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James V. Lacy

Bradford C. Brown

Michael R. Rubin

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James V. Lacy*, Bradford C. Brown**, Michael R. Rubin***

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I. INTRODUCTION

Last July, the National Institutes of Health (hereinafter NIH), a United States government agency, announced that it was granting a license to a pharmaceutical firm to make a generic form of the AIDS drug AZT. The license was granted prior to and conditional upon regulatory approval to market the drug as required by the Food and Drug Administration.[1] The decision by NIH was seen as an effort by the United States government to address the AIDS epidemic by widening the market for AZT and lowering its price by making it available as a less expensive generic drug. According to published accounts, a year's worth of AZT drug therapy can cost as much as $2800 as it is currently marketed. A generic AZT could reduce that cost by forty percent, thus significantly lowering health costs associated with

* Chief Counsel for Technology, United States Department of Commerce; B.A. University of Southern California, 1974; J.D. Pepperdine University School of Law, 1978. From 1987 to 1989, Mr. Lacy served as General Counsel to the U.S. Consumer Products Safety Commission.

** Assistant to the Chief Counsel for Technology, United States Department of Commerce; B.A. Providence College, 1980, A.L.M., in Government, Harvard University, 1982; J.D. Catholic University of America, Columbus School of Law, 1986. Mr. Brown is currently the Vice-Chairman of the Resolutions and Legislation Committee of the American Bar Association Section on Science and Technology.

*** Deputy Chief Counsel for the National Institute of Standards and Technology, United States Department of Commerce; A.B. Georgetown University, 1972; J.D. Georgetown University Law Center, 1976. Mr. Rubin is the author of PRIVATE RIGHTS, PUBLIC WRONGS; THE COMPUTER AND PERSONAL PRIVACY (Ablex Press, 1989).

1. Robin Goldwyn Blumenthal, *Barr Labs Granted Conditional License for AZT; Patent Fight Remains Hurdle*, WALL ST. J., July 18, 1991, at B4.

the deadly AIDS virus.[2]

The federal government's share of total U.S. spending on research and development (hereinafter R&D) is awesome, significantly outpacing that of our major international competitors. In 1989, for example, the U.S. government spent over $62 billion in R&D, both on research conducted by contractors and grantees, and throughout the network of 700 federal laboratories ranging from the Department of Energy's Oak Ridge and Sandia Laboratories to NIH's National Cancer Institute; the Department of Commerce's National Institute of Standards and Technology to the labyrinth of laboratories associated with the Department of Defense.[3] While much of federal R&D spending is appropriated to military projects, significant basic technologies are being developed across the board in federal laboratories and by federal contractors and grantees that have commercial applications.

According to the General Accounting Office (hereinafter GAO), twelve federal agencies funded over $16.2 billion for research and development directly in their own laboratories in fiscal year 1990.[4] These agencies are the principal patenting and licensing agencies in the government. In the period between 1981-90, the agencies applied for 15,669 patents based on research conducted in their laboratories, and were issued 11,075 patents.[5] During that time, these agencies granted 1436 licenses, 455 of them exclusive to the private sector, and thereby generated over $37.5 million in license income.[6]

Increasing emphasis is being placed by policy-makers on building United States international competitiveness through the creation and exploitation of new technologies,[7] and some have been vocal in urging that more be done to make federal research and development

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2. *Id.*

3. BUREAU OF THE CENSUS, 989 (1990) [hereinafter STATISTICAL ABSTRACT].

4. GOVERNMENT ACCOUNTING OFFICE, TECHNOLOGY TRANSFER: FEDERAL AGENCIES PATENT LICENSING ACTIVITIES 14 (1991). The twelve agencies are the Departments of: Agriculture; Commerce; Defense; Energy; Health and Human Services; Interior; Transportation and Veterans Affairs; the Environmental Protection Agency; the National Aeronautics Space Association; the National Science Foundation and the Tennessee Valley Authority.

