many grounds, but to the extent that it reduces utilization of some medical technologies, it will have the undesirable side effect of diminishing private sector incentives to conduct research leading to innovations in health care. Everything else equal, this change calls for increased public support for biomedical research. In the near term, the best policy response may therefore be one that combines expanded government support for research in some areas with stronger property rights and a shift toward more reliance on the private sector in other areas.

Garber & Romer, *supra* note 4, at 12,724.

R&D.[26] However, tax deductions and tax credits taken by pharmaceutical corporations are another major indirect source of taxpayer support for health-related R&D.

Since 1954, the tax code has encouraged all U.S. taxpaying firms to invest in R&D by allowing them to deduct R&D expenditures from their taxable income.[27] In addition to tax deductions, firms receive a variety of tax credits for increasing research expenses.[28] Tax credits that companies receive under section 936 of the Internal Revenue Code for manufacturing products in Puerto Rico constitute one of the most substantial tax subsidies to the pharmaceutical industry.[29] The pharmaceutical industry has received approximately half of the total tax benefits from section 936.[30] From 1980 through 1990, the General Accounting Office (GAO) estimated that twenty-six pharmaceutical companies had tax savings of $10.1 billion from Puerto Rico operations and that these tax savings translated into $24.7 billion (1990 dollars) in tax-exempt earnings.[31] What is more surprising is that the tax benefits received by pharmaceutical firms were nearly three times the compensation paid to their employees, an odd finding given the fact that when Congress enacted section 936 in 1976 it sought to help Puerto Rico obtain employment-generating investments.[32] Partially in response to the windfall savings received by the pharmaceutical industry, section 936 tax benefits were to be reduced and then eventually phased out.[33]

In addition to the possessions, or Puerto Rico, tax credit, the pharmaceutical industry has realized significant tax savings from at least three other tax provisions: the foreign tax credit, the orphan drug

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26. The NIH is the lead public agency supporting health-related R&D; it funds more than 80% of all federal government spending in this area. *See* NIH FEDERAL OBLIGATIONS, *supra* note 21.

27. I.R.C. § 174 (1994).

28. *See* U.S. OFFICE OF TECH. ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS AND REWARDS 183-99 (1993).

29. I.R.C. § 936 (Supp. IV 1998).

30. U.S. GEN. ACCOUNTING OFFICE, GAO/GGD-92-72BR, PHARMACEUTICAL INDUSTRY: TAX BENEFITS OF OPERATING IN PUERTO RICO 4 (1992).

31. *Id.* at 5.

32. *See id.* at 1, 4.

33. One expert summarized the impact of section 936 as follows:

> The possessions credit, which is being phased out under the Small Business Job Protection Act of 1996, encouraged drug firms to establish a significant manufacturing presence in Puerto Rico and other U.S. territorial possessions by giving a tax credit equal to the entire amount of federal income tax liability on possessions-source income.

Guenther Memorandum, *supra* note 24, at 6.

tax credit, and the general business tax credit.[34] These tax provisions not only provide a significant public subsidy to the pharmaceutical industry, but they also help it maintain one of the lowest effective tax rates and one of the highest after-tax profit rates of any industry.[35] Between 1990 and 1996, these four tax provisions generated savings of $27.9 billion for the pharmaceutical industry; specifically, it saved $4.5 billion in 1996.[36] The provisions do not distinguish between short-term, bottom-line investments and longer-term, riskier investments that may yield products fifteen or twenty years later.[37] Nor are the provisions associated with any requirement that the tax credit be used for R&D, rather than for administration or marketing expenses. For the pharmaceutical industry, administration or marketing expenses overshadow purported R&D expenses by a factor of three.[38] Moreover, there are claims that the pharmaceutical industry inflates its R&D expenses by including administration and marketing costs.[39]

The vast public resources devoted to health-related research through direct government funding or indirectly through the tax code underscore the importance of determining whether adequate benefits are accruing to the American public. In the entire ten-year period from 1985 through 1994, the NIH received slightly under $76 million in royalties, including $40 million from just one license, the HIV antibody test kit.[40] This represents less than 1% of the NIH's intramural funding during this time period. During the next seven-year period, from 1993 through 1999, total royalties were almost $200 million, reaching an annual peak in 1999 of almost $45 million, which

34. *Id.*

35. *See id.* at 2-5.

36. *Id.* at 6-7.

37. *Is Today's Science Policy Preparing Us for the Future? Hearing Before the House Comm. on Sci.*, 104th Cong. 36 (1995) (testimony of Hon. Ronald H. Brown, Sec'y, Dep't of Commerce) ("However, the R&E tax credit does *not* differentiate between investments directed toward short-term product delivery and longer term, higher risk investments that will yield products fifteen or twenty years into the future.").

38. *A Brave New World*, MEDADNEWS, Sept. 1999, at 3, 6-10.

39. As one commentator explained:

> The marketing budgets of the drug industry are enormous—much larger than the research and development costs—although exact figures are difficult to come by, in part because marketing and administrative expenses are often folded together and in part because some of the research and development budget is for marketing research.

Angell, *supra* note 5, at 1903.

40. NAT'L INSTS. OF HEALTH, NIH TECHNOLOGY TRANSFER ACTIVITIES FY1993-FY1999, *available at* http://ott.od.nih.gov/newpages/webstats99.pdf (last visited Jan. 21, 2001).

is more than triple the 1993 amount.[41] The royalties still represent, however, less than 1% of the NIH's funding for 1999.[42] Whatever can be said of the scientific advances made with this public investment, the concrete financial return to taxpayers is minimal. But perhaps more importantly than the absence of any concrete return is the inevitability of even greater public or consumer expenditures demanded by the monopolies obtained by industry over publicly financed inventions, and the resulting supracompetitive profits and prices. The public has already paid for the cost of research. The government's failure to police these economic abuses is the untold scandal of federally financed inventions and of the failure of the Bayh-Dole Act, which was meant to provide that policing.

III. AN OVERVIEW OF TECHNOLOGY-TRANSFER ACTIVITY

Prior to the 1980s, there was effectively a free market technology-transfer policy in the United States.[43] For the most part, the government argued that if public funds produced patentable inventions, then title to those inventions should remain with the government and the public.[44] Despite the fact that government patent rights were available to all on a come-one-come-all basis, that free and unregulated situation paradoxically led to a large number of government-owned patents that were not licensed.[45] Industry had insufficient incentive to commercialize government-developed inventions, because federal research was disseminated without restriction.[46] The lack of commercialization persisted despite the fact

41. *Id.*

42. NIH FEDERAL OBLIGATIONS, *supra* note 21.

43. *See* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1663-64 (1996).

44. *Cf. id.* at 1663 ("Previous legislation had typically encouraged or required that federal agencies sponsoring research make the results widely available to the public through government ownership or dedication to the public domain.").

45. *See* James V. Lacy et al., *Technology Transfer Laws Governing Federally Funded Research and Development*, 19 PEPP. L. REV. 1, 8 (1991).

46. The evidence marshaled to support this claim is elusive at best. A few voices noted, when the Bayh-Dole Act was being considered, that figures on the utilization of government patents were hopelessly insufficient because the government did not enforce those patents—to the contrary, it gave them away on a come-one-come-all basis—and thus had no way of knowing, in any respect at all, how much of its patented technology was being used by others. *See, e.g.*, *Patent and Trademark Law Amendments of 1980: Hearings on H.R. 6933 Before a Subcomm. of the House Comm. on Gov't Operations*, 96th Cong. 79-83 (1980) [hereinafter *1980 House Gov't Operations Hearings*] (statement of Adm. H.G. Rickover, Deputy Commander for Nuclear Power, Naval Sea Sys. Command); *Patent Policy: Hearings on S.1215 Before the Subcomm. on Sci., Tech., & Space of the S. Comm. on Commerce, Sci., & Transp.*, 96th Cong. 389-396 (1979) [hereinafter *1979 Senate Sci.*

that, because all R&D had been completed, much of the risky investment had already been made by the government.[47]

There were some exceptions in which patent rights were not made available on this come-one-come-all basis. Between World War II and 1980, for instance, patent policy for inventions made with government resources was often based on statutes governing specific agencies.[48] The Department of Defense, for instance, permitted contractors to acquire exclusive commercial rights to inventions while obtaining a royalty-free license for itself.[49] The Federal Aviation Administration's policy was to retain all invention rights in its contracts for R&D as well as to recoup development costs from industry.[50] Notwithstanding these exceptions, the bulk of government inventions, and certainly almost all health-related inventions, were freely available to private industry. While the Department of Health, Education, and Welfare (HEW) formally retained full rights to its intramural inventions and those developed under its research contracts, it in fact excluded no one from this technology.[51] Historically, HEW's policy objective was to make the results of its research freely available to the public. This was done by patenting or publishing inventions and by issuing nonexclusive licenses to all applicants.[52] While the stated policy objective of the Department (now known as the Department of Health and Human Services (HHS)) has not changed,[53] post-1980 technology-transfer legislation removes many federally supported inventions from government ownership and places them in the private sector.[54] This legislation represents a massive shift of the fruit of public investment to the private sector.

Hearings] (statement of Adm. H.G. Rickover); *The University and Small Business Patent Procedures Act: Hearings on S.414 Before the S. Comm. on the Judiciary*, 96th Cong. 159-71 (1979) [hereinafter *1979 Senate Judiciary Hearings*] (testimony of Adm. H.G. Rickover); *Government Patent Policies: Hearings Before the Subcomm. on Monopoly & Anticompetitive Activities of the S. Select Comm. on Small Bus.*, 95th Cong. 3-53 (1977) [hereinafter *1977 Senate Small Bus. Hearings*] (testimony and statement of Adm. H.G. Rickover).

47. *See* Eisenberg, *supra* note 43, at 1668, 1680.

48. Eisenberg, *supra* note 43, at 1671-95; Lacy et al., *supra* note 45, at 3-10.

49. Lacy et al., *supra* note 45, at 6.

50. Parke M. Banta & Manuel B. Hiller, *Patent Policies of the Department of Health, Education, and Welfare*, 21 FED. B.J. 89, 98 n.36 (1961).

51. *Id.* at 93.

52. 45 C.F.R. § 6 (1960), *rescinded by* 61 Fed. Reg. 54,743, 54,743-44 (Oct. 22, 1996) (effectuating the removal of obsolete patent regulations); Banta & Hiller, *supra* note 50, at 93.

53. *See* 45 C.F.R. § 6 (1960). For current government policy, as enacted by the Department of Commerce, which has assumed overall responsibility for regulating inventions and patents, see 37 C.F.R. pt. 401 (2000).

54. *See* Eisenberg, *supra* note 43, at 1663-64.

In 1963, President Kennedy attempted to standardize the federal patent system by issuing a memorandum that recognized that the rights to publicly funded, health-related inventions should remain in government.[55] Prior to the issuance of the memorandum, a system of waivers had developed under which various government agencies either waived rights to title entirely or granted exclusive licenses to the contractor.[56] Some agencies had resorted to waivers so much that the term became a misnomer, and the basic policy of the agency actually became one of presumptive licensing or title.[57] When Kennedy promoted a standardization of the patent system, he recommended that the government retain principal rights when the invention was commercially useful to the general public or useful for public health and welfare, or when government was the principal developer in the field.[58] In contrast to Kennedy's policy, much of the technology-transfer legislation introduced in the 1980s—including, of course, the Bayh-Dole Act—does not consider the social utility of an invention, such as its impact on public health, for the purpose of assigning a new patent. However, some statutory regimes in those areas unaffected by the Bayh-Dole Act still consider social value as a part of the decision to either license or wholly transfer title.[59] At the present time, there are a number of laws, such as the Bayh-Dole Act, that address technology transfer and that also provide price-control mechanisms. Unfortunately, these mechanisms, especially and most specifically the "march-in" provisions, have never been enforced and seem to be purposely disregarded, even though they effectively provide price control over research performed under most, though not all, federal programs.[60] A description of the major pieces of current technology transfer legislation follows.

55. *See* Memorandum for the Heads of Executive Departments and Agencies (Government Patent Policy), 3 C.F.R. 861 (1959-1963).

56. *See 1979 Senate Judiciary Hearings*, *supra* note 46, at 3; *1977 Senate Small Bus. Hearings*, *supra* note 46, at 3.

57. *See 1979 Senate Judiciary Hearings*, *supra* note 46, at 183; *1977 Senate Small Bus. Hearings*, *supra* note 46, at 3 ("[T]oday, many Government agencies routinely grant contractors exclusive rights . . . .").

58. *See* Memorandum for the Heads of Executive Departments and Agencies (Government Patent Policy), 3 C.F.R. 861 (1959-1963).

59. *See, e.g.*, 35 U.S.C. § 209(c)(1)(A) (1994) (considering whether "the interests of the Federal Government and the public will best be served" by granting a license). Outside the small business blanket transfer policy of the Bayh-Dole Act, and without regard to presidential directives, agency discretion to grant exclusive or nonexclusive licenses is theoretically cabined by the requirement to consider the "interests of the Federal Government and the public." *Id.*

60. The GAO asserts that "the basic provisions of the act—which apply only to universities, other nonprofit organizations, and small businesses—were extended to large

Stevenson-Wydler Technology Innovation Act of 1980.[61] The Stevenson-Wydler Act made technology transfer a mission of government-owned, contractor-operated laboratories.[62] It also required that all federal labs establish an Office of Research and Technology Applications.[63]

Bayh-Dole University and Small Business Patent Act of 1980.[64] The Bayh-Dole Act was designed to promote interaction between industry and academia by allowing universities to license inventions developed with federal funds to private companies.[65] The Act allows nonprofit and small business government contractors to retain title to, and obtain royalties from, most government-funded inventions.[66] A 1987 presidential memorandum instructed federal agencies to apply some Bayh-Dole rights to all contractors, regardless of their size.[67] This regime applies to virtually all research funded by the

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businesses by Executive Order 12591, dated April 10, 1987." ADMINISTRATION OF THE BAYH-DOLE ACT, *supra* note 2, at 4. It is probably true that most transfers, whether by title or licensing, are subject to the march-in provisions as well as the reasonable pricing requirements imposed by the "practical application" mandate of the Act, though this Article is limited to a discussion of the Bayh-Dole Act. *See infra* note 67.

61. 15 U.S.C.A. §§ 3701-3717 (West 1998 & Supp. 2000).
62. *Id.* §§ 3701(3), (8), (10), 3702(2)-(3), 3704(c)(11)-(12), 3710a.
63. *Id.* § 3710(b).
64. 35 U.S.C.A. §§ 200-212 (West 1984 & Supp. 2000).
65. *Id.*
66. *Id.* § 201(a).
67. *See* Exec. Order No. 12,591, 3 C.F.R. 220 (1988). However, at least with respect to Cooperative Research and Development Agreements (CRADAs) and other similar arrangements, the issue of the application of the Bayh-Dole Act to all contractors is unresolved. Two executive orders frequently cited in this area are Executive Order 12,591 and Executive Order 12,618. Although both orders do extend the reach of the Bayh-Dole Act to funding recipients other than small businesses and nonprofits, they do so primarily only with respect to § 202(7), which simply provides parameters for how royalties are to be divided between the government and others. The more relevant provision of the Bayh-Dole Act with respect to its application to such recipients is § 210(c). It demonstrates that Congress intended that the Act, at least with respect to the price-control march-in provision (§ 203), should apply to virtually all recipients of government funds. Section 210(c) provides, "Nothing in this chapter is intended to limit the authority of agencies . . . except that all funding agreements, *including those with other than small business firms and nonprofit organizations*, shall include the requirements established in . . . section 203 . . . ." 35 U.S.C. § 210(c) (1994) (emphasis added). The only qualification is that contained in § 210(e), which states that the provisions of the Stevenson-Wydler Technology Innovation Act of 1980, the Act that authorizes CRADAs, "shall take precedence . . . to the extent they permit or require a disposition of rights . . . inconsistent with this chapter." *Id.* § 210(e). Whether there are such inconsistencies is arguable, especially in view of 15 U.S.C. § 3710a(b)(1)(B)(i), which allows for licensing to a "responsible applicant . . . on terms that are reasonable," but because such licensing can only be done when there are "health or safety needs that are not reasonably satisfied by the collaborating party," an argument can be made that this specifically excludes the "practical application" requirement. 15 U.S.C. § 3710a(b)(1)(C)(i) (Supp. III 1997).

government,[68] either in whole or in part, and effects a price-control strategy to insure that private industry does not abuse what would otherwise be a massive giveaway of public investment.[69] This price-control mechanism has never been implemented or publicly discussed or explained by any administration and apparently has been grossly misunderstood by bureaucrats, including, recently, the NIH itself.[70]

Federal Technology Transfer Act of 1986 (FTTA).[71] The FTTA was a 1986 amendment to the Stevenson-Wydler Act. It encouraged federal laboratories to work cooperatively with universities or the private sector by allowing government-owned and -operated laboratories to enter directly into Cooperative Research and Development Agreements (CRADAs) with industry and universities.[72] The legislation permits laboratories to assign a patent or grant a manufacturing license to cost-sharing CRADA partners.[73] The Act also requires that government inventors share in royalties from patent licenses.[74] To the extent, however, that CRADAs are also

68. There seems to be disagreement in some areas, wholly outside pharmaceutical research, about whether the Bayh-Dole Act controls other programs with which it overlaps, including, for instance, those of the Advanced Research Projects Agency of the Department of Defense (ARPA). The Bayh-Dole Act comes into play when the research is conducted under a government "funding agreement," which is further defined in the statute to be a "contract, grant, or cooperative agreement." 35 U.S.C. § 201(b) (1994). Congress has endorsed the view that ARPA's "other transactions" fall outside the scope of the Bayh-Dole Act. The conference report of the House and Senate Armed Services Committees on the National Defense Authorization Act for Fiscal Year 1992 stated:

> The conferees also recognize that the regulations applicable to the allocation of patent and data rights under the procurement statutes may not be appropriate to partnership arrangements in certain cases. The conferees believe that the option to support "partnerships" pursuant to section 2371 of title 10, United States Code, provides adequate flexibility for the Defense Department and other partnership participants to agree to allocations of intellectual property rights in a manner that will meet the needs of all parties involved in a transaction.

