Myth: ***Technology Transfer is a major source of revenue for universities.***

Reality: While successful technology transfer activities may be an important source of discretionary revenues for universities, comparison data[v] show that annual gross revenues generated from a university's technology transfer activities generally total less than three percent of research dollars spent by that university and a far lesser percent of total university revenues.

Myth: ***University inventors are receiving substantial personal financial benefit from University licensing.***

Reality: No more than one-third of all university patent applications and patents are licensed and producing revenues at any given time. Because the majority of university inventions are very early stage, a large number go unlicensed and produce no revenues. Among those that are successfully licensed, there is wide disparity as to the amount of licensing revenue generated. Relatively few are large earners. While university revenue-sharing policies vary, the most commonly reported percentage of royalties paid to university inventors is a total of 30% of revenues earned, after deducting patent and marketing expenses. This percentage is shared among all inventors named on the licensed patent.

Myth: ***Universities over-inflate the value of their inventions, setting rates too high.***

Reality: Royalty rates are dependent upon market factors and determined through negotiation. While defining an "average" royalty rate will not reflect the true value of an invention, one study [vi] cites an average royalty at approximately 2% of the revenues generated by a licensee-company from its sales of products or services under the license. A small study conducted by the Association of University Technology Mangers finds the rate at 2.3%.

Myth: ***Universities are more likely to license big companies because they can afford to pay more. Small companies cannot afford to license university inventions.***

Reality: Data for FY '98 reported by 179 U.S. and Canadian institutions show that 63% of the licenses granted were to small businesses (those with fewer than 500 employees). This figure is consistent with activity reported by the universities from prior years.[vii]

Myth: ***University technology transfer offices are prospering through charging high royalties.***

Reality: The vast majority of university-licensed inventions result from research funded by the federal government. Under Bayh-Dole (35 USC 202 et.seq.), universities have an obligation to commercialize these inventions and distribute a portion of licensing revenues to inventors. This obligation is carried out by the technology transfer office, usually an administrative unit within each university. Universities are permitted to recoup only those expenses incurred in the patenting and licensing process. Any excess revenues must be used by the institution for purposes of education and research and may not be accumulated for the benefit of the technology transfer office.

Myth: ***Universities are more interested in patenting inventions than publishing research findings for the public to use.***

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Myth: ***Universities are more interested in patenting inventions than publishing research findings for the public to use.***

Reality: All universities must adhere to the academic tradition of publication. Publication remains a primary factor in tenure decisions. Publication is also the main vehicle for academic professional recognition and is important to establish credibility in grant applications. Most importantly, publication in peer-reviewed journals is validation of the findings of the academic scientist. Patenting does not mean there is no publication. All university research findings are available for publication whether or not patenting occurs. Publication, on the other hand, does not necessarily result in public use. Most often new products would not be developed without the exclusivity afforded by patent protection. Further evidence of the preference for publishing over patenting is provided by figures cited in an NSF study[viii], showing that -73% of patent applications citing publications as published disclosures of the art which the new patent application has advanced and seeks to protect-cited academic, government or non-profit publications.

Myth: ***Universities are doing too much patenting. It would be better for economic growth and U.S. competitiveness to put more inventions into the public domain.***

Reality: As the United States enters a period where articles attributing economic growth to a pro-patenting environment are commonplace, it is difficult to quantify how much patenting is "too" much. Universities are filing at an annual rate of less than one new U.S. application for every three inventions disclosed to the technology transfer office.[ix] The real measure of useful patenting for universities is whether patenting encourages commercial licensing. FY '98 data show that the universities issued 3,668 licenses/options during the same year in which they were filing 4,808 new patent applications.[x] Whether companies would have picked up the 3,668 new university technologies to commercialize from the public domain is highly questionable.
A further reality is that patenting is expensive. Since no university has the resources for indiscriminate patent filing, we know that budgetary limitations, alone, require technology transfer professionals to carefully select for filing only those inventions most likely to be licensable.