5. *Id.*

6. *Id.* at 16. Over $30 million of this income is generated through licensing activities of the National Technical Information Service (NTIS), an agency of the U.S. Department of Commerce. NTIS licenses patents for other federal agencies as a service. For the period, $22.6 million in licensing revenue was received from two non-exclusive licenses handled for the Public Health Service at the Department of Health and Human Services regarding an AIDS test kit and hepatitis B vaccine licenses.

7. During remarks at the Presentation Ceremony for the National Medals of Science and Technology, President Bush said: "If America is to maintain and strengthen our competitive position, we must continue not only to create new technologies but learn to more effectively translate those technologies into commercial products." 26 WEEKLY COMP. PRES. DOC. 1807, 1808 (Nov. 13, 1990).

more accessible to the private sector for commercial development.[8] A view expressed within the United States business community is that, while government should not decide what types of products should be developed for the market, it makes sense for industry to take advantage of the basic, pre-competitive research conducted in federal laboratories.[9]

This article examines the legal authority of the federal government to promote the commercialization of inventions made through government funding. The scope of this article is two-fold: first, to explore the legal authority of NIH, and other federal agencies, to patent and license technology created in federal laboratories to the private sector; and second, to shed light upon the government's authority to permit its contractors and grantees to commercialize the inventions they make in the course of their research, which is partially or wholly funded by the government. This article will review the historical background of the development of federal technology transfer law, discuss its relevance and implementation, and finally, present its recent arrival into the case law. Part II of this article presents a historical background on the transfer of federally-funded research and development. Part III discusses the changes in federal law that now permit federal contractors and grantees to obtain title to inventions they make in the course of federally-funded research. Part IV explains certain additional changes in federal law, which greatly facilitate the transfer of technology developed in federal laboratories. Part V examines recent developments in federal technology transfer case law. Part VI concludes with the remarks of the authors.

II. HISTORICAL PERSPECTIVE

A. Federal Technology Transfer Policies from 1940 to 1980

Since World War II, the United States government has been the single largest source of funding for research and development in this country. As such, the technology transfer policies it follows have a major effect upon the commercialization of the fruits of this R&D. However, these policies, and particularly government policy toward the ownership and commercialization of inventions created by private contractors with Government funds, have been slow to adjust. Before World War II, most government research and development

8. *See Technology Transfer: Commercializing Inventions from the Federal Laboratory*, 102nd Cong., 1st Sess. (July 25, 1991) (opening statement of Rep. Ron Wyden).
9. *Federal Labs*, J. COM., July 30, 1991, at 8A.

work was conducted in federal facilities by federal employees.[10] Throughout that period, the general policy of the United States was to make patents available for use by the entire population.[11]

It was not until World War II that the complexities of technological advancements required the government to increase its use of private contractors in federal R&D projects. The government needed the assistance of private companies, universities and non-profit organizations, especially in the fields of defense and medicine.[12] Table 1, below, demonstrates both the overwhelming role that the government plays in funding R&D in the United States and the steadily decreasing role that government laboratories alone have played in that research from 1941 until 1988.[13]

GOVERNMENT SHARE OF FUNDING FOR ALL R&D IN THE U.S.[14]
(Amounts of R&D shown in Millions of Dollars)

Year	Total R&D	Government Funder R&D	Percent	R&D Performed	Percent
1941	900	370	41.1	200	22.2
1945	1,520	1,070	70.4	430	28.3
1950	2,870	1,610	56.1	570	19.9
1955	6,279	3,510	55.9	905	14.1
1960	13,730	8,746	63.7	1,726	12.6
1965	20,439	13,040	63.8	3,093	15.1
1970	26,134	14,892	57.0	4,079	15.6
1975	35,213	18,109	51.4	5,354	15.2
1980	62,594	29,453	47.1	7,632	12.2
1985	107,757	51,668	47.9	12,945	12.0
1988	126,115	60,500	48.0	14,500	11.5