NASA Procurement in the Earth-Space Economy: Hearing Before the House Comm. on Sci., 104th Cong. 26, 36 (1995) (testimony of Richard L. Dunn, Gen. Counsel, Advanced Research Projects Agency).

69. The price-control mechanism, of course, is the requirement that contractors or their licensees achieve "practical application," which is uniformly defined by statute as requiring that the invention be supplied to the public on "reasonable terms." 35 U.S.C. § 201(f) (1994). Section 201(f) and its accompanying legislative history make clear that the focus should be on price. *See infra* notes 175-227 and accompanying text.

70. As we discuss *infra* notes 294-313 and accompanying text, the NIH failed to understand and apply, in the *CellPro* case, the requirement for "practical application" mandated by the Bayh-Dole Act, collapsing it into a much simpler, but nonexistent, mandate for mere utilization.

71. 15 U.S.C.A. §§ 3701-3714 (West 1998 & Supp. 2000).

72. *See id.* § 3702(5).

73. *Id.* § 3710a(b)(2).

74. *Id.* § 3710c.

government-funded, in whole or in part, or to the extent that the Bayh-Dole Act's definition of funding (which includes cooperative agreements)[75] embraces CRADAs irrespective of literal funding, they may nevertheless also be regulated by the Bayh-Dole Act and thus subject to its unexercised price-control mechanism.[76] The FTTA gives federal labs the option to retain intellectual property rights to work that has been jointly developed with private parties.[77] Industry concern that the government had retained a channel for claiming rights to jointly developed work led to proposed legislation in 1993 that would have amended the FTTA to mandate that the private collaborator be granted title to jointly developed projects.[78] The bill was defeated, but it was reintroduced in June 1995 and passed with some changes in 1996.[79] The law as it now stands gives the federal lab the option to grant the collaborating party an exclusive license.[80]

Section 5171 of the Omnibus Trade and Competitiveness Act of 1988.[81] Section 5171 requires that federally supported international science and technology agreements be negotiated to ensure that intellectual property rights are properly protected.[82] Again, the Bayh-Dole Act would still apply as another layer of public protection, including, most importantly, its price-control mechanism.

National Competitiveness Technology Transfer Act.[83] This Act is a 1989 amendment to the Stevenson-Wydler Act that extends the CRADA authority of the FTTA to labs owned by the government and operated by private contractors.[84] Once again, as long as the arrangements involve federal funding, the Bayh-Dole Act and its price-control mechanism might constitute another layer of public protection.[85]

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75. The Act defines "funding agreement" to mean "any contract, grant, or cooperative agreement." 35 U.S.C. § 201(b) (1994).

76. *See supra* note 67.

77. 15 U.S.C.A. § 3710a(b)(2) (West 1998 & Supp. 2000).

78. Technology Transfer Improvement Act, H.R. 3590, 103d Cong. (1993).

79. *See* National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, 110 Stat. 775 (codified as amended in scattered sections of 15 U.S.C.A.).

80. *Id.*

81. Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 1988 U.S.C.C.A.N. (102 Stat.) 1107.

82. *Id.* at 1211-16.

83. *See* 15 U.S.C.A. §§ 3701-3710 (West 1998 & Supp. 2000).

84. *See id.* § 3710a(a).

85. As one commentator explained:

> Ownership of inventions made during a CRADA is governed by much the same scheme in the Bayh-Dole Act. Specifically, 15 U.S.C. § 3710a allows the Federal laboratory to grant licenses or assignments to an invention made in whole or in part

The Bayh-Dole Act is the most relevant of these and is the focus of this Article.

IV. THE BAYH-DOLE ACT

A. General Overview

The Bayh-Dole Act, passed in 1980, was a major departure from the government's earlier practice of retaining title to nearly all the inventions it funded.[86] The new policy was designed to provide an incentive for research and to increase the competitiveness of U.S. industry by granting title to certain recipients of federal R&D funds[87] and then encouraging those recipients to develop the inventions or to license others in industry to put the inventions to commercial use. At the same time, the policy ensured that there could be no abuse of the title incentive by enacting a strict price-control mechanism as part of

by a laboratory employee to a collaborating partner and/or to waive ownership to an invention made during the agreement by a collaborating party.

Mark R. Wisner, *Proposed Changes to the Laws Governing Ownership of Inventions Made with Federal Funding*, 2 TEX. INTELL. PROP. L.J. 193, 196 (1994). Moreover, under 15 U.S.C.A. § 3710a(a)(2), authority is granted "to negotiate licensing agreements under section 207 of title 35."

As it turns out, although 35 U.S.C. § 207, part of the Bayh-Dole Act, does not impose the same requirements of "practical application," § 209, which applies to "any license under a patent or patent application on a federally owned invention," is replete with references to the "practical application" requirement. 35 U.S.C. § 209 (1994). It is thus not clear that there is even a "funding" requirement necessary to trigger the Bayh-Dole Act. It seems likely that any license of CRADA patents is subject to the resulting reasonable price requirements.

86. Eisenberg, *supra* note 43, at 1663-64. Eisenberg notes that

> [t]he year 1980 marked a sea change in U.S. government policy toward intellectual property rights in the results of government-sponsored research. In two statutes passed that year, Congress endorsed a new vision of how best to get these research results utilized in the private sector. Previous legislation had typically encouraged or required that federal agencies sponsoring research make the results widely available to the public through government ownership or dedication to the public domain.

Id. at 1663 (footnotes omitted).

87. *See* 35 U.S.C. § 200 (1994). The stated purposes of the Bayh-Dole Act are:

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

Id.

the so-called march-in rights maintained by the government to oversee its investments.[88]

The Act automatically grants small businesses and nonprofit organizations, defined almost exclusively as academic institutions, the right to retain ownership of "subject inventions" made in whole or in part with federal dollars.[89] Subject inventions are defined as any inventions that the "contractor conceived or first actually reduced to practice in the performance of work under a funding agreement."[90] This means that any ideas conceived during funding—by the contractor or others—that ultimately lead to patents (even if actually reduced to practice long after the funding expires), in addition to those inventions that are actually reduced to practice during the funding grant, are subject to the Act, including its price-control mechanisms. In exchange, the government receives a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention on behalf of the United States anywhere in the world.[91] The government also receives certain minimal royalties[92] and, most importantly, the right to "march-in" when the contractor, or any person to whom the patent is ultimately assigned, does not provide the invention to the public at a reasonable price.[93]

To claim these rights, the government must be informed of the progress, patents, and inventions resulting from its funding agreements. The Act gives contractors two months from the time their patent counsel is informed of an invention to disclose it to the federal agency and two years to decide whether to retain title.[94] Once the contractor elects to retain title, it has one year to file a patent

88. *Id.* § 203.
89. 35 U.S.C.A. §§ 200-212 (West 1984 & Supp. 2000).
90. 35 U.S.C. § 201(e).
91. *Id.* § 203.
92. 37 C.F.R. § 401.5(g)(3) (2000).
93. 35 U.S.C. §§ 201(f), 203. March-in rights require a license-holding agent to yield the license to a responsible applicant if there is an inappropriate delay in achieving "practical application" of the invention. *Id.* § 203(a). Practical application means both of the following: (1) that the invention is being utilized and (2) that its benefits are, to the extent permitted by law or government regulations, available to the public at reasonable prices. *Id.* Thus, the requirement for reasonable prices derives directly from the mandate that all such inventions achieve "practical application" and, therefore, be available to the public on "reasonable terms." *See infra* Parts V-VII. There are other grounds, not at issue here, upon which march-in rights can be based, including health and safety needs, public use needs, and domestic manufacturing requirements. 35 U.S.C. § 203(b)-(d). If the contractor does not yield the license, then the federal agency may grant the license itself. *Id.* § 203.
94. 35 U.S.C. § 202(c)(1)-(2) (1994); 37 C.F.R. § 401.14(c)(1)-(2) (2000).

application that includes a legend regarding the government's rights to the invention.[95]

Various provisions impose obligations upon the contractor, including the duties to disclose a subject invention to the federal agency that funded it,[96] to decide within a reasonable period of time whether to retain title to the invention or give it to the government to patent,[97] and to ensure that there is a legend on the patent application (and, thereby, on any resulting patent) specifying that the invention was made with federal funds and that the government has certain rights in it.[98] Importantly, this last requirement and the resulting march-in rights do not only apply to the contractor. The rights attach to the invention and any resulting patent.[99] Thus, even if a patent is eventually granted to others, if it resulted from the original federal funding (meaning that it yielded the bare idea or conception of the invention), the later patent should bear the legend and be subject to the entire Act.

The Act leaves much, including enforcement, up to individual federal agencies. The implementing regulations state that the contractor "shall establish . . . procedures to ensure that subject inventions are promptly identified and timely disclosed."[100] The Act itself does not require that the federal government elect to retain title if the contractor fails to fulfill the above requirements, but merely states that it may.[101] It states that agencies have a "right" to receive periodic reports on utilization, but does not require it.[102] It does not expressly establish any mechanism whereby the funding agencies can reliably learn whether patentees are honoring their obligation to charge no more than a reasonable price for an invention.[103] What is worse, it appears that funding grantees have engaged in a more or less wholesale flouting of their responsibilities to self-report,[104] which has

95. 37 C.F.R. § 401.14(c)(3). This is referred to as the "Bayh-Dole legend."
96. 35 U.S.C. § 202(c)(1).
97. *Id.* § 202(c)(2).
98. *Id.* § 202(c)(6).
99. *See id.* § 203. Section 203 applies march-in rights to *any* "subject invention" and does not limit itself to the contractor who discovered or patented it. *See also* 35 U.S.C. § 201(d), which broadly defines "invention" as "any invention or discovery which is or may be patentable or otherwise protectable under this title."
100. 37 C.F.R. § 401.5(h)(5) (2000).
101. 35 U.S.C. § 202(a).
102. *Id.* § 202(c)(5).
103. 35 U.S.C.A. §§ 200-212 (West 1984 & Supp. 2000).
104. The GAO recognizes what is essentially an honor system not only as the Bayh-Dole Act's chief characteristic but also as its major flaw: "The administration of the Bayh-Dole Act is decentralized and relies heavily on voluntary compliance by the universities." ADMINISTRATION OF THE BAYH-DOLE ACT, *supra* note 2, at 6.

resulted in a kind of land grab in which researchers receive funding but uniformly fail to include the Bayh-Dole legend in any resulting patents.[105] Ironically, although the goal of the Bayh-Dole Act was to make policies for government inventions uniform, the fact that each agency imposed its own rules seriously undermined and balkanized the statute until the uniform Commerce Department rules were enacted. The result is possibly worse, however, under the Commerce Department rules, because the Commerce Department issued implementing regulations with no facilities for oversight,[106] leaving the agencies to enforce the Act with no direction and little expertise.[107]

B. *The Meaning of "Reasonable Terms"*

What "*available to the public on reasonable terms*"[108] means is not jurisprudentially troublesome, even absent the clear legislative history of the term.[109] U.S. law has always held that, absent a clearly explicit statutory intent to the contrary, ordinary words such as these

105. Wendy Baldwin, Deputy Director for Extramural Research for the NIH, noted evidence of this land grab in her statement to Congress:

> As a pilot project to further evaluate reporting compliance, we have contacted 20 institutions to reconcile our records with theirs and to provide additional utilization information. Fifteen of these institutions are among those that report the greatest number of patents supported by Federal funding agreements and their responses will help to determine the completeness of their previous reporting. Five of the institutions report few patents with Federal support even though they are among our top 100 recipients.

Underreporting Federal Involvement in New Technologies Developed at Scripps Research Institute: Hearing Before the Subcomm. on Regulation, Bus. Opportunities, & Tech. of the House Comm. on Small Bus., 103d Cong. 104 (1994) [hereinafter *Underreporting Federal Involvement*] (statement of Wendy Baldwin, Ph.D., Deputy Dir. of Extramural Research, Nat'l Insts. of Health).

106. The lack of oversight is both total and somewhat shocking: "Despite the perception that Bayh-Dole is working well, none of the federal agencies or universities we contacted evaluated the effects of Bayh-Dole." ADMINISTRATION OF THE BAYH-DOLE ACT, *supra* note 2, at 15.

107. The GAO reported:

> The administration of the [Bayh-Dole Act] is decentralized. Each federal agency awarding R&D funds is required to ensure that the universities receiving such funds abide by the [A]ct's requirements. The agency that comes closest to coordinating the Bayh-Dole Act is the Department of Commerce. The [A]ct, as amended, provided that Commerce could issue regulations for the program and establish standards for provisions in the funding agreement entered into by federal agencies and universities, other nonprofit institutions, and small businesses. Commerce did so in 1987. Commerce is looked upon by the other agencies as a type of coordinator and may be consulted when questions arise. However, Commerce does not maintain any overall Bayh-Dole database.

Id. at 6.

108. 35 U.S.C. § 201(f) (1994) (emphasis added).

109. *See infra* notes 146-266 and accompanying text.

must be interpreted with their ordinary meaning.[110] The Supreme Court has said, "When we find the terms of a statute unambiguous, judicial inquiry is complete except in rare and exceptional circumstances."[111] Justice Scalia has stated the rule succinctly:

> [F]irst, find the ordinary meaning of the language in its textual context; and second, using established canons of construction, ask whether there is any clear indication that some permissible meaning other than the ordinary one applies. If not—and especially if a good reason for the ordinary meaning appears plain—we apply that ordinary meaning.[112]

Lower courts, following the Supreme Court, have noted that the "ordinary meaning" rule is binding. The Federal Circuit, quoting Supreme Court cases, has stated the rule thus: "[L]egislative purpose is expressed by the ordinary meaning of the words used . . . ."[113] The court also noted that "[i]t is a basic principle of statutory interpretation . . . that undefined terms in a statute are deemed to have their ordinarily understood meaning."[114]

In the United States in similar contexts, the words "reasonable terms" have uniformly been interpreted to include price. In *Byars v. Bluff City News Co.*, the United States Court of Appeals for the Sixth Circuit, recognizing that establishing "reasonable terms" is necessary to remedy a monopolistic market, noted that "[t]he difficulty of setting reasonable terms, *especially price*, should be a substantial factor" in how to proceed.[115] Similarly, in *American Liberty Oil Co. v. Federal Power Commission*, the United States Court of Appeals for the Fifth Circuit, interpreting a statute that allows the Federal Power Commission to establish "reasonable terms and conditions," concluded that this meant that the "price . . . must be reasonable."[116] In *Commercial Solvents Corp. v. Mellon*, the United States Court of Appeals for the D.C. Circuit addressed prices under a statute that demanded "reasonable terms as to quality, price and delivery"; this language shows that the word "terms" includes, as a matter of common sense, the element of price.[117] In *United States v. Mississippi Vocational Rehabilitation for the Blind*, the United States District

110. *See* Smith v. United States, 508 U.S. 223, 232 (1993).
111. Demarest v. Manspeaker, 498 U.S. 184, 190 (1991).
112. Chisom v. Roemer, 501 U.S. 380, 404 (1991) (Scalia, J., dissenting).
113. Cook v. Brown, 68 F.3d 447, 451 (Fed. Cir. 1995) (internal quotations omitted) (quoting Ardestani v. INS, 502 U.S. 129, 136 (1991)).
114. *Id.* (alteration in original) (internal quotations omitted) (quoting Best Power Tech. Sales Corp. v. Austin, 984 F.2d 1172, 1177 (Fed. Cir. 1993)).
115. 609 F.2d 843, 864 n.58 (6th Cir. 1979) (emphasis added).
116. 301 F.2d 15, 18 (5th Cir. 1962).
117. 277 F. 548, 549 (D.C. Cir. 1922).