Myth: ***University patenting of biological materials and research tools is harmful to the advancement of science and is hampering the efforts of researchers.***

Reality: The patenting of research tools is currently a high-profile debate among universities, industry and the government. To aid universities, NIH has recently issued principles and guidelines to underscore the importance of striking a balance between preserving access for research use and the broader public interest in the acquiring the intellectual property protection required for commercialization. The university community, itself a community of academic researchers, has always been acutely aware of the importance of preserving rights to use patents for research purposes.

Myth: ***The recent focus on industrial relationships and entrepreneurial activities in U.S. universities is detrimental to the university's fundamental mission of educating students.***

Reality: In fulfilling their educational mission in today's changing world, universities must seek to provide students with experience that is more closely aligned with contemporary industry. Enabling students to participate in industry research gives students a window to the industrial world and provides them with the opportunity to assist in solving real world problems. It also provides them with experience in teaming with industrial scientists as well as giving them an

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opportunity to become comfortable with the industrial workplace environment. Often companies are funding university research in anticipation of finding future talented future employees. As universities involve students in relationships with industry or provide them with opportunities to start new companies, universities recognize an obligation to do so in a manner that preserves the students' sense of balance and perspective as to the long-term value of the university experience.

Myth: ***Partnering with industry will skew the academic research agenda from basic to applied research.***

Reality: The research agenda at many of the major U.S. universities is not exclusively restricted to basic research. There is general agreement in many universities that both faculty and students find benefit from participating in more applied research funded by industry. Industry-funded programs permit faculty to keep abreast of the current trends and practices important to American industry and give students an opportunity to learn the teaming and other knowledge skills that will be important to their success as they join the workforce. The growing number of research programs jointly supported by industry and government agencies clearly shows a convergence of interest in supporting both basic and more applied research. Carefully managed, university-industrial partnerships provide universities with new educational opportunities, expand infrastructure, provide alternative sources of research revenue and contribute new and useful science to the commercial marketplace.

Myth: ***By taking industry sponsorship, universities are inviting industry to determine the direction of university research.***

Reality: Industrial funded research programs are collaborative from inception. They match the commercially-oriented objectives of companies with the scientific interest of the university principal investigator and students. If there is not commonality of interest in the science to be pursued, there is no prospect for success. Universities insist on directing the conduct of the research program; require the research to be supervised by the university investigator; and require final control of research work product and publication.

Myth: ***Collaboration with industry invariably creates financial conflicts of interest for academics.***

Reality: University faculty interact with industry as educators, principal investigators under research programs, consultants, creators of intellectual property used by industry and as entrepreneurs. It is the responsibility of universities to continually explore the implications of these relationships and to establish effective policies to manage them. Accordingly, universities' conflict of interest policies seek to ensure that the personal financial interests of faculty do not improperly affect the content, quality or timely release of research. These conflict of interest policies have become fairly uniform among universities since they must meet standards that have been established by the federal granting agencies.

[i] AUTM Licensing Survey: FY1998. The Association of University Technology Managers, Survey Summary, page 2

[ii] Ibid. Survey Table S-12

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[i] AUTM Licensing Survey: FY1998. The Association of University Technology Managers, Survey Summary, page 2

[ii] Ibid. Survey Table S-12

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[iii] Stevens, Ashley: "Measuring Economic Impact" and Pressman, Lori, et.al.: "Pre-Production Investment and Jobs Induced by MIT Exclusive Patent Licenses"

[iv] Campbell, Kenneth D.: "R&D yields public rewards," Mass High Tech, May 11-17, 1998.