Table 1

Since World War II, the government has consistently been a massive contributor to national R&D. In 1988, the government continued this trend by accounting for approximately one half of all R&D funding in the United States. At the same time, the performance of R&D in government laboratories has declined relative to the overall conduct of R&D. However, this relative decline should not obscure the fact that, in recent years, R&D conducted in government laboratories has

10. *The University and Small Business Patent Procedures Act, Hearings on § 414 Before the Committee on the Judiciary, United States Senate*, 96th Cong., 1st Sess. 195 (1979) (testimony of Howard W. Bremer) [hereinafter "Hearings"].

11. Note, *Effective Use of Government-Owned Rights to Inventions: Publication Versus Patenting*, 55 GEO. L.J. 1083, 1091 (1967).

12. *See* Hearings, *supra* note 10, at 196.

13. 1988 is the most recent year for which statistical data are available.

14. *See* FRITZ MACHLUP, THE PRODUCTION AND DISTRIBUTION OF KNOWLEDGE IN THE UNITED STATES 145-207 (1962) (statistics for years 1941 through 1955) [hereinafter MACHLUP]. *See also* STATISTICAL ABSTRACT (statistics for subsequent years) [hereinafter STATISTICAL ABSTRACT].

accounted for approximately 11.5% of all R&D conducted in America.

The size of the government's direct conduct of research and development, however, is dwarfed by the size, both relative and absolute, of the government's support of private R&D efforts by industry, universities, independent research organizations and other entities that receive government funds for R&D. As Table 2, below, demonstrates, the government presently contributes well over forty percent of all funding used in private sector R&D, or about $46 billion in recent years.

PERCENTAGE OF PRIVATE RESEARCH FUNDED BY THE GOVERNMENT[15]
(Amounts of R&D shown in Millions of Dollars)

Year	Total Private R&D	Private R&D Funded by Government	Percent
1941	700	170	24.3
1945	1,090	640	58.7
1950	2,300	1,040	45.2
1955	5,374	2,605	48.5
1960	12,004	7,020	58.5
1965	17,346	9,947	57.3
1970	22,055	10,813	49.0
1975	29,859	12,755	42.7
1980	54,962	21,821	39.7
1985	94,812	38,723	40.8
1988	111,615	46,000	41.2

Table 2

Throughout the post-war period and until relatively recently, however, the government had not promulgated any overriding policies to encourage the use of this vast reservoir of government funded research and development for the public good. There were no government-wide policies to place the ownership of inventions made by government contractors and grantees into the hands of those private parties who might best use the technology to create something productive for society. There was no established mechanism to license government-owned inventions to the private sector for commercialization. As a result, the practices that controlled the granting of own-

15. *See* MACHLUP, *supra* note 14, at 145-206; STATISTICAL ABSTRACT *supra* note 14 (statistics for subsequent years). A detailed discussion of trends in Governmental funding of R&D is also contained in MICHAEL RUBIN & MARY HUBER, THE KNOWLEDGE INDUSTRY IN THE UNITED STATES 1960-1980 (1986).

ership of inventions to contractors and grantees were as varied as the agencies themselves. For example, the Department of Defense had a policy of obtaining royalty-free licenses to inventions and allowing contractors to acquire exclusive commercial rights. In contrast, the policy of the Department of Health, Education and Welfare was to acquire full rights, title and interest to inventions that were developed under its research and development contracts.[16]

Between World War II and 1980, the patent policies of several departments were based on legislation. The Department of Energy patent policy was based on the Atomic Energy Act of 1954,[17] which restricted its ability to give title rights to inventions.[18] The National Aeronautics and Space Act of 1958[19] was the basis for the National Aeronautics and Space Administration's (NASA) patent policy. This legislation required NASA to take title to inventions unless it granted a waiver to the contractor.[20]