Court for the Southern District of Mississippi similarly interpreted a statute that allowed organizations to operate vending machines on "reasonable terms" at the Stennis Space Center.[118] Such reasonable terms, the court implied, include "prices and vending operations."[119] In *Topps Chewing Gum, Inc. v. Major League Baseball Players Ass'n*, the United States District Court for the Southern District of New York resolved a dispute between baseball players and a playing card company that had agreed to pay "commercially reasonable terms"; the court said, "I assume [commercially reasonable terms] means at a price higher than Topps currently pays under its player contracts."[120] In *United States v. United States Gypsum Co.*, the United States District Court for the D.C. Circuit held that "reasonable terms and conditions" includes prices.[121] Finally, in *South Central Bell Telephone Co. v. Louisiana Public Service Commission*, the Louisiana Supreme Court considered the meaning of "reasonable terms" and concluded that, although such things as timing and performance might be important, the most important and central factor is, of course, price:

> Thus . . . regulation must make it possible . . . to compete . . . . The utility's earnings, i.e., its *return*, both actual and prospective, must be sufficient . . . so that it can attract . . . capital on reasonable terms. The rate of return is but an intermediate factor; the basic requirement is a fair and reasonable dollar return.
>
> In order to attract capital on reasonable terms, the utility [must] be able to pay the going price . . . . In the last analysis regulation seeks to set utility prices . . . .[122]

The requirement for "practical application" seems clearly to authorize the federal government to review the prices of drugs developed with public funding under Bayh-Dole terms and to mandate march-in when prices exceed a reasonable level. The terms required by the Bayh-Dole Act include, but are not limited to, reasonable prices.[123] Terms may be considered unreasonable if the unit price is too high or if its use over the long term makes it too costly with respect to the investment, costs, and profits of the manufacturer.[124] Despite somewhat unbelievable complaints from the NIH that this price review is beyond its ability, the traditional judicial and agency competence to

118. 812 F. Supp. 85, 87-89 (S.D. Miss. 1992).
119. *Id.* at 87.
120. 641 F. Supp. 1179, 1191 (S.D.N.Y. 1986).
121. 67 F. Supp. 397, 433-41 (D.D.C. 1946).
122. 373 So. 2d 478, 480-81 n.1 (La. 1979).
123. *See infra* notes 175-227 and accompanying text.
124. *See United States Gypsum Co.*, 67 F. Supp. at 433-41; *S. Cent. Bell Tel. Co.*, 373 So. 2d at 480-81 n.1.

determine reasonableness of prices is supported by countless cases and a host of statutes, including, for instance, the reasonable price provisions of the Uniform Commercial Code (UCC),[125] the reasonable royalty remedies of patent law,[126] the similar provisions of copyright law,[127] the compulsory licensing provisions of antitrust law,[128] the

125. U.C.C. § 2-305(1)(a) (2000); *see also* Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE L.J. 87, 95-97 (1989). *See generally* Koch Hydrocarbon Co. v. MDU Res. Group, Inc., 988 F.2d 1529, 1534-35 (8th Cir. 1993) (determining what constitutes a "reasonable price" for natural gas after deregulation pursuant to U.C.C. § 2-305); N. Cent. Airlines, Inc. v. Cont'l Oil Co., 574 F.2d 582, 592-93 (D.C. Cir. 1978) (determining what constitutes a "reasonable price" for aviation fuel in the wake of the early 1970s OPEC oil embargo and the resulting federal price controls, pursuant to U.C.C. § 2-305); Kellam Energy, Inc. v. Duncan, 668 F. Supp. 861, 877-879 (D. Del. 1987). The UCC, which governs commercial transactions in forty-nine states, gives courts the power to determine reasonable prices and even to enforce contracts on the basis of what a reasonable price would be, for instance, where the contract does not specifically state any price (the so-called open-price situation): "The parties if they so intend can conclude a contract for sale even though the price is not settled. In such a case the price is a reasonable price at the time for delivery . . . ." U.C.C. § 2-305(1). The drafters of the UCC unabashedly placed their faith in the ability of a court to determine what a reasonable price would be: "In many valid contracts for sale the parties do not mention the price in express terms, the buyer being bound to pay and the seller to accept a reasonable price which the trier of the fact may well be trusted to determine." *Id.* § 2-201, cmt. n.1.

126. The Patent Act expressly grants a reasonable royalty, the amount to be determined by the court after hearing evidence, to an aggrieved patent owner: "Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." 35 U.S.C. § 284 (1994).

127. The copyright statute, unlike the patent law, does not expressly grant a reasonable royalty. However, in many cases, assessing profits unlawfully garnered by an infringing defendant requires a court to determine what a reasonable royalty would be. *See, e.g.*, Sherry Mfg. Co. v. Towel King of Fla., Inc., 220 U.S.P.Q. (BNA) 855 (S.D. Fla. 1983), *rev'd on other grounds*, 753 F.2d 1565 (11th Cir. 1985). Furthermore, the assessment of reasonable royalties by courts and agencies is an integral part of the administration of the copyright regime. The copyright law, in section 118, grants public broadcasting a compulsory license for use of nondramatic literary and musical works, as well as pictorial, graphic, and sculptural works, subject to the payment of reasonable royalty fees to be set by the Copyright Royalty Tribunal. *See* H. REP. NO. 94-1476, at 116 (1976), *reprinted in* 1976 U.S.C.C.A.N. 5659, 5732.

128. A compulsory license, at reasonable royalty rates, is a remedy occasionally granted in response to antitrust violations. "The appropriateness of compulsory licensing at reasonable royalty rates as an antitrust remedy has long been recognized." A. Samuel Oddi, *Contributory Infringement/Patent Misuse: Metaphysics and Metamorphosis*, 44 U. PITT. L. REV. 73, 125 (1982); *see* Carlisle M. Moore, Note, *A Study of Compulsory Licensing and Dedication of Patents as Relief Measures in Antitrust Cases*, 24 GEO. WASH. L. REV. 223, 223-27 (1955).

price control provisions of the Orphan Drug Act,[129] and public utility rate regulation cases.[130]

The language of the Bayh-Dole Act implies that the contractor has the burden of providing, upon a good faith request by the government, data showing that it charged a reasonable price.[131] At present, the federal government may not grant a license on a federally owned invention unless it has been supplied with a development or marketing plan.[132] It would be appropriate to require the contractor to provide the data necessary to determine a reasonable price as part of the development or marketing plan.

C. *The Reach of the Act and the Broad Scope of "Subject Inventions"*

Determining whether an invention was made with government funds (and is therefore a "subject invention") is a complex task that can easily lead to, and be the subject of, unpredictable litigation.[133] The Bayh-Dole Act defines a subject invention as any invention that the "contractor conceived or first actually reduced to practice in the performance of work under a funding agreement."[134] However the implementing regulations of the legislation, which attempt to specify what is meant by "subject invention," do not settle the issue.[135] The regulations state that a closely related project that falls "outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities . . . would not be subject to the conditions of these regulations."[136] The language here seems to invite litigation and almost defies comprehension.

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129. Orphan Drug Act of 1983, Pub. L. No. 97-414, 1983 U.S.C.C.A.N. (96 Stat.) 2049-66.

130. *See, e.g.*, S. Cent. Bell Tel. Co. v. La. Pub. Serv. Comm'n, 373 So. 2d 478, 480-81 n.1 (La. 1979) (discussing the importance of price controls).

131. There is some support in the legislative history for concluding that the contractor bears the burden of proof on this question. *Cf. Government Patent Policies: Institutional Patent Agreements: Hearings Before the Subcomm. on Monopoly & Anticompetitive Activities of the Select S. Comm. on Small Bus.*, 95th Cong. 397 (1978) [hereinafter *1978 Hearings*] (statement of Howard W. Bremer, patent counsel, Wis. Alumni Research Found.).

132. 35 U.S.C.A. § 209(a) (West 1984 & Supp. 2000).

133. *See* S. Research Inst. v. Griffin Corp., 938 F.2d 1249 (11th Cir. 1991); Johns Hopkins Univ. v. CellPro, 978 F. Supp. 184 (D. Del. 1997); Gen-Probe Inc. v. Ctr. for Neurologic Study, 853 F. Supp. 1215 (S.D. Cal. 1993); Ciba-Geigy Corp. v. Alza Corp., 804 F. Supp. 614 (D.N.J. 1992).

134. 35 U.S.C. § 201(e) (1994).

135. *See* 37 C.F.R. §§ 401.1-.17 (2000).

136. *Id.* § 401.1(a)(1).

Because the regulations limit the reach of the Bayh-Dole Act to "planned," as opposed to unexpected, events, there is some question as to whether they faithfully implement the intent of the statute. In fact, they seem to negate the very essence of invention and thus of the Bayh-Dole Act itself. Inventions, by definition, are technological advances that are unexpected and unplanned.[137] The Bayh-Dole Act seeks to preserve a governmental interest in such unexpected events that owe their genesis to government funding. But these regulations seem to exempt inventions that were not "planned"—i.e., those that were unexpected—which means that they may exclude from the Act exactly that which it was intended to govern.[138] Furthermore, "conditions of these regulations" could be interpreted to mean that extracontractual work is beyond the reach of the statute, a result unsupported by administrative law.[139]

The Act applies to any patents for subject inventions, not merely patents held or obtained by the recipients of government funds.[140] Thus, if a firm were to buy intellectual property rights from an Act recipient, any resulting patent would remain subject to the Act and would have to state that the invention was made with federal funds and that the government has certain rights to it.[141]

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137. The Patent Act requires that, to be patentable, an invention must be "nonobvious." "A patent may not be obtained . . . if the . . . subject matter . . . would have been obvious . . . ." 35 U.S.C.A. § 103(a) (West 1984 & Supp. 2000). Nonobviousness is defined in the Act as a technological advance that would not be obvious "to a person having ordinary skill" in the relevant technology. *Id.* The Supreme Court has often likened nonobviousness to unexpectedness. "[T]he Adams battery was . . . nonobvious. As we have seen, the operating characteristics of the Adams battery have been shown to have been unexpected and to have far surpassed then-existing wet batteries." United States v. Adams, 383 U.S. 39, 51 (1966). The Federal Circuit has held "a finding of 'unexpected results' to be tantamount to a finding of nonobviousness." Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 954 n.28 (Fed. Cir. 1993). Inventions are, therefore, by legal definition, unexpected events (among other things, of course). The implementing regulations of the Bayh-Dole Act, by excluding the "unexpected," seem to exclude exactly that which they might otherwise regulate; that is, they seem to regulate the Act out of much of its relevance.

138. Indeed, a patent cannot be obtained if the innovation "would have been obvious at the time the invention was made to a person having ordinary skill." 35 U.S.C.A. § 103(a). Therefore, nonobvious, unexpected, unplanned events are precisely the events that furnish the substance of patentable inventions.

139. *See* Presley v. Etowah County Comm'n, 502 U.S. 491, 508 (1992) ("Deference does not mean acquiescence. As in other contexts in which we defer to an administrative interpretation of a statute, we do so only if Congress has not expressed its intent with respect to the question, and then only if the administrative interpretation is reasonable.").

140. *See supra* note 99 and accompanying text.

141. It should be noted that if an Act recipient obtains a patent and is subject to the Act, any licensing to commercial entities would be similarly subject to the Act, since the patent under which both parties are operating must, at least legally, bear the Act's legend and thus be subject to march-in rights. *See* 35 U.S.C. § 202(c)(6) (1994) (requiring that patent applications for subject inventions contain, on "the specification of such application and any

In *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, the Federal Circuit held that an invention is conceived as soon as someone has the idea of the invention, even if no work has been performed to test its practicability.[142] The inventor, however, need not know that the invention will work nor obtain any experimental data to demonstrate its workability.[143] It follows that if an invention is conceived as soon as someone has a bare, untested idea, the provisions of the Bayh-Dole Act are likely to apply to most inventions made with, or perhaps only even associated with, government funding. Thus, when a company purchases a recipient's intellectual property rights, it cannot claim that it is doing the inventive work. Under *Burroughs Wellcome*, if the recipient had a bare, untested idea while receiving government funds (and most will have done far more than that), any resulting patent obtained by commercial transferees must bear the Bayh-Dole legend and is subject to march-in rights.[144]

Because the Act is aimed at the resulting patent and the *Burroughs Wellcome* decision moves the date of conception of a subject invention to a much earlier point in time, the Act will apply to far more commercial transferees of patent rights than it would have

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patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention"). Perhaps the most important aspect of the Bayh-Dole Act, therefore, is that the Act and its reasonable pricing requirement attach not to the contractor, but to the invention itself, no matter who might eventually obtain a patent upon it.

Thus, while it might appear to a commercial entity that it could buy the rights from a recipient, especially if the recipient agrees not to pursue the patent itself, the Act clearly states that a patent resulting from a recipient's research, rather than a patent obtained by a recipient, is subject to the Act. *See id.* §§ 201(e), 202(c)(6), 203(1). It nevertheless appears, though this would have to be confirmed by further research and perhaps litigation, that many contractors transfer their research prior to the patent application. This is not so much a violation of the law as it is what should be held to be a legally unsuccessful attempt to evade it. However, because the government has given itself only sixty days in which to act, these attempts at evasion may be practically, if not legally, effective. *See* 37 C.F.R. § 401.14(d)(1) (2000) (requiring that the government take action within sixty days of learning of the failure of a contractor to disclose an invention or to elect title to it).

142. *See* 40 F.3d 1223, 1227-28 (Fed. Cir. 1994).

143. The Federal Circuit has defined "conception" in such a way that not only will a "wild guess" qualify, but it can be *so* wild that even an inventor might reject it as beyond the limits of scientific possibility:

> Thus, the test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention . . . .
>
> But an inventor need not know that his invention will work for conception to be complete. . . .
>
> . . . An inventor's belief that his invention will work or his reasons for choosing a particular approach are irrelevant to conception . . . .

Id. at 1228.

144. *See supra* note 99 and accompanying text.

prior to *Burroughs Wellcome*. Almost any research performed by a recipient that results in conception, however untested or apparently impractical, will give rise to a resulting patent under the Act, no matter who might later apply for the patent.

There are undoubtedly many such pharmaceuticals now on the market that should be subject to the Act but lack the Bayh-Dole legend. These include drugs patented by Bayh-Dole contractors as well as those patented by manufacturers for which the rights to the underlying research or even mere conceptions were purchased or licensed from Bayh-Dole contractors. These also include drugs based on an idea, qualifying under *Burroughs Wellcome*, that an employee of the funded contractor took with him or her to a new employer such as a drug manufacturer.[145]

V. THE LEGISLATIVE HISTORY OF THE BAYH-DOLE ACT

A. Overview

Many of the controversial issues that currently surround public-private combinations were first discussed in the congressional hearings when the Bayh-Dole legislation was considered in the late 1970s.[146] For example, many in favor of the legislation expressed fears that a slump in American innovation threatened the nation's well-being.[147] There were also complaints about confusing and contradictory policies among various federal agencies.[148] Proponents noted that contractors must balance the benefits of receiving federal R&D assistance with the

145. This is because the statute requires only that conception occur during the federal contract. *See* 35 U.S.C. § 201(e) ("The term 'subject invention' means any invention of the contractor *conceived* or first actually reduced to practice in the performance of work under a funding agreement." (emphasis added)). Under *Burrough Wellcome*, of course, conception can be the wildest of guesses. *See supra* note 143 and accompanying text.

146. *See infra* notes 175-227 and accompanying text.

147. One author observed that Congress sought to

> ensure effective transfer and commercial development of discoveries that would otherwise languish in government and university archives. It would reinvigorate U.S. industry by giving it a fresh infusion of new ideas that would enhance productivity and create new jobs. And it would ensure that U.S.-sponsored research discoveries were developed by U.S. firms, rather than by foreign competitors who had too often come to dominate world markets for products based on technologies pioneered in the United States.

Eisenberg, *supra* note 43, at 1664-65; *see 1978 Hearings*, *supra* note 131, at 575 (statement of Donald R. Dunner, esq., on behalf of the Am. Patent Law Ass'n).

148. *See 1979 Senate Sci. Hearings*, *supra* note 46, at 216, 220 (testimony and statement of Peter F. McCloskey, President, Elec. Indus. Ass'n); *1978 Hearings*, *supra* note 131, at 572 (statement of Donald R. Dunner).

need to protect the investment of the company's shareholders.[149] The lack of a clearly defined mechanism for licensing government-owned technology was also cited as a purported reason for bureaucratic delays.[150]

In addition, burdensome patent policies were another barrier to innovation and increased competition.[151] Witnesses noted that fewer than 5% of the 28,000 government-held patents had been licensed in 1979.[152] A Justice Department analysis concluded that federal patent policy did not properly benefit public investment because government-funded inventions were inadequately commercialized.[153] However, one knowledgeable witness said that those kinds of conclusions were completely unfounded and insupportable and that the very nature of government patents—which were freely available without policing—made it impossible to know utilization rates.[154] Penicillin was cited as evidence of industry's reluctance to commercialize products for which patents and title are not available for private ownership.[155] In that case, for eleven years prior to World War II, the federal government tried to make penicillin available to industry, but no company was willing to commercialize it. The war forced the government itself to develop penicillin.[156] There was also some testimony indicating that the pharmaceutical industry acted as a bloc to extort a favorable government patent policy and boycotted government patents in order to gain greater rights.[157]

Opponents of the Bayh-Dole Act questioned the need to provide an automatic exclusive license. Witnesses from private industry, Congress, and government agencies testified that even without an

149. *See 1979 Senate Sci. Hearings, supra* note 46, at 217, 220 (testimony and statement of Peter F. McCloskey).

150. *See id.* at 216-22.

151. *Patent Policy: Joint Hearing Before the S. Comm. on Commerce, Sci., & Transp. & the S. Comm. on the Judiciary*, 96th Cong. 458-60 (1980) [hereinafter *1980 Joint Hearing*] (statement of Hon. Birch Bayh, U.S. Senator, Ind.).

152. S. REP. NO. 96-480, at 2 (1979).

153. *1980 House Gov't Operations Hearings, supra* note 46, at 95-96 (statement of Ky P. Ewing, Jr., Deputy Assistant Attorney Gen., Antitrust Div., U.S. Dep't of Justice).

154. *See id.* at 79 (statement of Adm. H.G. Rickover); *1979 Senate Judiciary Hearings, supra* note 46, at 159 (same); *1977 Senate Small Bus. Hearings, supra* note 46, at 3 (same).

155. *See 1979 Senate Judiciary Hearings, supra* note 46, at 146-47 (testimony of Dr. Betsy Ancker-Johnson, Vice President, Gen. Motors, Envtl. Activities Staff).

156. *See id.* at 179 (testimony of Frederick N. Andrews, Vice President for Research, Purdue Univ.).