[v] Op. cit., AUTM Licensing Survey: FY1998, page 14, Adjusted gross licensing income of $725M compares with $24.4B in total university FY98 sponsored research expenditures

[vi] AUTM Economic Impact Survey, October 24, 1966

[vii] Ibid, page 6

[viii] Narin, Francis; Hamilton, Kimberly and Olivastro, Dominic: "The Increasing Linkage between U.S. Technology and Public Science" Research Policy: 26, No.3, 1997

[ix] Op. cit, AUTM Licensing Survey, Survey Tables, S-6 and S-8

[x] Ibid, S-12 and S-8

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From: "Robert Hardy" <rhardy@cogr.edu>
To: <Njl@browdyneimark.com>
Date: Tue, Apr 2, 2002 11:20 AM
Subject: Fwd: Re: OP ED commentary in the Washington Post

Norm,

Here is the law review article we discussed.

It was good to hear from you. Keep in touch.

Bob Hardy

Robert Hardy
Associate Director
Council on Governmental Relations
(202)289-6655 Fax: (202)289-6698

From: "Peter Arno" <PARNO@montefiore.org>
To: <Sheinig@aamc.org>
Date: Fri, Mar 29, 2002 12:42 PM
Subject: Re: OP ED commentary in the Washington Post

Actually, I am not sure I agree with you that there is no reasonable pricing clause within Bayh-Dole. The main point of our legal analysis (and we went over >20,000 pages of documents, testimony, etc. leading up to B-D) was that the term "available to the public on reasonable terms," in fact means (consonant with Congressional intent) make available to the public at a "reasonable price." Have a look at our article (enlcosed) and see what you think.

Regards,
Peter

ps: I sent a copy of this article to Jordie Cohen a couple of months ago.

****

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Peter S. Arno, PhD
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****

>>> "Stephen Heinig" <Sheinig@aamc.org> 03/29/02 10:10AM >>>
Dear Dr. Arno,

I'm an analyst covering technology transfer and intellectual property (IP) issues at the Association of American Medical Colleges (AAMC). I read with interest your commentary in the Washington Post on Wednesday. I'd welcome a chance to discuss your views on this topic.

The AAMC has generally been very supportive of the NIH's tech transfer activities and their policies in compliance with the Bayh-Dole, Stevenson-Wydler and other relevant Acts. As you note, NIH promotes research and discovery that is the basis for development of new therapeutics. We believe that NIH diligently tries to see that this research is applied to new therapeutics, broadly available for public health, and also openly available to support further research. We agree with NIH's conclusion that licenses to technologies owned by NIH or its academic grantees have had, at most, marginal impact on the eventual market price of pharmaceuticals. While there is no fair-pricing clause within Bayh-Dole, NIH has been unable to implement such clauses arising elsewhere, such as in cooperative research and development agreements in the 1990s.

That said, these issues are part of a growing public debate and I'd benefit from knowing more about contrary views. Please let me know if I should follow up with you.

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That said, these issues are part of a growing public debate and I'd benefit from knowing more about contrary views. Please let me know if I should follow up with you.

Thank you,

Steve Heinig

==========

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Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research

Peter S. Arno
Michael H. Davis †

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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III. AN OVERVIEW OF TECHNOLOGY-TRANSFER ACTIVITY 640
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* Professor of Epidemiology and Social Medicine, Albert Einstein College of Medicine/Montefiore Medical Center. Ph.D., Economics 1984, Graduate Faculty of the New School for Social Research. We would like to thank Dr. Karen Bonuck for providing much of the early historical research for this Article. We owe a special debt of gratitude to Margaret Memmott, who for months has painstakingly tracked down hundreds of documents and citations. This work was supported in part by grants from the National Science Foundation (SBR-9412966) and the Henry J. Kaiser Family Foundation, but the views and mistakes reflect those of the authors alone.

† 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.

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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.

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.

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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.soufund.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 suspidous, 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.

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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 setion 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

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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 produds fifteen or twenty years into the future.").

38. *A Brave New World*, MEDADNEWS, Sept. 1999, at 3, 640.

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 FY 1993-FY 1999, *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.*

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

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* Eisenbeg, *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* Eisenbeg, *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

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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 purpose 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-VI I. 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).

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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 utiliz ation 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.