Most federal agencies that used contractors for research and development programs at some point acquired both licenses and titles to patented inventions originated by contractors. "But the heart of the controversies over patent policies [was] whether federal agencies should follow the general policy of acquiring licenses or the general policy of acquiring titles."[21]

In 1963, President Kennedy issued a memorandum to agency heads in an attempt to create a semblance of uniformity in the federal patent system.[22] The memorandum recognized the responsibility of the federal government for the exploitation of inventions for public benefit.[23] This not only allowed the government to acquire principal rights where the nature of the work or the past government investment favored full public access, but also recognized that the public interest is sometimes best served by allowing exclusive rights to the contractors responsible for the invention.[24]

The statement purported to establish a policy for all government agencies with respect to inventions or discoveries made in the course of work for or under contract to a government agency. The policy al-

16. FEDERAL COUNCIL FOR SCIENCE AND TECHNOLOGY, REPORT ON GOVERNMENT PATENT POLICY 1 (Sept. 30, 1976).

17. 42 U.S.C. § 2182 (1988).

18. GOVERNMENT ACCOUNTING OFFICE, PATENT POLICY 17 (1987).

19. 42 U.S.C. § 2457 (1988).

20. GOVERNMENT ACCOUNTING OFFICE, PATENT POLICY 19 (1987).

21. Donald S. Watson, *Research in Patent Policies in Federal Research and Development Contracts*, 21 FED. B. J. 146 (1961).

22. Memorandum for the Heads of Executive Departments and Agencies, Government Patent Policy, October 10, 1963, 3 C.F.R. 861 (1959-63).

23. *Id.* at 861.

24. *Id.*

lowed the government to acquire an exclusive or principal right in four situations:

1) where the purpose of the contract was to create, develop or improve products, processes or methods for commercial use by the general public or which were to be required for such use by government regulations;
2) where the purpose of the contract was for research concerning the public health or welfare;
3) where the research was in the field of science for technology where the government has been the principal developer in the field; and
4) where the contractor operates a government-owned research or production facility or coordinates and directs the work of others.[25]

The contractor was permitted to retain principal rights in other situations. Where the purpose of the contract was to "build upon existing knowledge or technology to develop information, products, processes, or methods for use by the government," and the contract was "in a field of technology in which the contractor [had] acquired technical competence" and a nongovernmental commercial position, the principal rights were to be given to the contractor.[26]

Contractors who assumed principal rights were required to report to the government regarding the use made of the patent.[27] If effective steps to bring the patent to the point of practical application were not made within three years, the government had the right to require the granting of a license to an applicant on a non-exclusive royalty-free basis.[28] The government also retained the right to require granting of the license royalty-free when in the public interest.[29]

Finally, the statement required the Federal Council for Science and Technology, in consultation with the Department of Justice, to prepare an annual report on the policy.[30] Later, a Patent Advisory Council was established to provide guidelines for implementation of the policy, to acquire data on the disposition of patent rights and to

25. *Id.* at 862-63.
26. *Id.* at 863.
27. *Id.* at 864.
28. *Id.*
29. *Id.*
30. *Id.*

prepare recommendations for the efficient exploitation of patents.[31]

The implementation of the Kennedy directive ultimately left to the individual agencies the decision of whether to take title or license to the patent, or award it to the inventor.[32] Despite the directive, a wide disparity in the application of patent policies within the federal government continued.[33]

In 1971, President Nixon again addressed the problem of the fragmented patent system by issuing a revised Statement of Government Patent Policy.[34] Studies prepared after the Kennedy memorandum indicated that a flexible policy of allocation of ownership rights was important.[35] Based on this finding, President Nixon revised the policy and granted agency heads more authority in the allocation of principal rights to contractors.[36] Where the government contribution to an invention was small or where the invention was not a primary object of the contract, equity principles were applied to give the contractor principal rights to the invention.[37] The revised policy also provided additional guidance to agencies in promoting utilization of government sponsored inventions.[38]