157. *Government Patent Policy: Hearings Before the Subcomm. on Domestic & Int'l Scientific Planning & Analysis of the House Comm. on Sci. & Tech.*, 94th Cong. 723 (1976) [hereinafter *1976 Hearings*] (testimony of Norman J. Latker, Patent Counsel, HEW).

exclusive patent, federal dollars and the sharing of scientific information were reward enough.[158] Representative Jack Brooks (Texas), perhaps the harshest critic of the proposed legislation, expressed doubts that granting an exclusive license to industry after paying to develop a patentable invention was an incentive to commercialize.[159] Admiral Hyman G. Rickover, then a Deputy Commander for Nuclear Power for the United States Navy, feared that the legislation would concentrate economic power in the hands of large corporations and, contrary to its stated purpose, hurt small businesses.[160] Representative Brooks, in fact, suggested that government patents be "put up for competitive bid," allowing both big business and small businesses the opportunity to obtain such patents.[161]

The legislation was repeatedly called a $30 billion "giveaway."[162] Senator Russell Long (Louisiana) testified that the public would have no access to the results of the research it had paid for and would not know whether products were being fairly priced.[163] He called the bill "deleterious to the public interest."[164] He further stated that there was "absolutely no reason why the taxpayer should be forced to subsidize a private monopoly and have to pay twice: first for the research and development and then through monopoly prices."[165]

Representative Brooks criticized the use of march-in rights as the primary mechanism for protecting the public interest: "The Government does not use its march-in rights one in a million times. . . . I think that is a paper tiger. I think we can forget [march-in rights] as a realistic protection for the public."[166] Brooks's statement proved prophetic—the NIH has never exercised its march-in rights.[167] An

158. *See generally 1980 House Gov't Operations Hearings*, *supra* note 46, at 49-137 (statements of Hon. Jack Brooks, Hon. Frank Horton, Adm. H.G. Rickover, Hon. John D. Dingell, and Ralph Nader).

159. *Id.* at 54.

160. *Id.* at 74-83 (statement of Adm. H.G. Rickover).

161. *Id.* at 56.

162. *See id.* at 99 (testimony of Ky P. Ewing, Jr.); *1979 Senate Sci. Hearings*, *supra* note 46, at 401 (statement of Adm. H.G. Rickover); *1977 Senate Small Bus. Hearings*, *supra* note 46, at 233 (statement of Hon. Russell B. Long, U.S. Senator, La.).

163. *See 1980 Joint Hearing*, *supra* note 151, at 463-65 (statement of Hon. Russell B. Long).

164. *Id.* at 464.

165. *Id.*

166. *See 1980 House Gov't Operations Hearings*, *supra* note 153, at 55.

167. Not only has the NIH never exercised its march-in rights, but the only time it was asked to do so by a private party, in the *CellPro* litigation, it refused. *See infra* text accompanying notes 294-313. There are some reports that "the NIH has on occasion threatened to use 'march in' rights with some positive results." *Underreporting Federal Involvement*, *supra* note 105, at 101 (statement of Wendy Baldwin). However, there is no record of any government agency ever actually exercising those rights.

alternative was to create a Patent Board to exercise march-in rights, rather than vesting that responsibility with the federal agency, another idea that current debates have echoed.[168]

A Department of Justice review of the pending legislation highlighted the need for government patent policy to offer "adequate protection of the public's equitable interest in inventions that result from government funding," once the inventions are commercialized.[169] Early versions of the bill included a payback provision that was supported, at least in principle, by most witnesses.[170] It required the licensee to compensate the government for any profits from a successful invention.[171] The bill would also have given the government 15% of any gross annual income above $70,000 that a contractor obtained from licensing an invention.[172] In addition, it also would have granted the government 5% of all income above one million dollars that the contractor made from sales of products using those inventions.[173] Ultimately the legislation did not contain a mechanism for ensuring a financial return on government investment. However, it did preserve the "march-in" mechanism that would, if enforced, effectively achieve the same goal of providing taxpayers with some benefit: a requirement that the products of these inventions be sold to the public at reasonable prices.[174]

B. March-in and Its Focus on Competition, Profits, and Prices

Congress's concern with march-in rights focused exclusively on maintaining competitive conditions, controlling profits, and doing so through price control. The march-in provisions became the linchpin of the entire enterprise because Congress wanted to balance the demands of private industry against the "public equity" that resulted from the massive public investment of funds to produce these patented inventions. The so-called government equities were not adequately protected by the government's "free and irrevocable license," which was "not always sufficient to protect the public interest."[175] This

168. *See 1976 Hearings*, *supra* note 157, at 785 (statement of William O. Quesenberry, Patent Counsel, Dep't of the Navy).

169. *See 1980 House Gov't Operations Hearings*, *supra* note 46, at 97 (testimony of Ky P. Ewing, Jr.).

170. S. REP. NO. 96-480, at 8-10, 25-26 (1979).

171. *Id.* at 9.

172. *Id.*

173. *Id.*

174. *See* 35 U.S.C. §§ 201(f), 203(1)(a) (1994).

175. 1 SUBCOMM. ON DOMESTIC & INT'L SCIENTIFIC PLANNING & ANALYSIS OF THE HOUSE COMM. ON SCI. & TECH., 94TH CONG., BACKGROUND MATERIALS ON GOVERNMENT

shortcoming was sometimes characterized as "the public's need for competition in the marketplace," which could be protected only by march-in rights.[176] There was a strong notion of public desert in the hearing testimony.[177] Congress uniformly viewed march-in rights as the mechanism (along with recoupment provisions) to protect the public.[178] "If an invention is of actual commercial importance," testified Donald R. Dunner, representing the American Patent Law Association, "there is actual and real market incentive for 'march-in' rights to protect the public interest."[179]

But there was strong industry resistance to any kind of revocability or march-in provision, though noticeably less resistance to recoupment or payment of royalties.[180] "Revocability of a contractor's patent rights is an area of considerable concern to many businessmen," said one witness.[181] "It is not a good concept that government should go into competition with private enterprise," voiced another.[182] "It is not a proper function of government .... Under socialism, the government owns the essential means of production .... Under capitalism production and distribution is privately owned. We firmly believe this is the best way. It is more efficient, [and] it provides us

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PATENT POLICIES: THE OWNERSHIP OF INVENTIONS RESULTING FROM FEDERALLY FUNDED RESEARCH AND DEVELOPMENT 1 (Comm. Print 1976) [hereinafter BACKGROUND MATERIALS].

176. *1976 Hearings*, *supra* note 157, at 666 (Report by Task Force No. 1 of Study Group No. 6 of the Comm'n on Gov't Procurement on the Allocation of Rights to Inventions Made in the Performance of Gov't Research and Dev. Contracts and Grants).

177. *1977 Senate Small Bus. Hearings*, *supra* note 46, at 189-95 (statement of John H. Shenefield, Assistant Attorney Gen.; Antitrust Div., Dep't of Justice).

178. *Id.*

179. *1978 Hearings*, *supra* note 131, at 597 (statement of Donald R. Dunner).

180. In fact, the legislative history indicates that the fact that royalties, cash payments, or recoupments would simply be absorbed into the cost of federally funded inventions is at least one reason why they were deleted from the Bayh-Dole Act. That lends support, therefore, to the conclusion that the Act was concemed with price control, not just reimbursement. It is also easier to understand why the pharmaceutical industry has favored royalties—because their cost can simply be passed along to consumers. *See* S. REP. NO. 96-480, at 30 (1979) (showing that the original version of the Act included a "payback" provision); *Government Patent Policy Act of 1980: Hearing on H.R. 5715 Before the Subcomm. on Sci., Research & Tech. of the House Comm. on Sci. & Tech.*, 96th Cong. 79 (1980) (supplement to the testimony of Charles H. Herz, Gen. Counsel, Nat'l Sci. Found.) (noting the National Science Foundation's opposition to the inclusion of the government recoupment provision in the Act); *1979 Government Patent Policy Hearings*, *supra* note 11, at 22-23, 59 (statements of Donald R. Dunner and Edward J. Brenner, President, Ass'n for the Advancement of Invention and Innovation) (objecting to the inclusion of the payback provision in the legislation).

181. *See 1976 Hearings*, *supra* note 157, at 173 (statement of Charles S. Haughey, Patent Counsel, Hughes Aircraft Co.).

182. *See id.* at 397 (statement of L. Lee Humphries in supplemental material submitted by Charles S. Haughey).

with more freedom."[183] A third stated, "[I]ndustry does not like either the concept of a revocable license or the 'march-in' rights, and views them with great suspicion."[184] A university representative testified, "I have always been a little concerned with that provision frankly, because it could be an arbitrary decision .... I would hope ... that an appropriate hearing would be given."[185] Another witness said that march-in rights would effectively kill the bill: "I think that the whole concept of march-in rights is a disincentive.... I think that [the bill] would be much more likely to achieve its goals if the march-in rights were deleted."[186] Finally, there was resistance not only to march-in rights but to the terms used to define the triggering events:

> Any march-in rights should only be exercisable by the Government after a full and complete hearing before an impartial arbitor based on clear and convincing evidence and should be limited to requiring the Contractor to grant non-exclusive licenses .... March-in rights which do not provide effective due process ... or extend beyond the granting of non-exclusive licenses are highly objectionable and would serve as a disincentive .... Likewise, the circumstances under which the rights can be exercised must be precisely defined and avoid such vague terms as "welfare" and the like.[187]

The language that so threatened industry was obviously the requirement for "reasonable terms" in the Bayh-Dole Act and its predecessor bills. The 1963 Kennedy Memorandum on patent policy required "licensing on reasonable terms."[188] The Nixon Patent Policy Statement of 1971 tied march-in rights to whether an invention is "being worked *and* ... its benefits are reasonably accessible to the public."[189] An industry-sponsored alternative bill interestingly embraced the language "reasonable terms and conditions" but required "resort to the Federal Courts by either the Contractor or members of the public" in case of a dispute.[190] Notwithstanding these objections,

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183. *See id.*

184. *See id.* at 435 (statement of James E. Denny, Assistant Gen. Counsel for Patents, U.S. Energy Research & Dev. Admin.).

185. *See 1978 Hearings, supra* note 131, at 397 (testimony of Howard W. Bremer).

186. *See 1980 Joint Hearing, supra* note 151, at 523-24 (testimony of Robert B. Benson, Dir., Patent Dep't, Allis-Chalmers Corp.).

187. *Industrial Innovation and Patent and Copyright Law Amendments: Hearings on H.R. 6033, H.R. 6934, H.R. 3806, and H.R. 2414 Before the Subcomm. on Courts, Civil Liberties & the Admin. of Justice of the House Comm. on the Judiciary*, 96th Cong. 161 (1980) (statement of Donald R. Dunner, President, Am. Patent Law Ass'n).

188. 1 BACKGROUND MATERIALS, *supra* note 175, at 6.

189. *See id.* at 10, 14-16 (emphasis added).

190. *See 1976 Hearings, supra* note 157, at 103 (statement of Franz O. Ohlson, Jr., Aerospace Indus. Ass'n of Am., Inc.).

existing agency regulations already defined the practical application to require that the invention be "reasonably accessible to the public."[191] In fact, from as far back as at least 1968, a government report had urged march-in rights triggered by a failure to license the invention "on reasonable terms."[192]

While proposals for recoupment, repayment, or royalty provisions in the Bayh-Dole Act were eventually abandoned (in fact, industry has often suggested cash payment and royalties as an alternative to price regulation[193]), march-in rights were preserved, with their requirement that practical application—defined as availability to the public on "reasonable terms"—be achieved.[194] There was never any doubt that this meant the control of profits, prices, and competitive conditions. There are countless references in the legislative record to the need to maintain competitive market conditions through the exercise of march-in rights.[195] One witness, summarizing the goals of a uniform federal patent policy, asserted that a "primary object[] of such a policy should be to . . . insure that patent rights in such inventions are not used for unfair, anticompetitive or suppressive purposes."[196] A Senator testified before a House subcommittee that "[t]he policy should foster competition and prevent undue market concentration."[197] A Senate witness favored march-in "where the contractor is misusing the invention to the detriment of competitive market forces."[198] An Assistant Attorney General in the Antitrust Division said, "'[M]arch in' provisions should help assure that the availability of exclusive rights . . . does not disrupt competition in the marketplace."[199]

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191. *See id.* at 256 (Armed Servs. Procurement Regulation 7-302.23(a) (1975)); *id.* at 971 (Appendix I, Attachment 2 to Letter of Frank A. Lukasik, describing proposed Dep't of the Interior Regulations).

192. 2 BACKGROUND MATERIALS, *supra* note 175, at 196.

193. *The Federal Government's Investment in New Drug Research and Development: Are We Getting Our Money's Worth? Hearing Before the S. Special Comm. on Aging*, 103d Cong. 145-46 (1993) [hereinafter *1993 Senate Investment Hearing*] (statement of George B. Rathmann, President & Chief Executive Officer, Icos Corp.).

194. *See* 1 BACKGROUND MATERIALS, *supra* note 175, at 6.

195. *See 1993 Senate Investment Hearing*, *supra* note 193, at 132-39 (statement of Gerald J. Mossinghoff, President, Pharm. Mfrs. Ass'n).

196. *1979 Senate Judiciary Hearings*, *supra* note 46, at 184 (testimony of Frederick N. Andrews, Vice President for Research, Purdue Univ.).

197. *1979 Gov't Patent Policy Hearings*, *supra* note 11, at 6 (statement of Hon. Harrison H. Schmitt).

198. *See 1979 Senate Sci. Hearings*, *supra* note 46, at 150 (additional comments of James E. Denny).

199. *1980 House Gov't Operations Hearings*, *supra* note 46, at 102 (testimony of Ky P. Ewing, Jr.).

Profits and unfair profiteering were a key topic in the debate over march-in rights. March-in rights were designed to prevent "windfall profits," about which there was much discussion.[200] The Senate committee overseeing the Bayh-Dole Act wrote in its Report, "The agencies will have the power to exercise march-in-rights to insure that no adverse effects result from retention of patent rights by these contractors. . . . Although there is no evidence of 'windfall profits' . . . the existence of the pay back provision reassures the public . . . ."[201] A witness testified, "The 'march-in' rights were developed to address issues of windfall, suppression and detrimental effects . . . to competition."[202] One witness tried to reassure Congress, saying, "'Windfall profits' do not result from contractors' retaining title to such inventions."[203] Another said, "[T]he Government will prevent the contractors from enjoying windfalls of commercial benefits from inventions paid for by the Government . . . ."[204] One industry witness tried to dismiss the very notion of windfall profits: "I had something in my statement about the windfall profits," he said, "which we hear all the time, is [sic] bad. I think that's a very misleading thing. When you look at what is accomplished if [an unused technology becomes] successful[,] . . . the rewards to the general public, the citizens, is [sic] tremendous. They have something which they never had before."[205]

Beyond the concerns with competition and windfall profits, pricing concerned Congress the most. If anything, march-in rights would prevent owners of exclusive rights from gouging the public through unregulated prices. One witness stated: "[T]here seems to be little disagreement on the objectives of a good patent policy for government procurement. . . . [A] policy is in the public interest if . . . [i]t promotes efficiency in the economic system by providing the consumer with the goods and services he requires *at the lowest possible prices*."[206] One witness said an independent Board should ensure that government inventions are "commercially available to adequately fulfill market demands and *at a reasonable price*."[207] The

200. *See, e.g.*, S. REP. No. 96-480, at 30 (1979).
201. *Id.*
202. *1979 Government Patent Policy Hearings, supra* note 180, at 16 (statement of James E. Denny).
203. *Id.* at 92 (statement of Edward J. Brenner).
204. *1979 Senate Sci. Hearings, supra* note 46, at 34 (statement of R. Tenney Johnson).
205. *1980 Joint Hearing, supra* note 151, at 524 (testimony of Robert B. Benson).
206. *1976 Hearings, supra* note 157, at 387 (emphasis added) (supplemental materials submitted by Charles H. Haughey).
207. *Id.* at 785 (emphasis added) (supplemental materials of William O. Quesenberry).

Board would decide if "commercial authorization" to others was appropriate based on whether: "(1) Commercial utilization has lapsed; (2) Market demands are not met; (3) *Market price is unreasonable*; or (4) Royalty rate is unreasonable."[208] One of the stars of the hearings (he testified at virtually all of them) was Admiral Hyman G. Rickover, who said that "[t]he public has been greatly *overcharged* for many years [for] drugs."[209] He was then questioned by Benjamin Gordon, a consultant to the Committee on Small Business: "When a Government agency . . . gives away patents resulting from Government-financed research, . . . it does not take any steps to insure that the contractor does not charge *exorbitant prices* to the public?"[210] Admiral Rickover responded, "That is correct."[211]

Mr. Gordon expressed palpable concern over pricing, saying, "The patent, the whole idea of a patent is to restrict the use. If you restrict the use, you can control the *prices* and the profits."[212] An industry spokesperson was no less candid about the centrality of prices in triggering march-in rights. He stated, "[I]f [a contractor] fails to supply the market adequately *at a fair price*, then there is reason for requiring it to license both the background patents and the patents stemming from the contract work."[213] A centerpiece of the hearings with respect to march-in rights and pricing was the story of a contractor who had balked at the march-in provisions in an EPA contract.[214] Patrick Iannotta, President of the contractor Ecolotrol, Inc., recounted the events whereby the company did not receive a patent waiver because it would not agree to an EPA demand that it make the invention "available at terms reasonable under the circumstances."[215] Iannotta stated:

> [W]e as a small company were unable to obtain from the Environmental Protection Agency the . . . patent rights . . . .
>
> . . . One of the things that I'm not sure you're aware of is the primary reason we turned down the EPA grant. . . . [W]e would have been

208. *Id.* (emphasis added).

209. *1977 Senate Small Bus. Hearings*, *supra* note 46, at 3 (emphasis added) (statement of Adm. H.G. Rickover).

210. *Id.* at 4 (emphasis added) (statement of Benjamin Gordon, Consultant to the Comm. on Small Bus.).

211. *Id.* (statement of Adm. H.G. Rickover).

212. *Id.* at 192 (emphasis added) (statement of Benjamin Gordon).

213. *1979 Government Patent Policy Hearings*, *supra* note 11, at 48 (statement of Harry F. Manbeck, Jr., Gen. Patent Counsel, Gen. Elec. Co.).

214. *See id.* at 209 (correspondence submitted by Patrick J. Iannotta, President, Ecolotrol, Inc.).