The actual effect of these revisions was minimal. There remained no incentive for private sector institutions and universities to pursue research with important private sector applications. As in the past, commercialization of federally-owned technology was not a priority. In Congressional hearings held well after the implementation of the Nixon statement, one speaker testified that little change had occurred in the federal patent system. He stated: "There is no real consistency among the Agencies, or even within an Agency, or even necessarily from one contract to the next within an Agency, as to what the disposition of patent rights will be."[39]

B. Economic Problems with the Pre-1980 Policy Framework

Since World War II, the federal government has spent billions of dollars on basic research and development. As previously noted, federal laboratories spent $16.2 billion at over 700 laboratories in fiscal

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31. *See* President's Memorandum for Heads of Executive Departments and Agencies, 7 WEEKLY COMP. PRES. DOC. 1209 (Aug. 30, 1971) [hereinafter "President's Memorandum"].

32. Note, *Effective Use of Government-Owned Rights to Inventions: Publication versus Patenting*, 55 GEO. L.J. 1083, 1091 (1967).

33. *Id.*

34. *See* President's Memorandum, *supra* note 31; *see also*, Statement of Government Patent Policy, 36 Fed. Reg. 16889 (1971).

35. *See supra* note 31.

36. *Id.*

37. Statement of Government Patent Policy, 36 Fed. Reg. 16889-90 (1971).

38. *Id.*

39. *See* Hearings, *supra* note 10, at 198.

year 1989 and currently employ a large percentage of the nation's scientists and engineers.[40] These laboratories develop new ideas and act as a mammoth storehouse of institutional technical knowledge. Much of this investment is made for the development of technology for governmental purposes, including the areas of public health, defense and space. In addition to fulfilling the needs of the government, a great deal of technology is created, which, if appropriately transferred, could be of great use in the private sector. For example, by 1986, the work of government inventors had resulted in 28,000 patents, of which only five percent have been licensed for commercial use.[41] Although a great many of these patents were defense-related, a significant number of unclassified inventions were never privatized.

Economists have long realized that innovation affects demand and is thus one of the key forces that drives capitalism.[42] A robust economy requires investment in research and development, as technological change most often results in production shifts, which can form the cornerstone of economic development and expansion.[43] Technological innovation, however, can only be economically meaningful when it impacts the market. Therefore, a good idea which is never commercialized simply remains only a good idea.

The absence of a federal technology transfer policy prior to 1980 resulted in an enormous investment of money in R&D, which yielded a great deal of government-owned, but unlicensed, patents. Technological, bureaucratic, legal and communications problems, as well as a lack of basic incentives, prevented the transfer of this technology to American industry.[44] However, changes in the global marketplace and stronger international competition forced United States policy makers to recognize that the government needed to take a more aggressive stance in federal technology transfer.[45] It was not enough to fund, invent and patent inventions. The government had to actually make its way into the market in order to produce positive economic results.

The commercialization of federal technology is a complicated problem. Historically, there were no incentives for institutions or individ-

40. *See supra* note 4 and accompanying text. *See generally* S. REP. NO. 283, 99th Cong., 2nd Sess. 3442 (1986).

41. *Id.* at 3443.

42. EDWARD SHAPIRO, MACROECONOMIC ANALYSIS 231 (1970).

43. *Id.* at 231-35.

44. *Id.*

45. H.R. REP. NO. 96-1307, 96th Cong., 2nd Sess. 6460-64 (1980).

uals who performed government research to produce commercially viable technology. A major stumbling block was the lack of a statutory basis for royalty sharing.[46] Without such explicit authority, it was unlikely that inventors in the public sector would be motivated by salary alone.

Technology transfer in the private sector model has also been difficult. However, profit-oriented management and goal structures exist to motivate employees. Corporate inventors know that they are guaranteed a royalty share in their inventions. From the perspective of the acceleration of technology development, this is a significant advantage over the pre-existing federal technology transfer policies.