215. *Id.*

> forced to agree to a march-in rights clause which I thought was confiscatory . . . .
>
> . . . Now, the march-in provision was such that we had to make the invention reasonably available, whatever that meant at a reasonable volume, whatever that meant. . . .
>
> . . . .
>
> . . . The problem is the Government says it shall be "reasonably available." What is "reasonably available" today to one administrator may be "unreasonably unavailable" to some other administrator . . . .
>
> . . . .
>
> On the question of march-in rights, I don't have a particularly difficult problem with the subject inventions. I think the key has to be this: The small businessman or large businessman or whatever, has to have an irrevocable license. . . .
>
> . . . .
>
> . . . The best argument ever given to me why I should not disagree with subject inventions or march-in provision is that they are never used. I said, if they are never used, then take them out of the contract.[216]

But even that sympathetic tale was not enough, perhaps because, once more, Admiral Rickover's sharp tongue apparently convinced Congress, or at least the Committee, that pricing was key. Admiral Rickover asked if it were wise "to exercise monopoly rights over the distribution, use, and *pricing* of the results for 17 years?"[217] In response, Senator Long rhetorically inquired, "Is this bill providing a limitation on just *how much the successful contractor can charge* the public for what the public has already paid for? . . . Is there any limitation in this proposal as to *how much he could charge* the public to have the benefit of what the public had already paid for when they paid for the research?"[218] Some time later, Admiral Rickover was in the House, dramatizing the importance of price control:

> Imagine the public furor that would ensue if, under the terms of this bill, a contractor . . . developed at public expense a major breakthrough . . . . Is it proper for that company to be able to exercise monopoly rights over the distribution, use, and *pricing* of the results for 17

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216. *Id.* at 169-71 (statement of Patrick J. Iannotta). Exhibits attached to Iannotta's testimony demonstrate that the issue was one of price. In a letter to the EPA, he had written, "In this grant[,] E.P.A. has required us to accept a *gross profit before taxes of only 7-_%.* We can do almost as well in the bank. . . . [W]hat would trigger such patent clause renegotiations[?] . . . Domination of the industry? Five hundred million dollars in annual sales?" *Id.* at 205 (correspondence submitted by Patrick J. Iannotta).

217. *1979 Senate Sci. Hearings*, *supra* note 46, at 389 (emphasis added) (statement of Adm. H.G. Rickover).

218. *Id.* at 392 (emphasis added) (statement of Hon. Russell B. Long).

> years—mind you, where the Government has paid for it? I think not. . . .
>
> . . . .
>
> . . . The bill provides that if a contractor who holds title to a Government-financed invention fails to develop and promote it, or creates a situation inconsistent with the antitrust laws, the Government can force widespread licensing or revoke the Contractor's patent or license.[219]

Congress, of course, insisted on march-in rights, but it is just as revealing to observe what Congress did not do. The price-control mechanism of the Bayh-Dole Act lies in its definition of "practical application,"[220] and Congress was urged to redefine that term to dispense with the price requirement.[221] Peter F. McCloskey, President of the Electronic Industry Association, stated that "[t]he definition of 'practical application' appears too stringent. We would suggest a rewrite to indicate that 'application' means . . . 'that the invention is being worked *or* that its benefits are available to the public either on reasonable terms or through reasonable licensing . . . .'"[222] The "or" is, obviously, crucial. That Congress refused McCloskey's rewrite and maintained a march-in provision that is triggered upon failure to work *and* reasonable price is perhaps the most telling fact of all.

Judging from the relevant testimony, the reasonable pricing requirement is an open secret, meaning that Congress acknowledges its presence, but the government seldom enforces it. In the latest congressional term, Representative Sanders offered an amendment to an appropriations bill, H.R. 4577, that forbade the use of funds for licensing government patents except in accord with the reasonable pricing provisions of 35 U.S.C. § 209, the section of the Bayh-Dole Act applicable to license, rather than title, transfers.[223] The congressional debate over the Sanders Amendment was explicitly addressed to the existing reasonable pricing provisions and cited the Bayh-Dole Act's requirement of "reasonable terms" time and again.[224] In fact, the text of the amendment was quite explicit in citing, parenthetically, the "reasonable terms" provisions:

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219. *1980 House Gov't Operations Hearings*, *supra* note 46, at 79 (emphasis added) (statement of Adm. H.G. Rickover).

220. "The term 'practical application' means . . . that the invention is being utilized *and* that its benefits are . . . available to the public on reasonable terms." 35 U.S.C. § 201(f) (1994) (emphasis added).

221. *1979 Senate Sci. Hearings*, *supra* note 46, at 221 (statement of Peter F. McCloskey).

222. *Id.* (emphasis added).

223. 146 CONG. REC. H4291 (daily ed. June 13, 2000).

224. *Id.* at H4291-93.

> None of the funds made available in this Act for the Department of Health and Human Services may be used to grant an exclusive or partially exclusive license pursuant to chapter 18 of title 35, United States Code, except in accordance with section 209 of such title (relating to the availability to the public of an invention and its benefits on reasonable terms).[225]

Actually, the debate was more in the nature of legislative theater, or even circus, because there was no argument about the import of the reasonable terms language.[226] What was being debated was an amendment that did not impose new requirements but instead simply demanded that existing law be respected.[227]

VI. THE ROLES OF GOVERNMENT, ACADEMIA, AND INDUSTRY

One of the complexities of assessing and, especially, policing the equity of technology-transfer legislation in particular, and public-private combinations in general, is the substantial confusion over the appropriate roles of government, academia, and industry. Conflicting interests and clashing organizational cultures may complicate the effective implementation of public-private combinations.

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225. *Id.* at H4291.

226. *Id.* at H4291-93.

227. In making the following statement, Congressman Sanders did not even pretend that what he was offering was anything different than what current law requires:

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

Id. at H4291-92 (emphasis added). Despite this, news reports the following day held this to be a departure from existing law. For instance, the *New York Times*, in its report, implied that the provisions of the Sanders Amendment would require new legislation, rather than enforcement of the existing Bayh-Dole statute:

> In another demonstration of the significance of the issue to lawmakers, the House today overwhelmingly passed legislation offered by Representative Bernard Sanders, a Vermont Independent, that would require "reasonable pricing" on drugs developed through collaboration between the National Institutes of Health and pharmaceutical companies.
>
> The legislation, a response to charges that drug companies are overcharging patients for drugs developed in part with federal money, does not establish a specific formula for pricing the drugs. But is it intended to lower some drug prices. Its prospects in the Senate are unclear.

Robert Pear, *In Policy Change, House Republicans Call for Government Guarantee of Drug Benefits*, N.Y. TIMES, June 14, 2000, at A25.

Historically, universities have placed greater emphasis on basic science and the pursuit of knowledge than on the practical application of scientific discoveries.[228] However, from the 1920s through the early 1940s, cooperation between academia and industry began to grow,[229] despite the disdainful view that many academics had of faculty members who collaborated with industry.[230] This disdain began to dissipate as academic inventors themselves sought to commercialize their research by seeking patents and licenses for university research results, beginning on a large scale with the establishment of the Wisconsin Alumni Research Foundation in 1925.[231]

The Bayh-Dole Act has undoubtedly spurred these collaborative activities between universities and private enterprises. Since the 1980s, there has been a dramatic increase in collaborations between academic scientists, who still receive a substantial portion of their funding from the government, and industry.[232] This reflects a slowdown in the growth of federal support for health-related research, which has been caused by national policy shifts and the growth in universities' commitments to commercialize their own research themselves.[233] Increasingly, universities have started their own for-profit companies. In one notable case, a university, along with its individual members of the Board of Trustees, the university president, and members of the faculty, owned equity in a company.[234] According to one recent study of 800 biotechnology faculty members at forty research universities, 47% consulted with industry, nearly 25% received industry-supported grants and contracts, and 8% owned equity in a company whose products were related to their research.[235] Perhaps more troubling was the finding that 30% of those with industry funding said that their choice of research topics was

228. Sheldon Krimsky, *University Entrepreneurship and the Public Purpose, in* COMM. ON SCIENTIFIC FREEDOM & RESPONSIBILITY, AM. ASSOC. FOR THE ADVANCEMENT OF SCI., BIOTECHNOLOGY: PROFESSIONAL ISSUES AND SOCIAL CONCERNS 35 (P. DeForest et al. eds., 1998).

229. JOHN P. SWANN, ACADEMIC SCIENTISTS AND THE PHARMACEUTICAL INDUSTRY: COOPERATIVE RESEARCH IN TWENTIETH-CENTURY AMERICA 170 (1988).

230. *Id.* at 24, 30-35.

231. David Blumenthal et al., *Commercializing University Research*, 314 NEW ENG. J. MED. 1621, 1621-26 (1986).

232. Udayan Gupta, *Hungry for Funds, Universities Embrace Technology Transfer*, WALL ST. J., July 1, 1994, at A1.

233. *See id.*

234. *See* David Blumenthal, *Academic-Industry Relationships in the Life Sciences: Extent, Consequences, and Management*, 268 JAMA 3344, 3346 (1992).

235. *See id.* at 3345.

influenced by their perceived commercial potential; only 7% of those without industry support were likewise influenced.

In a survey of thirty-five universities with the largest grants from the NIH and the National Science Foundation (NSF), the GAO found that thirty-four had technology licensing offices; by contrast, only twenty-two had established such offices before 1980.[236] During fiscal years 1989 and 1990, technologies developed with acknowledged[237] NIH or NSF funding accounted for approximately 73% of all license income.[238]

At many universities, private corporations can gain access to federally funded technologies through membership in industrial liaison programs (ILPs).[239] For an annual fee, corporate members are able to attend research symposia and seminars and receive research reports, abstracts, and newsletters. This fee also buys corporate members virtually unrestricted access to faculty research prior to publication, usually through interactions or consultations with university faculty. In the GAO study mentioned above, thirty universities out of thirty-five surveyed had such a program.[240]

Many ILPs offer membership to foreign companies. Twenty-four of the thirty-five ILPs examined had at least one foreign member,[241] which raises questions about the appropriateness of transferring U.S. taxpayer-funded technology to foreign countries.[242]

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236. U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-92-104, *University Research: Controlling Inappropriate Access to Federally Funded Research Results* 11 (1992) [hereinafter GAO UNIVERSITY RESEARCH REPORT].

237. As we have already stated, one of the most daunting tasks is to discover the true numbers, largely because the reported numbers depend upon self-reporting. There is a difference between whether technology is the product of federal funding, in whole or in part, and whether an academic institution (or government agency) believes it is. Because, in the case of academic institutions and businesses that may benefit from federally funded research, the decision to characterize technology as publicly supported or not carries with it the decision to recognize public rights, including most especially, the reasonable-pricing clause of the Bayh-Dole Act, the conflict of interest involved in such a decision makes the results of such self-reporting suspect by definition. *See, e.g.*, Gosselin & Jacobs, *supra* note 20 (claiming that DNA research was partially funded by the federal government despite the inventors' protestations to the contrary); NAT'L INSTS. OF HEALTH, OFFICE OF THE DIR., DETERMINATION *IN RE* PETITION OF CELLPRO, INC., *available at* http://www.nih.gov/news/pr/aug97/nihb-01.htm (last visited Feb. 10, 2001) [hereinafter CELLPRO DETERMINATION] (determining whether to exercise march-in rights against holders of a government-funded patent).

238. GAO UNIVERSITY RESEARCH REPORT, *supra* note 236, at 12.

239. *Id.* at 17.

240. *Id.*

241. *Id.*

242. Nevertheless, note that this question is also separate and apart from the applicability of the Bayh-Dole Act. The Act makes no distinction between foreign and domestic patentees, and, to the extent that foreign enterprises obtain patents granted by the

For example, approximately 50% of the Massachusetts Institute of Technology's (MIT) corporate ILP members were foreign, and, together, they have early access to the results of 86% of MIT's $500 million of federal research support.[243] While the return to U.S. taxpayers is questionable, university researchers can earn generous returns in the form of royalties and other incentives for collaboration.[244]

Whether information gained through access to federally funded research is subject to the restrictions of the Bayh-Dole Act, especially its reasonable-pricing requirements, seems an almost unanswerable question. The answer, however, is hardly daunting: To the extent that the language of the Act covers the research, patents gained through that research must bear the Bayh-Dole legend, as well as be subject to the price-control and other requirements. To the extent that such patents fail to bear the legend, their owners are clearly misleading the public about its rights.

Whether the lack of return to U.S. taxpayers is troubling depends on how one characterizes the missions of government, academia, and industry. Despite the fact that private industry would never tolerate a relationship in which the benefits of a particular investment would be limited to the ambiguous notion of an unaudited and vaguely defined return, an analogous argument is often proposed to justify similar public benefits from taxpayer-funded research. This argument proposes that research subsidized with public funds, whether funneled through industry, academia, or a combination of the two, repays taxpayers through the marketing of new products. This view is held by NIH leaders, who are more concerned with developing and commercializing inventions than with ensuring that the government is repaid for its investment or controlling the price at which new technologies are sold.[245] Of course, the NIH's position is at odds with

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U.S. Patent and Trademark Office, the underlying innovations of which are due to federal funding consistent with the Bayh-Dole Act, those patents demand the Bayh-Dole legend as well. Thus, the question of the appropriateness of foreign benefits based on U.S. taxpayer-supported research is simply heightened when those patents escape Bayh-Dole oversight, and the situation is doubly inappropriate.

243. H.R. REP. NO. 102-1052, at 7 (1992).

244. *See id.* at 9-11.

245. One report noted:

> The National Institutes of Health is not equipped, either by its expertise or by its legislative mandate, to analyze private sector product pricing decisions, NIH Director Bernadine Healy said Feb. 24.
>
> . . . Healy said that NIH can contribute to assessments of pricing by providing "expert technical advice and the relative merits of various products, as

the Bayh-Dole Act, which is not satisfied with an unaudited return, but demands that the public receive a demonstrable and valuable benefit by restricting pricing to levels that are reasonable.

Not surprisingly, many in industry agree with the ephemeral return argument, asserting that government's role is merely to serve as the catalyst for useful, marketable inventions. As the head of one biotech company stated:

> The purpose of government basic research is not simply to provide employment for scientists . . . [but] . . . also to conduct research that can improve our standard of living, improve our health and welfare, and improve the competitiveness of U.S. firms. The bottom line in which these objectives are measured is in the market place, not just in the laboratory.[246]

It is true that government and academic researchers typically emphasize longer-term, basic research, which is a markedly different emphasis than industry's short-term, market-driven aims. The conflict between socially and commercially valuable goals goes to the heart of the concerns regarding public-private combinations. For instance, the virtual absence of anti-addiction medications—only two such treatments have been marketed in the last thirty years—illustrates the possible result.[247] The Medications Development Division of the National Institute on Drug Abuse is intended to be a catalyst for private sector R&D, which it prefers to conduct through CRADAs.[248] Despite an estimated three million people with opiate and cocaine addictions in the United States, only two anti-addiction CRADAs have been established with industry.[249]

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well as the difficulty of the discovery by informing policymakers and potential regulators of the cost of NIH's role in the co-development of such products."

However, for the NIH to undertake pricing analyses or regulation "would radically change its fundamental nature, potentially undermine its research mission, and place it squarely in conflict with its technology transfer responsibilities," according to Healy.

Drugs: NIH Said Not Equipped to Analyze Pricing Decisions of Private Firms, DAILY REP. FOR EXECUTIVES (BNA) No. 9 (Feb. 25, 1993) [hereinafter *NIH Not Equipped*]; *see also infra* notes 294-313 and accompanying text (discussing the *CellPro* litigation).

246. *The Bayh-Dole Act, A Review of Patent Issues in Federally Funded Research: Hearing Before the Subcomm. on Patents, Copyrights & Trademarks of the S. Comm. on the Judiciary*, 103d Cong. 93 (1994) (statement of Barbara Conta, Dir., Regeneron Pharm. Corp.).

247. INST. OF MED., THE DEVELOPMENT OF MEDICATIONS FOR THE TREATMENT OF OPIATE AND COCAINE ADDICTIONS: ISSUES FOR THE GOVERNMENT AND PRIVATE SECTOR 1 (Carolyn E. Fulco et al. eds., 1995).

248. *See id.* at 80-81.

249. *Id.* at 81.

VII. CONFLICTS OF INTEREST

A conflict exists between the purported objectivity of science and the potential bias introduced by commercial interests.[250] At a theoretical level, Henry Etzkowitz argues that the increasingly strong ties between science and industry are not in conflict with legitimate scientific goals; rather, they represent the emergence of new norms about the proper conduct of science.[251] Etzkowitz believes that internal pressures from reduced federal funding have driven the rise of entrepreneurial science, while externally, technology-transfer legislation has encouraged university researchers to view their work in new, economically relevant ways.[252] Nonetheless, the new model raises concerns about conflicts of interest. For example, a tension exists between the academic and governmental mandate to publish research results rapidly in order to disseminate knowledge and the commercial pressures on industry to keep research confidential.[253] This is especially troubling in areas of basic research.

A GAO report acknowledges that the problems surrounding the flow of information between governmental, industrial, and academic partners can be problematic: "[T]he public interest is better served if the Government ensures that appropriate controls and safeguards are in place governing who gets the access to, and ultimately will benefit from, the results of federally funded research."[254] One concern is that, in the rush to patent, powerful research tools may become inaccessible to the research community.[255] Another study revealed serious concerns about the free flow of information among biomedical faculty at leading universities due to their allegiances to so many competing companies.[256] The Bayh-Dole Act allows federal agencies to prohibit public disclosure of an invention for "a reasonable time in order for a

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250. Robert K. Merton, *A Note on Science and Democracy*, 1 J. LEGAL & POL. SCI. 115, 115-26 (1942).

251. *See* Henry Etzkowitz, *Entrepreneurial Science in the Academy: A Case of the Transformation of Norms*, 36 SOC. PROBS. 14 (1989).

252. *Id.* at 17.

253. *Id.*

254. *Conflict of Interest, Protection of Public Ownership, in Drug Development Deals Between Tax-Exempt, Federally Supported Labs and the Pharmaceutical Industry: Hearing Before the Subcomm. on Regulation, Bus. Opportunities, & Tech. of the House Comm. on Small Bus.*, 103d Cong. 40 (1993) [hereinafter *1993 Conflict of Interest Hearing*] (testimony of Jim Wells, Assoc. Dir., Energy & Sci. Issues, Res., Cmty., & Econ. Dev. Div., U.S. Gen. Accounting Office).

255. NAT'L INSTS. OF HEALTH, PANEL REPORT OF THE FORUM ON SPONSORED RESEARCH AGREEMENTS: PERSPECTIVES, OUTLOOK, AND POLICY DEVELOPMENT 3 (1994).

256. *See* Sheldon Krimsky et al., *Academic-Corporate Ties in Biotechnology: A Quantitative Study*, 16 SCI., TECH., & HUMAN VALUES 275, 275-287 (1991).

patent application to be filed."[257] This precludes other fields from benefiting until the patent is filed.

The NIH has had a difficult time enacting conflict of interest guidelines for its fund recipients. Guidelines developed in 1989, which specifically prohibited researchers from holding equity options in companies that could be affected by their research outcome, were criticized as too restrictive and were withdrawn.[258] The NIH Revitalization Act required the NIH to issue clear guidelines in 1993, but the NIH declined to comply with a congressional requirement that it define the "specific circumstances that constitute" a financial conflict of interest.[259] When the NIH issued draft guidelines in 1993, it required only that universities and other institutions form three-person committees to decide when financial ties created a conflict or compromised HHS research.[260] That suggestion was abandoned, however, in favor of "institutional official(s)," whose job is "to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research."[261] The obligation of the institution is simply to take undefined "reasonable steps"[262] to assure compliance with the institution's rules and the regulations, which essentially require disclosure and nothing more.[263]

Another potential conflict exists between the possibility of future royalties and scientists' accurate interpretation of their research. The FTTA, which allows government inventors to retain 15% of the royalty income that an agency receives from an invention, addresses this issue.[264] While royalties are certainly a potent incentive, they do not differ appreciably from equity positions or other financial relationships that the NIH has sought to prohibit among its extramural researchers. The possibility of future royalties may compromise a researcher's conduct, interpretation, or representation of research. Whether a 15% stake in royalty income would be enough to induce such a compromise depends in part on the individual inventor and the invention's commercial potential.

257. 35 U.S.C.A. § 205 (West 1994 & Supp. 2000).
258. *See* Michael D. Witt & Lawrence O. Gostin, *Conflict of Interest Dilemmas in Biomedical Research*, 271 JAMA 547, 548 (1994).
259. Bruce Agnew, *Congress Demands Final Conflict-of-Interest Regulations*, J. NIH RES., Aug. 1993, at 48, 48.
260. *See id.*
261. 42 C.F.R. § 50.604(b) (2000).
262. *Id.* § 50.604(a).
263. *Id.* § 50.604(c)(2).
264. 15 U.S.C. § 3710c(a)(1)(A)(i) (1994).

Another conflict of interest exists with respect to what is essentially the self-reporting arrangement by which federally funded institutions decide whether inventions are the product of federal funding and whether such inventions should bear the Bayh-Dole legend. These are two separate questions, of course. Apart from the clear temptation to err on the side of nondisclosure, note that the latter issue is somewhat more complex than whether the invention is a product of federal funding.[265] Because the system is one of self-reporting, there is no reason to believe—except for pure faith, of course—that, where millions of dollars are at stake,[266] such institutions, even when they understand that the legend is required, will decide to adopt the legend, especially knowing that there is no meaningful penalty for failure to do so.

VIII. FAILURE TO UNDERSTAND AND ASSERT MARCH-IN RIGHTS

Because patents are obtained in secret, there is no way to know whether recipients have acknowledged the government's support and its rights to the invention, as required by law, until after the patent is granted. Yet the regulations adopted by the government soon after the Bayh-Dole Act's enactment established that, if the appropriate legend were discovered to be missing, the government's right to march-in could only be invoked if asserted within sixty days after the discovery

265. *See supra* notes 133-145 and accompanying text.

266. A recent GAO report reveals the startlingly large sums involved: The University of California received $63,000,000 *annually* in licensing fees based on more than one billion dollars of annual federal funding; Stanford received $43,000,000 annually; Columbia, $40,000,000; Michigan State, $17,000,000; the University of Wisconsin at Madison, $13,000,000. All told, universities polled in the GAO report received $208,000,000 in 1996 for licensing. ADMINISTRATION OF THE BAYH-DOLE ACT, *supra* note 2, at 10. How likely is it that those institutions that have their own constituencies, especially those that frequently complain of underfunding, as universities often do, will willingly put these kinds of funds at risk for federal appropriation? Consider this recent news item:

> Universities also have become adept at tapping . . . health-related royalties, which totaled roughly $300 million in 1996, almost triple the 1991 level.
>
> Profits on drugs that emerge from university labs offer the biggest potential for the federal government to get a return on its research investment. However, it would also raise the hackles of the education lobby, which would fight to keep university royalties flowing undiluted by any federal cut.
>
> "At a time when academic medical centers are struggling from Medicare and Medicaid cutbacks, trying to tax another small revenue stream they may get from royalties doesn't make any sense to me," says David Korn, a senior vice president at the Association of American Medical Colleges.

Chris Adams & Gardiner Harris, *When NIH Helps Discover Drugs, Should Taxpayers Share Wealth?*, WALL ST. J., June 5, 2000, at B1.

of the contractor's failure to disclose the invention.[267] Both the government and the funded entities admit that the Act has not been policed and, at the same time, offer varied excuses for that neglect, which range from the impossibility of proving that an invention was really conceived while the project was receiving government funding to the limited time available to unearth such proof.[268]

Effectively, the government has enacted a statute of limitations against itself that makes enforcement of the Act impossible and abrogates all public rights to Bayh-Dole patents. With only two people at the NIH charged with handling invention information coming from thousands of funding agreements awarded each year,[269] it is virtually impossible to discover and notify all, or even most, violators of the Act within sixty days. While the NIH has implemented a computerized system for handling invention information in response to an investigation by its Inspector General,

267. 35 U.S.C. § 202(c)(6) (1994); 37 C.F.R. § 401.3(a) (2000). Together, these rules require that standard patent rights clauses be part of every subject funding arrangement. Pursuant to 37 C.F.R. § 401.14, the following legend has to be included in any patent subject to the regulations: "This invention was made with government support under (identify the *contract*) awarded by (identify the Federal agency). The government has certain rights in the invention." 37 C.F.R. § 401.14(f)(4) (2000) (internal quotations omitted). However, if a contractor obtains a patent without including the legend in the patent, the government must (1) discover this failure and (2) attempt to regain title to the invention. The government has compounded the difficulty of its task by including in its regulations the requirement that: "the *agency* may only request title within 60 days after learning of the failure of the *contractor* to disclose or elect within the specified times." *Id.* § 401.14 (d)(1). What makes this even more troublesome is that the regulations do not specify whether the government must actually be aware of the absence of the legend or whether "constructive knowledge" will suffice. Because patents are a matter of public record, one of the first arguments an errant contractor can be expected to make is that the government constructively knows of each issued patent and, thus, the sixty-day period has passed.

268. Universities, for example, admitted that they had some difficulty complying with Bayh-Dole's reporting requirement:

> Each of the universities visited had systems that allowed them to track dates and meet reporting deadlines for all Bayh-Dole requirements. However, some university officials noted that determining compliance with certain requirements can be difficult. For example, as noted above, it may be difficult to tell when an invention actually was conceived or when the university first learned of it. University officials told us that, as a practical matter, it may not be possible to know whether an invention exists until there is at least a preliminary patent search. Thus, how to meet the requirement in the regulations to report an invention within 2 months is unclear.

ADMINISTRATION OF THE BAYH-DOLE ACT, *supra* note 2, at 12-13. Note that the government, the universities, or both have failed, once again, to understand the terms of the Act. The two month period is the period in which the government, not the university, is required to act in order to take title to inventions that are not properly reported.

269. OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., NIH OVERSIGHT OF EXTRAMURAL RESEARCH INVENTIONS 3 (1994) [hereinafter NIH OVERSIGHT OF EXTRAMURAL RESEARCH].

budget pressures preclude the agency from hiring additional staff for these activities.[270] To make matters worse, the NIH would have to conduct thousands of investigations every year in order to discover legend omissions. In order to police this kind of "negative" violation, the NIH would have to audit every patent granted to contractors or anyone operating with their authority. This additional procedure would amount to more than 100,000 investigations annually.[271] Finally, the NIH has abdicated its responsibility by announcing that it has no interest in enforcing these provisions of the Bayh-Dole Act and by operating what has been referred to as a "lackadaisical" "honor system" with "a policy of 'don't ask, don't tell and don't pursue.'"[272]

Enforcement of the Bayh-Dole Act is further weakened because of the astonishing and virtually unbelievable fact that the government does not understand, let alone acknowledge, the nature of its march-in rights. To a large extent, government agencies, when addressing march-in rights, confuse them with a simple utilization or working requirement.[273] This failure to understand the full impact of the Bayh-

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270. Telephone interview with Sue Ohata, Nat'l Insts. of Health, Dir., Div. of Extramural Invention Reports (May 15, 1995).

271. Over 100,000 new patents are issued by the U.S. Patent and Trademark Office annually. Morton Int'l Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 1472 (Fed. Cir. 1993) (Mayer, J., concurring). A search of the patents issued by the office between Jan. 1, 1999, and Jan. 1, 2000, for instance, reveals that there were 154,485 patents issued; this number is, unsurprisingly, increasing. The figure for a similar period between 1994 and 1995 was only 102,230. And this does not include patents issued abroad that are also subject to the Bayh-Dole rules. For instance, the European Patent Office, just one part, though a substantial one, of the international patent regime, issues about 24,000 new patents annually out of approximately 126,000 new applications each year. Samson Helfgott, *Super2 P Group News*, 18 INTELL. PROP. L. NEWSL. 32, 34 (2000); David W. Okey, *Constitutionality of a Multi-National Patent System, Part II*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 927, 959 n.144 (1999). The point of all this, however, is not to show how daunting a task it would be to police this effectively. Instead, these numbers send the clear message to contractors that they can ignore or violate the Bayh-Dole Act with effective impunity. Note that, since the Scripps-Sandoz deal came under scrutiny in 1993, the NIH has again investigated contractors and discovered similarly large and grave violations of the Bayh-Dole Act, with no explanations offered by the contractors. U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-99-242, TECHNOLOGY TRANSFER: REPORTING REQUIREMENTS FOR FEDERALLY SPONSORED INVENTIONS NEED REVISION 2 (1999) [hereinafter REPORTING REQUIREMENTS].

272. *Underreporting Federal Involvement*, *supra* note 105, at 2 (statement of Hon. Ron Wyden, U.S. Congressman, Or.); *see also* Mark Z. Barabak, *U.S. May Be Losing Out on Medical Research*, SAN DIEGO UNION-TRIBUNE, July 12, 1994, at C1 (reporting on the widespread noncompliance with the Bayh-Dole Act among research universities and quoting Congressman Wyden).

273. In one of the most recent government reports on the administration of the Bayh-Dole Act, the GAO committed the fatal error of confusing march-in rights with simple working requirements without regard to pricing or the other guarantees of public benefit which were supposed to be the *raison d'etre* of the Act. Describing universities' obligations under the Bayh-Dole Act, the report erroneously states, "The university must attempt to develop the invention. Otherwise, the government retains the right to take control of the

Dole Act, and certainly its most profound element—a reasonable pricing requirement extending broadly across all inventions that are produced as a result of federal funding (including pharmaceuticals)—means that even minimal oversight has no significance.[274] The GAO recently reported massive violations of the Bayh-Dole Act.[275] However, because it failed to understand the true breadth of march-in rights—that is, of reasonable pricing requirements—it failed to understand the import of those violations. The report simply noted that, absent responsible reporting by contractors, the government would lose its right to work those inventions itself.[276] But because there is no real possibility that the government would work any of those inventions, the failure to report was, at best, interesting trivia. Had the GAO reported that the public has lost its right to require reasonably priced drugs, such a report would have had a meaningful impact.[277]

The GAO's ignorance of march-in rights is not the end of the story, because, as it turns out, contractors, including universities, are engaging in regular, recurring, and unexplained violations of the Act.[278] The most serious violation is the complete failure to report the patents that they obtain due to government funding.[279] This failure manifests itself most immediately in patents that do not bear the Bayh-Dole legend. Obviously, without serious and expensive investigation

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invention." ADMINISTRATION OF THE BAYH-DOLE ACT, *supra* note 2, at 4. But, of course, the requirement is not that the university simply "develop" the invention; the responsibility of the university, or of any contractor subject to the Act, is to ensure that the invention is priced reasonably. The failure of contractors to do so is surely outweighed, on the scale of what might be acceptable, by the government's utter failure to understand its responsibility to police the Act properly and knowingly.

274. *See* 35 U.S.C. § 201(b)-(c),(e) (1994) (defining the terms "funding agreement," "contractor," and "subject invention," respectively).

275. REPORTING REQUIREMENTS, *supra* note 271, at 6.

276. *Id.* at 15-19.

277. This is how the government reported violations of the Bayh-Dole Act:

> Federal agencies and their contractors and grantees are not complying with provisions on the disclosure, reporting, retention, and licensing of federally sponsored inventions under the regulations implementing the Bayh-Dole Act and Executive Order 12591. In our review of more than 2,000 patents issued in calendar year 1997 as well as an Inspector General's draft report on 12 large grantees of the National Institutes of Health, we found that the databases for recording the government's royalty-free licenses are inaccurate, incomplete, and inconsistent and that some inventions are not being recorded at all. As a result, the government is not always aware of federally sponsored inventions to which it has royalty-free rights.

Id. at 2.

278. *Id.* at 6.

279. *Id.* at 10-12.

of each and every government contractor (or worse, their undisclosed transferees), there is no way the government can discover inventions that were patented without its knowledge. As a recent report found:

> In July 1999, the Inspector General submitted a draft report to NIH on the most recent review and concluded that compliance with Bayh-Dole requirements remained insufficient. The Inspector General found that, of 633 medically related patents issued to the 12 grantees in calendar year 1997, 490 were recorded in Edison. The remaining 143 patents were not in Edison, and the patents did not include government interest statements. After comparing the information in the 143 patents with information from NIH's grant records, the Inspector General concluded that all 143 inventions most likely resulted from NIH-sponsored research and questioned the 12 grantees about these findings. The grantees then reviewed their records and agreed that 79, or 55.2 percent, of the 143 inventions were in fact supported with NIH's funding. The grantees also acknowledged that they had not properly notified NIH of the inventions or included a statement on their patent applications that the inventions had been created with federal support. They did not agree that the remaining 64 patents resulted from government-sponsored research.[280]

The failure to include the legend is a kind of insurance against discovery and, without mincing words, amounts to theft of government property and ongoing fraud of massive proportions. The GAO figure—143 unreported medically related patents out of a total of 633 such patents—yields a failure rate of about 25%, and, of course, this is a rate that the GAO has discovered without the kind of intensive investigation necessary to uncover the true dimensions of the fraud.[281] Even the contractors' admission of 79 unreported inventions out of 633 yields a 13% failure rate.[282] Equally shocking is the GAO's conclusion that contractors fail to comply with the Bayh-Dole Act's general reporting requirements (that is, the required combination of both the Bayh-Dole legend and a confirmatory government license statement) at a rate of 94%![283] In what seems to be a typical situation, the GAO visited ten government contractors and examined the patents obtained by those contractors without regard to government funding.[284] The GAO found that these contractors typically failed to

280. *Id.* at 12-13.

281. *Id.*

282. *Id.* at 13.

283. *Id.* at 6 ("[W]hile 2,083 patents issued in 1997 had either a government interest statement or a confirmatory license on file, only 128, or 6.1 percent, were recorded in both databases.").

284. *Id.* at 1-2, 6-7, 12, 27.

report about 20% of the patents issued to them, even though they were subject to the Bayh-Dole Act reporting requirements.[285] What is again shocking is that, when confronted with this evidence, none of the contractors were able or willing to explain why they failed to take steps necessary to reveal that they were in wrongful possession of government property.[286]

Although the recent GAO and other reports on the Bayh-Dole Act indicate some continuing governmental interest in the indifference that contractors have demonstrated toward their responsibilities under the Act, little has been done. This is surely due to the fact that even the GAO fails to understand exactly what it is investigating. It seems thoroughly obvious that the most serious consequence of a failure to report the government interest in granted patents is that the government will not be able to police the pricing of inventions for which the public has already paid. With that at stake, the GAO's interest in discovering individual and systematic failures to comply should be high and its investigations well motivated. But the GAO does not understand the stakes; instead, the GAO itself has stated that the failure to report means that the government is unable to exercise its royalty-free license when contractors do not comply, even though, in the same breath, the GAO notes that such a license is rarely used.[287]

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285. *Id.* at 12. Specifically, the GAO found that:

> During visits to 10 contractors and grantees, we asked the contractors and grantees whether there might be federally sponsored inventions that had not been reported at all. In this regard, we reviewed other patents that were issued to them during calendar year 1997 that did not contain government interest statements and for which no confirmatory licenses were on file at PTO. In each case, we asked contractor or grantee officials to show us from the records available how they determined that the inventions were not the result of government funding.
>
> Our review of 56 patents showed that 11, or 19.6 percent, of the 56 inventions in question had not been reported even though the inventions appeared to have been the result of government funding. Officials from the five contractors and grantees responsible for these 11 patents agreed with our findings but did not explain why the inventions had not been reported. Again, each had systems designed to ensure that all government-sponsored inventions were disclosed.