An economic parable states: "Lease a man a garden and in time he will leave you a patch of sand. Make a man a full owner of a patch of sand and he will grow there a garden on the sand."[47] This parable highlights one of the basic problems with federal patent policy and technology transfer prior to 1980. There was no incentive for government inventors or institutions to create commercially viable technology[48] because there was no legal basis to gain a piece of the resulting monetary rewards. As a result, commercially viable technology was not being created, and the wealth of federal inventions that were available for licensing were not being transferred for use in the private sector.

Policy makers came to realize that the technology transfer problem was creating a crisis in terms of U.S. productivity. As Congress has stated:

> The United States can no longer afford the luxury of isolating its government laboratories from university and industry laboratories. Already endowed with the best research institutions in the world, this country is increasingly challenged in its military and economic competitiveness. The national interest demands that the Federal laboratories collaborate with universities and industry to ensure continued advances in scientific knowledge and its translation into useful technology. The Federal laboratories must be more responsive to national needs.[49]

As a result of this concern, Congress enacted a series of bipartisan initiatives in the 1980s. These initiatives were aimed at revising government patent policy, reducing legal and bureaucratic barriers, and creating incentives to improve federal technology transfer to the private sector.

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46. An exception, however, was the National Technical Information Service, which, prior to 1980, was using its authority to share royalties resulting from inventions of which it had custody.

47. GEORGE GILDER, THE SPIRIT OF ENTERPRISE 26 (1984).

48. *See* H.R. CONF. REP. NO. 953, 99th Cong., 2d Sess. (1986), *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 3457, 3460.

49. S. REP. NO. 283, 99th Cong., 2d Sess. 2 (1986), *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 3442, 3443.

III. OWNERSHIP RIGHTS TO INVENTIONS MADE BY GOVERNMENT CONTRACTORS AND GRANTEES

A. The Bayh-Dole Act of 1980 and Related Policy Guidelines

The first of the bipartisan initiatives enacted by Congress to improve the commercialization of government-funded research and development was aimed at statutorily achieving a uniform, beneficial policy on the ownership of inventions made by government contractors and grantees. The net effect of the changes in the law described below has been the establishment of a statutory government policy which normally places ownership of inventions made by government contractors and grantees in the hands of those parties, thus promoting commercialization.

The enactment of the Bayh-Dole Act[50] (hereinafter Bayh-Dole) in 1980 established new, uniform guidelines for determining the ownership of inventions made by government contractors and grantees working on research and development projects funded in whole or in part by the government. In short, recipients of government contracts, grants and cooperative agreements for the performance of experimental, developmental or research work funded in whole or in part by the federal government may now elect to retain title to any subject invention made in the course of that work. The legal framework that implements this general policy is set out in the Bayh-Dole Act, as amended; a related Presidential policy statement;[51] Executive Order 12591;[52] and government-wide implementing regulations.[53] As enacted, the Bayh-Dole Act made a disposition of rights only in those cases where the contractor or grantee was a nonprofit organization or small business firm. However, in 1983, President Reagan made the decision to extend the policies set out in the Bayh-Dole Act to virtually all government contracts, grants and cooperative agreements.[54]

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50. Bayh-Dole Act, Pub. L. No. 96-517 (amended by Pub. L. No. 97-256 at 35 U.S.C. Ch. 18).

51. Memorandum on Government Patent Policy, 1983 PUB. PAPERS 248, 252 (Feb. 18, 1983).

52. Exec. Order No. 12591, 3 C.F.R. § 220 (1988), *reprinted in* 15 U.S.C. § 3710 app. at 1374-75 (1988).

53. *See* 37 C.F.R. 401 (1990).

54. In the Memorandum to the Heads of Executive Departments and Agencies dated February 18, 1983, President Reagan directed that:

> To the extent permitted by law, agency policy with respect to the disposition of any invention made in the performance of a federally-funded research and development contract, grant or cooperative agreement award shall be the same or substantially the same as applied to small business firms and nonprofit organizations . . . under the Bayh-Dole Act.