Id.

286. *Id.* It is tempting to be more sanguine and charitable and characterize this simply as a "failure to comply" or, as the GAO put it, "inventions [that] had not been reported." *Id.* But the Bayh-Dole Act march-in rights are, as is true of many rights, a type of property, and what can be phrased as a "failure to comply" is, in reality, wrongful possession of property. This is, at the very least, a kind of conversion.

287. *Id.* at 2 ("As a result [of widespread Bayh-Dole noncompliance], the government is not always aware of federally sponsored inventions to which it has royalty-free rights."). In a concluding section of its most recent review of the Bayh-Dole Act, entitled "The Primary Use of a License Is for Research and Infringement Protection," the GAO reports,

> No government wide data exist on how the government actually uses its royalty-free licenses, and agencies did not have records showing how often and under what

With so little apparently at stake in the GAO's mind, it is no wonder that the Bayh-Dole Act is not enforced. It seems clear, then, that the Bayh-Dole Act will never be enforced until the true nature of march-in rights are understood and the price-control rights vested in the government are recognized.

As an example of the government's continuing confusion and ignorance regarding the price-control provisions of the Bayh-Dole Act, consider that in its most recent report, the GAO accurately identified some fatal flaws of the administration of the Bayh-Dole Act but omitted discussion of the price-control provision.[288] In doing so, the GAO utterly failed to identify the most devastating consequence of noncompliance with the Bayh-Dole Act, the absence of price controls, believing instead that the true loss suffered by the public was the underutilization of royalty-free government licenses. As the GAO concluded:

> Federal agencies are not sufficiently aware of the royalty-free rights the government has to inventions subject to the Bayh-Dole Act and Executive Order 12591. This is because the two primary resources for information on federally sponsored inventions—the Government Register and the patent database—are inaccurate, incomplete, and inconsistent. These errors and omissions are the result of federal funding agencies', contractors', and grantees' not always complying with reporting requirements that are themselves often complicated and redundant.[289]

Clearly, the GAO is wrong. It is not that the government is "not sufficiently aware of the royalty-free rights [that it] has" but that the government is not at all aware of its price-control authority.[290]

The GAO has misread the Bayh-Dole Act on more than one occasion. In a 1998 review of Bayh-Dole and university research, the

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> circumstances these licenses have been employed. Agency officials told us, however, that they value the royalty-free licenses because they allow the government to use the inventions without concern about possible challenges that the use was unauthorized. The agency officials also noted that, while the government can use its royalty-free licenses to reduce procurement costs in those cases in which royalties are disclosed as a cost element in the contract, such cases seldom occur.

Id. at 17.

288. *Id.* at 19 (failing to recognize the government's inability to control prices under the current Bayh-Dole administration).

289. *Id.*

290. Clearly, the GAO has failed to incorporate into its understanding of march-in rights the notion that "practical application," as defined in the statute, requires public availability *upon reasonable terms*—not simply public availability. 35 U.S.C. § 201(f) (1994).

GAO described, or, more accurately, misdescribed, the nature of march-in rights:

> The university must attempt to develop the invention. Otherwise, the government retains the right to take control of the invention. The government also may take control of the invention for other reasons, such as a need to alleviate health or safety concerns. This provision is referred to in the law as the government's "march-in" rights.[291]

But, of course, this is the same error compounded. The university, or any federally funded contractor subject to the Bayh-Dole Act (which was extended to large businesses in many cases by Executive Order 12,591)[292] is required to do far more than "develop" the invention. By the terms of the Act, the contractor must take steps to ensure that the invention is made available to the public at a reasonable price, and, one may assume, at other reasonable terms, to the extent that those terms are in some way important.[293]

The GAO is not alone in its failure to understand and recognize the price-control mechanism inherent in Bayh-Dole march-in rights. In the only known case in which march-in rights were demanded, the government and commentators together failed to fully grasp the notion of march-in rights.[294] In 1994, Johns Hopkins University and others sued CellPro for the infringement of patents that had been funded by the NIH.[295] In 1997, a jury found CellPro liable for infringement.[296] CellPro then petitioned the NIH to institute march-in procedures against the patent owners, seeking an order that would require Johns Hopkins to license CellPro to use the patent "on reasonable terms" or, alternatively, to have the NIH issue a license directly to CellPro so that it could work the patent.[297] CellPro apparently asserted that this was necessary because of health or safety needs or, alternatively, because Johns Hopkins had failed to achieve "practical application."[298] Actually, it is not clear whether CellPro made this exact allegation, which would have been proper under the statute, because the NIH, in its determination, stated that CellPro had instead asserted that Johns

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291. ADMINISTRATION OF THE BAYH-DOLE ACT, *supra* note 2, at 4.

292. Exec. Order No. 12,591, 3 C.F.R. 220 (1988).

293. 35 U.S.C. § 201(f). Although our discussion of "reasonable terms" shows that price is at least one decisive factor, Congress's decision to use the broader term seems to contemplate other factors as well. These might include whether the product is available in small and large quantities and any other terms considered subject to reasonability constraints.

294. *See* Johns Hopkins Univ. v. CellPro, 978 F. Supp. 184 (D. Del. 1997).

295. *Id.* at 186.

296. *Id.* at 191-92.

297. *See* CELLPRO DETERMINATION, *supra* note 237.

298. *Id.*

Hopkins had "failed to take reasonable steps to commercialize the technology."[299] This was probably sloppiness on the part of the NIH, because its determination explores in depth—although ineffectually and mistakenly—whether "practical application" was in fact achieved.[300] In the end, the NIH rejected CellPro's petition, but it did so based on a misreading of the applicable statute and regulation.[301]

In its determination, the NIH found that Johns Hopkins had "clearly met" the requirement for practical application.[302] The NIH found that Johns Hopkins and its licensees had sold the invention "worldwide," that machines incorporating the patent had been installed in many medical centers, and that Johns Hopkins and its licensees (namely Becton-Dickinson and Baxter Healthcare Corporation) had "aggressively defended [their] patents in court."[303] The NIH determination concluded that these steps evidenced that the patent owners had taken effective measures to achieve practical application.[304] Additionally, the NIH found that Johns Hopkins' licensing and Baxter's manufacture, practice, and operation of the patented technology demonstrated its availability to and use by the public to the extent required by law.[305]

However, the NIH's determination was clearly wrong. The NIH treated "practical application" as if it merely required licensing, manufacture, practice, operation, availability, and use; however, these conditions are not enough.[306] In fact, these actions merely constitute working the patent, a standard Congress rejected as a minimal trigger for march-in rights under the Bayh-Dole Act.[307] Instead, the Bayh-Dole Act adopted a more stringent standard. A patent must be worked *and* made "available to the public on reasonable terms."[308] Among other things, the NIH completely failed to determine whether Johns

299. *Id.*
300. *Id.*
301. *Id.*
302. *Id.*
303. *Id.*
304. *Id.*
305. *Id.*
306. The statute is clear. Mere availability is insufficient. The statute requires availability on "reasonable terms." 35 U.S.C. § 201(f) (1994).
307. The language of the statute suffices to demonstrate that merely working the patent is insufficient. *See id.* However, the statutory history shows even more clearly that, although industry would have preferred simple availability, Congress rejected that standard. *1979 Senate Sci. Hearings*, *supra* note 46, at 221 (statement of Peter F. McCloskey) (suggesting that it should be sufficient that an invention "is being worked *or* that its benefits are available to the public on reasonable terms or through reasonable licensing arrangements" (emphasis added)).
308. 35 U.S.C. § 201(f).

Hopkins and its licensees demanded reasonable terms.[309] This conclusion is not surprising because the NIH determination began with a mischaracterization of CellPro's position as claiming that Johns Hopkins did not "commercialize" the invention, when the statute does not address "commercialization." The statute addresses the reasonableness of the *terms* of commercialization—not commercialization by itself.[310] The NIH, in other words, confused "practical application," which requires working *and* reasonable terms, with a simple working or utilization requirement.

The NIH's determination not only flies in the face of the legislative history, it is also flatly inconsistent with the language of the Act itself, the "policy and objective" of which are explained in the Act's introductory paragraph.[311] That language explains that the Act intends to "protect the public against nonuse *or unreasonable use* of inventions."[312] Therefore it is crystal clear that simple utilization is not sufficient to justify continued title under the Bayh-Dole Act. Such utilization must be reasonable and, as later sections of the Act make clear, reasonable use means achieving "practical application," which entails reasonable price terms.[313]

Unfortunately, not only has the NIH determination failed, resisted, or refused to understand and apply march-in rights appropriately. The published commentary on the determination also fails to grasp the legal issues involved. In *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, the authors conflate "practical application" with simple commercialization or utilization.[314] In praising march-in rights, the authors conclude:

> Despite economic incentives to license, there are times when march-in may be necessary .... For example, a company may exclusively license certain patents primarily to raise capital or to block competitors. If the patent owner has licensed without milestones and benchmarks, it loses the ability to address problems of public availability of the technology.... Because march-in authority is such a blunt and powerful means to ensure that a government-funded technology does not languish to the detriment of the public, it exerts an *in terrorem* effect on the conduct of funding recipients and exclusive licensees.... Thus, exclusive licensees are encouraged by the presence of the march-

309. *See* CELLPRO DETERMINATION, *supra* note 237.
310. 35 U.S.C. § 201(f).
311. 35 U.S.C.A. § 200 (West 1984 & Supp. 2000).
312. *Id.* (emphasis added).
313. 35 U.S.C. § 201(f).
314. *See* Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 BERKELEY TECH. L.J. 1095 (1999).

> in authority to develop or sublicense a technology, both of which benefit the public.[315]

But the Bayh-Dole Act is not simply about "public availability," avoiding "languishing," or simple "development." It requires more than that. The Act requires the contractor to ensure that the public investment is protected by assuring that the invention is sold at a fair and reasonable price.[316] An invention for which the public has already paid the price of R&D must be available on reasonable terms.[317] Otherwise, the public pays twice, and the contractor receives the "windfall profit" that Congress sought to avoid.[318]

IX. THE NIH'S ABDICATION OF OVERSIGHT

Increasing the NIH's access to grantee data would bolster its position in its relationships with its grantees. The extent to which the NIH is in a weak position in relation to its grantees, by virtue of its lack of information, is illustrated below. A highly publicized arrangement between the Scripps Research Institute (Scripps), a biomedical research organization, and the Swiss-based Sandoz Pharmaceutical Corporation illustrates the NIH's sometimes-lax oversight of its funding arrangements and, at the same time, raises serious concerns over returns on taxpayer investment.[319]

Scripps' dealings with Sandoz created a stir after the two institutions signed a ten-year contract under which Scripps was slated to receive $30 million a year over the life of the agreement in exchange for first option on exclusive licenses by Sandoz to virtually all of Scripps' inventions.[320] The proposed agreement provided Sandoz representation on Scripps' board, the right to review Scripps' invention disclosure reports before they were submitted to the NIH, and the right to move research from Scripps to Sandoz anywhere in the world.[321] Because Scripps was expected to receive around $700

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315. *Id.* at 1113.

316. *See supra* notes 175-227 and accompanying text (discussing the Bayh-Dole Act's legislative history).

317. *See supra* notes 175-227 and accompanying text.

318. *See supra* notes 175-227 and accompanying text.

319. *See Underreporting Federal Involvement*, *supra* note 105, at 5-7 (testimony of Michael R. Hill, Assistant Inspector Gen., Dep't of Health & Human Servs.) (noting "fundamental problems with . . . NIH oversight").

320. Philip J. Hilts, *Health Chief Assails Deal Between U.S. Research Lab and Swiss Company*, N.Y. TIMES, Mar. 12, 1993, at A16; *see also 1993 Conflict of Interest Hearing*, *supra* note 254, at 7-14 (1993) (testimony of Bernadine Healy, Dir., Nat'l Insts. of Health) (criticizing the Scripps-Sandoz deal).

321. NAT'L INSTS. OF HEALTH, PANEL REPORT OF THE FORUM ON SPONSORED RESEARCH AGREEMENTS: PERSPECTIVES, OUTLOOK, AND POLICY DEVELOPMENT 9 (1994).

million in public funding from the NIH over the ten-year contract period, many viewed this agreement as a public subsidy to a foreign corporation that would facilitate the export of American technology and impose serious constraints on the flow of scientific knowledge.[322] Because of the public controversy surrounding the contract, it was renegotiated so that Sandoz would pay $20 million, rather than $30 million, per year, in exchange for first-refusal rights to 47% of Scripps' research.[323]

While the Scripps-Sandoz deal may not have violated the letter of the Bayh-Dole Act, it was clearly contrary to its spirit. One of the statute's main objectives, "to promote the commercialization and public availability of inventions made in the United States by United States industry and labor," was virtually ignored.[324] In addition, the law was enacted to encourage small business firms to participate in federally supported R&D efforts.[325] Although the codifying regulations state that Congress did not intend to prevent nonprofit organizations from providing big firms with invention options,[326] the Act was not intended to be a subsidy to large firms that are presumably well equipped to compete in the marketplace.[327] However, the Act contains no means of enforcing the small business or domestic preferences, and the Scripps-Sandoz deal shows that contractors are willing to ignore them.[328] What is probably worse, however, is that this arrangement provides another layer of non-Bayh-Dole contractors to shield Bayh-Dole patents from discovery.[329]

Following the controversy over the Scripps-Sandoz deal, the Office of the Investigator General reviewed the 125 patents that Scripps had filed with the Patent and Trademark Office and found that only fifty-one, or 41%, acknowledged U.S government support.[330] The Investigator General believed that many of the remaining seventy-four grants may have been supported with NIH funds.[331] Scripps

322. *See 1993 Conflict of Interest Hearing*, *supra* note 254, at 14 (testimony of Bernadine Healy).

323. Tim Beardsley, *Big-Time Biology*, SCI. AM., Nov. 1994, at 90, 91-92.

324. 35 U.S.C. § 200 (1994).

325. *Id.*

326. 37 C.F.R. § 401.7 (2000).

327. The Act explicitly supports small business patent interests. *See* 35 U.S.C. § 200.

328. *See 1993 Conflict of Interest Hearing*, *supra* note 254, at 6-14 (testimony of Bernadine Healy) (criticizing the Scripps-Sandoz deal and commenting on the absence of a strong Bayh-Dole enforcement mechanism).

329. *See supra* notes 267-293 and accompanying text.

330. *Underreporting Federal Involvement*, *supra* note 105, at 2 (opening statement of Hon. Ron Wyden).

331. *Id.* at 26-28.

initially claimed it was obliged to give the government credit only if federal funds had been directly linked to a patent claim, but the Act clearly defines "subject invention" more broadly.[332] Ultimately, Scripps submitted a revised list to the NIH that acknowledged government support for ninety-four, or 75%, of the 125 patents.[333]

Scripps characterized its failure to include the Bayh-Dole legend on the additional forty-three patents as an unintentional error from which it derived no benefits.[334] While Scripps admits it may have erred, the company claims that the government was not harmed because the government was still able to practice the inventions.[335] In an odd bit of false magnanimity, Scripps also said that the NIH did not have to pay it a royalty, even though the agency was not named on the patent legend.[336] In fact, this royalty waiver is automatic because the Bayh-Dole Act explicitly protects the government's worldwide right to practice subject inventions free of royalties.[337]

To determine whether the Scripps-Sandoz case was an aberration or indicative of a pattern, the Investigator General and the NIH staff examined the patent policies of the top twenty-five patent-generating universities.[338] This study compared the number of patents acknowledging federal support filed by these universities to the total number of patents they filed.[339] Of the more than 4500 patents reviewed, only 37% contained the government rights clause,[340] which is quite similar to the false rate (41%) initially reported by Scripps. The NIH concluded, "Some of these proportions appear low in light of the total Federal funding."[341]

In another study, the Investigator General also found deficiencies in the NIH's oversight procedures, partly because of inadequate agency staffing.[342] The NIH's Division of Extramural Invention Reports has just two people to handle thousands of funding

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332. *Id.* at 70 (report of June Gibbs Brown, Inspector Gen., Dep't of Health & Human Servs.).

333. *Id.* at 2 (opening statement of Hon. Ron Wyden).

334. *Id.* at 113-14 (statement of Dr. William H. Beers, Senior Vice President, Scripps Research Inst. and Douglas A. Bingham, Gen. Counsel, Scripps Research Inst.).

335. *Id.* at 20-21 (testimony of Dr. William H. Beers).

336. *Id.*

337. 35 U.S.C. § 202(c)(4) (1994).

338. *Underreporting Federal Involvement*, *supra* note 105, at 7 (testimony of Michael R. Hill).

339. *Id.*

340. *Id.*

341. *Id.* at 104 (statement of Wendy Baldwin).

342. NIH OVERSIGHT OF EXTRAMURAL RESEARCH, *supra* note 269, at 12.

agreements yearly.[343] This study determined that the NIH limits its oversight of the U.S. industry preference; only 20% of the 100 universities surveyed have established U.S. manufacturing clauses in their agreements.[344] It also found that the NIH did not emphasize the small business preference expressed in the Bayh-Dole Act and provided only limited oversight to ensure that royalties were shared with inventors and that excess income was distributed for research and education purposes.[345] The NIH has claimed that inventors themselves will enforce these provisions.[346]

The NIH requires inventors to make, in writing, disclosure of inventions and of the election to retain title, as well as annual reports on utilization of research, patent applications, and patents.[347] However, the NIH does not review invention disclosures or title elections for timeliness.[348] Nor does it examine annual utilization reports to monitor commercialization efforts, an oversight that effectively limits the government's opportunity to take advantage of march-in rights.[349] Further, no penalties have ever been levied against grantees who submit patent applications for inventions that were never disclosed or for which rights were never elected.[350]

The Investigator General recommended that the NIH develop procedures to secure information directly from the Patent and Trademark Office.[351] In congressional hearings on this issue, Representative Ron Wyden termed this recommendation "underwhelming" in light of the approximately $8 billion that the government pays for research through the NIH.[352] He stated that the NIH was overly reliant on "*grantees voluntarily doing the right thing.*"[353] If the NIH continued not to oversee its technology transfer arrangements, he proposed either that an outside contractor be hired or that the Department of Commerce be assigned to enforcement.[354]

The NIH responded to the Investigator General's suggestion of greater oversight by pointing out that other agencies do not conduct

343. *Id.* at 3.
344. *Id.* at 11.
345. *Id.*
346. *Id.* at 12.
347. *Id.*
348. *Id.*
349. *Id.* at 13.
350. *Id.* at 12.
351. *Underreporting Federal Involvement, supra* note 105, at 8 (testimony of Michael R. Hill).
352. *Id.* at 53 (opening statement of Hon. Ron Wyden).
353. *Id.*
354. *Id.*

case-by-case oversight as recommended by the Inspector General's report.[355] The Public Health Service's (PHS) reply that this would entail too much work certainly does not seem to be a sufficient reason.[356] The NIH's adoption of an electronic database system (EDISON) designed to track inventions did not resolve the problem as apparently had been hoped. Largely, this was because EDISON, too, relied upon self-reporting by contractors for its accuracy and comprehensiveness.[357] The GAO has reported that this simply does not work.[358]

The situation seems essentially unchanged today. The most recent report of the GAO indicates that Bayh-Dole compliance is unmonitored and can be fairly characterized as out of control.[359] In fact, the matter seems now to be even more complicated by interagency jealousies. The GAO report included findings of an NIH draft report in its conclusions, to which the NIH objected.[360] However, the GAO proceeded to publish its report intact and without the deletions demanded by the NIH.[361]

It is not surprising that these kinds of stories recur. What is disturbing is their misconceived fatalism. Last year, it was revealed

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355. *Id.* at 101 (statement of Wendy Baldwin).

356. *Id.* at 80 (memorandum of Philip R. Lee, M.D., Assistant Sec'y for Health, Dep't of Health & Human Servs.) ("Implementation of a process like that just described would result in an enormous burden . . . .").

357. *See* REPORTING REQUIREMENTS, *supra* note 271, at 12-14.

358. According to the GAO, information on compliance with the Bayh-Dole Act was either not available or highly inaccessible: "Neither the Government Register nor the patent database is a sufficient source for determining the rights the government possesses to federally sponsored inventions. Besides being inaccurate, incomplete, and inconsistent, the databases can be difficult to use." *Id.* at 13.

359. The Report described the background in this way:

> Prior to 1980, the government generally retained title to any inventions created under federal research grants and contracts, although the specific policies varied among the agencies. Increasingly, however, this situation had become a source of dissatisfaction. One reason was a general belief that the results of government-owned research were not being made available to those who could use them.

Id. at 2. The Report summarized its findings as follows:

> Federal agencies and their contractors and grantees are not complying with provisions on the disclosure, reporting, retention, and licensing of federally sponsored inventions under the regulations implementing the Bayh-Dole Act and Executive Order 12591. In our review of more than 2,000 patents issued in calendar year 1997 as well as an Inspector General's draft report on 12 large grantees of the National Institutes of Health, we found that the databases for recording the government's royalty-free licenses are inaccurate, incomplete, and inconsistent and that some inventions are not being recorded at all.

Id.

360. *Id.* at 20-21.

361. *Id.*

that the government is investigating activity at the California Institute of Technology (Caltech) related to the acquisition of important DNA-related patents by private industry.[362] Whether the invention was federally funded, when it was conceived, and whether the Bayh-Dole legend should be on the patent are key issues. However, no one is discussing what should be the central consequence of all this: whether the price can be regulated.[363]

A similar story surfaced recently describing the government-funded research and development of Xalatan, a best-selling eyedrop for glaucoma. The *New York Times* described the commercial success of the drug as follows: "With $507 million in sales last year—and the potential for billions more, most of it pure profit—the four-year-old medicine is the equivalent of liquid gold for its manufacturer, the Pharmacia Corporation. The eyedrop [also] earned Columbia University about $20 million in royalties last year . . . ."[364] The public debate is dominated, however, not by accusations that manufacturers are evading existing price controls but, instead, by the repeated misconception that no such price controls exist.[365]

The NIH's lax oversight and its reluctance to enforce the march-in provisions of the Bayh-Dole Act, though regrettable, do not have any easy legal remedy. Whether there is any private remedy to enforce march-in rights is, at best, questionable. There is case law indicating that if agency inaction is based solely on its mistaken belief that it lacks jurisdiction, or on a policy that is so extreme as to be an abdication of its responsibilities, then a legal remedy may be available.[366] The NIH's jurisdictional misbeliefs and weak monitoring

362. Gosselin & Jacobs, *supra* note 20.

363. *Id.* In response to government inquiries, Caltech claimed that the invention at issue was developed prior to the acquisition of a particular funding request. There was a working prototype sequencer, it claimed, in March 1985, six months before Caltech received the federal money. What Caltech did not say is whether there were any other funding grants prior to the invention during which it may have been conceived. *Id.*

364. *See* Gerth & Stolberg, *supra* note 20.

365. The *New York Times* article contains a fatalistic (and erroneous) regret of a former NIH head: "As Dr. Bernadine Healy, a former director of the National Institutes of Health, said in a recent interview, 'We sold away government research so cheap.'" *Id.*

366. *See* Heckler v. Chaney, 470 U.S. 821, 831 (1985). The Administrative Procedure Act governs whether agency decisions, including decisions not to enforce a statute, are judicially reviewable. 5 U.S.C. §§ 701-706 (1994). Section 702 allows any person "adversely affected or aggrieved" to challenge agency action, including failure to act, as long as such a challenge is not barred by statute or unless the matter is committed by law to the discretion of the agency. *Id.* § 701(a). The *Heckler* Court held that failure to enforce a statute is presumptively discretionary and therefore unreviewable. 470 U.S. at 837-38. On the other hand, the Court noted that this is only a presumption that can be rebutted "where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers." *Id.* at 832-33. In the case of the Bayh-Dole Act, an argument

procedures lead to its nonenforcement of march-in rights, but do not necessarily supply the basis for judicial review.[367]

Thus it is not clear, especially from the legislative history, that individuals or third parties have any enforceable claims over the Bayh-Dole Act's reasonable pricing provision. Standing could be difficult to show. Proving causation may also be difficult without the disclosure of privileged data from industry.[368] Though the NIH's position—that the public benefits from technology transfers through a better economy, more jobs, and the privilege of being able to buy the product in the marketplace without regard to the product's price—is questionable,[369] it is not clear that a private remedy is available. And

(unsuccessful in the cases cited in the following footnote) can be made that the detailed clauses appearing in § 202 of the Act amount to the kind of guidelines that should render agencies' actions reviewable. In any event, the *Heckler* Court was careful to note that a failure to enforce because of an agency's mistaken "belief that it lacks jurisdiction" or "that the agency has 'consciously and expressly adopted a general policy' that is so extreme as to amount to an abdication of its statutory responsibilities . . . might indicate that such decisions were not 'committed to agency discretion.'" *Id.* at 833 n.4 (quoting Adams v. Richardson, 480 F.2d 1159 (D.C. Cir. 1973) (en banc)).

367. Unfortunately, several courts have already refused to enforce various provisions of the Bayh-Dole Act, although none of them have attempted to enforce the policing of publicly funded inventions, nor have any of them claimed the public right to "reasonable" prices, which the Bayh-Dole Act seems to guarantee. *See* S. Research Inst. v. Griffin Corp., 938 F.2d 1249, 1254 (11th Cir. 1991); Gen-Probe Inc. v. Ctr. for Neurologic Study, 853 F. Supp. 1215 (S.D. Cal. 1993); Ciba-Geigy Corp. v. Alza Corp., 804 F. Supp. 614, 629 (D.N.J. 1992); Platzer v. Sloan-Kettering Inst. for Cancer Research, 787 F. Supp. 360, 365 (S.D.N.Y. 1992). All of these cases involved claims by companies to rival companies' patent rights, a type of claim that courts might easily consider either committed to agency discretion or unintended by Congress. These types of claims, however, seem far different than demands by medical patients to have necessary drugs available to them on the reasonable terms commanded by the Bayh-Dole Act. In terms of law, these potential plaintiffs would have the kind of concrete claim expressly contemplated by Congress, the absence of which arguably distinguishes all of the above-cited cases.

368. Former NIH head Bernadine Healy's statement that prices cannot be controlled because of the legal inability to procure confidential financial information is, in addition to being politically arguable, simply naive from a legal standpoint. *NIH Not Equipped, supra* note 245. Financial information that is otherwise deemed confidential is routinely available to litigants under state and federal rules of civil procedure. The Federal Rules of Civil Procedure, for example, provide for "protective orders" so that confidential information that is disclosed to adverse litigants will not be communicated to third parties. FED. R. CIV. P. 26(c). When private companies enter into relationships with the government, they are held to waive their rights to confidential information to the extent that information is necessary to ensure compliance with federal policies. CNA Fin. Corp. v. Donovan, 830 F.2d 1132 (D.C. Cir. 1987) (determining whether a company that contracted with the federal government must disclose confidential hiring information under the Freedom of Information Act). Bayh-Dole contractors, by virtue of their agreement to standard government patent clauses, are, legally speaking, indistinguishable from other kinds of government contractors.

369. The HHS, the PHS, and the NIH have published a kind of Bayh-Dole manifesto committing themselves to a partnership between public monies and private industry and emphasizing technology transfer without ever mentioning any express need to police prices as Bayh-Dole requires:

even if judicial review could force march-in, it would be difficult to achieve because of the sixty-day limitation placed on these rights. Whether the sixty-day period would itself be vulnerable to challenge as an extreme abdication of agency obligations is itself a large question.

X. CONCLUSION

The existing, all-too-frequently unacknowledged, and utterly unenforced price controls of the Bayh-Dole Act have potential significance because they appear to apply to a large number of important drugs. Because the Bayh-Dole Act only applies to inventions that are at least partially federally funded, the key question is how many drugs result from such federal assistance. It appears that a large proportion of all new patents, and a larger percentage of new pharmaceuticals,[370] derive in one way or another from federal funding.

Analyses of U.S.-granted patents that cited research papers suggests that the linkage between patents and public research was

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> Both the public and private sectors must work together to foster rapid development and commercialization of useful products to benefit human health, stimulate the economy, and enhance our international competitiveness, while at the same time protecting taxpayers' investment and safeguarding the principles of scientific integrity and academic freedom. . . .
>
> . . . .
>
> Recipients are required to maximize the use of their research findings . . . through their timely and effective transfer to industry for development.

Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts, 59 Fed. Reg. 55,673, 55,673-75 (Nov. 8, 1994). The policy further states that

> [t]he Act serves the public not only by encouraging the development of useful commercial products such as drugs and clinical diagnostic materials, but also by providing economic benefits, and enhancing U.S. competitiveness in the global market place.
>
> Since its passage, the Bayh-Dole Act has been effective in promoting the transfer of technology from Recipients to industry as evidenced by the aggressive pursuit of patenting and licensing and the proliferation of university/industry collaborations. . . .
>
> In keeping with the objectives and policies of Bayh-Dole, it is incumbent upon Recipients to effectively and efficiently transfer technology to industry for commercial development.

Id. at 55,675-76.

370. As the National Science Foundation noted: "The linkage [between patents and public research] is particularly evident in patents for 'drugs and medicines.' Applications in this category cited, on average, several times the number of research papers cited, for example, in the category of 'communication equipment and electronic components.'" NAT'L SCI. FOUND., INDUSTRY TRENDS IN RESEARCH SUPPORT AND LINKS TO PUBLIC RESEARCH 2 (1999). The figure for pharmaceuticals is 50%. *Id.* at 4.

growing at a steady rate across five major industrialized nations.[371] "This was particularly true for the half of U.S. patents granted to U.S. inventors."[372] These American inventors "overwhelmingly cited U.S.-authored research papers, two-thirds of which were published by organizations primarily supported by public funding."[373]

More importantly, available information indicates that not only do many drugs benefit from federal funding, but the most important, so-called blockbuster drugs owe most of their development to federal funding.[374] As a result, the Bayh-Dole Act is as much a potential blockbuster, given the political will, in terms of controlling health care costs, as are the drugs its price-control mechanism embraces. Given the political will, the government might even decide to exercise other portions of the Act, such as its royalty-free right to produce these drugs

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371. *Id.* at 2.

372. *Id.*

373. *Id.*

374. The available data indicate that federally funded drugs constitute the majority of truly effective drugs. While the FDA approves hundreds of drugs for marketing every year, the number of new or important drugs is relatively small. In testimony before the Senate Committee on Governmental Affairs, one witness illustrated the federal government's role in supporting innovative drug development:

> During [the] 5 year period [from 1987-1991] the FDA issued 2,270 drug approvals, but most were for generic drugs or new combinations of existing compounds. Only 117 of the new drug approvals involved so called "New Molecular Entities" (NMEs), which is the name given to drugs which are distinctly different in composition from drugs already on the market. Of these 117 NMEs, only 30 were judged by the FDA to be drugs that were used in the treatment of several illnesses (FDA class E or AA drugs) or to represent a substantial gain in therapeutic value (FDA efficacy rating of A).
>
> Of these 30 "important new drugs" approved by the FDA, 15 benefited from significant funding by the U.S. government. When one considers the country where the drug was discovered the government's role is even more important. 17 of the "important" new drugs were discovered in the U.S. Of these drugs, 12 were developed with significant government funding—that is, 71 percent were developed with significant government funding.

1994 Drug Pricing Hearing, supra note 6, at 71-72 (statement of James P. Love, Dir. of Econ. Studies, Ctr. for Study of Responsive Law).

Of the eighty-four anticancer drugs receiving FDA approval as of January 1, 1997, fifty-four were the product of federal funding. CTEP, FDA APPROVED ANTI-CANCER DRUGS, at http://ctep.info.nih.gov/handbook/handbook/fda_agen.htm (last modified Jan. 27, 1999). In April 2000, the University of Rochester was awarded a broad biotech patent covering an entire class of drugs known as "cox-2 inhibitors." Harry Schwartz, *Patent Lawyers, Prepare: A Cox-2 Patent Awarded to the University of Rochester Years After Filing Raises Fundamental Questions About the Future of the Entire U.S. Patent Protection System*, PHARMACEUTICAL EXECUTIVE, June 2000, at 18. The press release from the University said the patent is likely to be "the most lucrative pharmaceutical patent in U.S. history." The U.S. patent (No. 6,048,850) bears the Bayh-Dole legend. Rochester has sued Searle and Pfizer over the sale of Celebrex, which they say infringes on the patent, and the University says it will have broad application in many other areas of medicine, including cancer and Alzheimer's disease. *Id.*

at cost (or less) for the Medicare program.[375] But political will, of course, cannot be supplied by statute.

375. *See supra* note 337 and accompanying text.

Footnote 131

Page 654 "planned events" – research planning under a sponsored research agreement does not contemplate planned invention.
(really strained interpretation)

page 654 time can't buy (i.e. take title to IP rights) because of prohibition to assign except with agency permission.

Footnote 141
Government has 60 days to act----but tied to time it becomes aware of failure to comply.

Page 661 x---x how can one come to this conclusion???

Page 662 again – "licensing on reasonable terms" is NOT the same as setting reasonable prices on licensed inventions reaching the marketplace i.e. price fixing. Price fixing raises Further potential anti-trust issues (collusion) and liability potential is the contractor – licensor.

"There was never any doubt that this meant the control of profits, prices, and competitive conditions." IN WHOSE VIEW???

Page 676 footnote 273
XX conclusion in footnote on pricing
Author's interpretation
Fixing prices in a license externally impossible – not sufficient data available.

Page 677 footnote 277
Government not aware of inventions to which it has royalty-free rights.
Government can practice any invention for government purposes – resort in through Ct. of Claims (1498 suit) – at such time the Fed support for the invention will come out.

Page 680 author's theory

Page 687 reference to Wyden re: lack of NIHG procedures to oversee tech transfer arrangements

Page 690 footnote 367
Footnote 369

Page 692 ---"so-called blockbuster drugs owe most of their development to Fed. Funding.
What about development for the marketplace AND market development
Ignored!!!

NOTES FROM HOWARD

page 632 footnote 2
- indicates that authors have no concept of why B-D was ultimately developed on the V. Bush theory to support basic research

They do not appear to have read 35 US 200 – Objective of B-D Act – or the role Of the private sector (actually all three sectors) in bringing new inventions to market.

Seems to ignore the publication aspect of university risk – benefit consideration for the private sector

page 638x Fix the taxes of the private health care sector by changing the applicable tax laws re: tax credits, R&D credits, Puerto Rico operations, etc.

page 640 Same old anti-B-D argument that the taxpayer has already paid for the research and seeking a concrete financial return.

page 640 footnote 46
Ref. to Rickover position – he was in procurement and did not need patents.

page 641 "much of the risky investment had already been made by the government"
Product development
FDA
Market development
(factors of 10 up the ladder)
No understanding of the R&D to market sequence

page 644 footnote 69
201(f) legislative history make clear that the focus should be on price.
Are "practical application" and "utilization" not synonyms?

Page 647 and footnote 93
(not a consideration in the formulation of B-D rather leaves to the private sector the pricing based on risk-benefit ratio.

Page 649 footnote 106
What about AUTM survey?

Page 650 "reasonable terms" have uniformly been interpreted to include price"
Believe the B-D concern was the imposition of terms which would result in the non-licensing of an invention including exhorbitant royalty terms, thus denying the potential public access to the invention.

Page 651 PREMISE OF ARTICLE!!
Reasonableness of royalty rates is NOT the same as setting reasonable prices.