The right of the government funding recipients to elect to retain title to their inventions is limited in several significant ways by the Bayh-Dole Act and its related policy statements. These limitations may be divided into three groups as follows:

* The grantee or contractor must agree to certain statutory conditions in order to qualify to make the election;
* In limited circumstances, the federal government may make exceptions to the general policy and prevent the grantee or contractor from taking title; and
* The government retains certain residual rights after a grantee or contractor makes the election.

B. Contractual Limitations Required by the Bayh-Dole Act

The Bayh-Dole Act requires that each funding agreement for the performance of experimental, developmental or research work funded in whole or part by the federal government shall contain provisions to effectuate the following:

* Various administrative requirements pertaining to: (1) the disclosure of the invention to the government by the contractor or grantee; (2) timing of the election by the contractor or grantee; (3) requirements on deadlines for filing domestic and foreign patents, and so on;[55] and
* The disposition of royalties earned by contractors and grantees from patents obtained by the Bayh-Dole Act in accordance with that statute. Specifically, royalties must be shared with the inventor and used for the support of scientific research or education.[56]

Once these administrative requirements are met, contractors and grantees may generally obtain title to inventions made in whole or in part with government funds, limited only by certain conditions.

C. Exceptions to the General Bayh-Dole Policy

The Bayh-Dole Act allows recipients of federal funds to elect to retain title to any subject invention made in the course of a contract, grant or cooperative agreement for experimental, developmental or research work funded in whole or in part by the federal government. This policy is limited, however, by a provision which states that:

> [A] funding agreement may provide otherwise (i) when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government, (ii) in ex-

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Memorandum on Government Patent Policy, 1983 PUB. PAPERS 248, 252 (Feb. 18, 1983).

55. 35 U.S.C. § 202(c) (1988).

56. *Id.* § 202(c)(7)(B) and (C) (1988).

> ceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter . . . .[57]

The Bayh-Dole Act requires that this provision be closely monitored for abuse by the Secretary of Commerce and the Office of Federal Procurement Policy.[58]

This provision of the Bayh-Dole Act forms a legal basis for the government to waive that Act in order to give preference to United States firms in the commercialization of government-funded inventions. This has become a matter of particular concern in recent years, as new government-supported research programs have been initiated with the objective of improving the competitive position of United States industry in world markets.

Innovative uses of the government's authority to waive the Bayh-Dole Act's requirements for the disposition of rights in federally-funded inventions are now beginning to appear. The Advanced Technology Program currently being implemented by the National Institute of Standards and Technology of the Department of Commerce, for example, has the objective of developing new advanced generic technology and putting it into the hands of domestic firms for commercialization. The implementing regulations for that program highlight the ability of the program to limit foreign ownership in technology developed with government funds.[59] Only time will tell whether this use of the waiver provisions of the Bayh-Dole Act will prove to be an anomaly in government programs.

D. Residual Government Rights and Requirements

In addition to the contractual requirements that Bayh-Dole imposes, the government by statute must retain certain residual rights to the invention, including a government-use license to practice the invention, the right to limit exclusive licenses into which the funding recipient may wish to enter, and so-called "march-in" rights.

The government-use license that the Bayh-Dole Act imposes on contractors and grantees must provide the federal government with, at a minimum, "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."[60] The statute

57. *Id.* § 202(a) (1988).
58. *Id.* § 202(b) (1988).
59. 15 C.F.R. § 295.5(a) (1988).
60. 35 U.S.C. § 202(c)(4) (1988).

also provides that the license may provide for such additional rights in favor of the government as are determined to be necessary by the government agency entering into grant, contract or cooperative agreement.[61]

In addition to the government-use license, the Bayh-Dole Act also places restrictions upon the ability of funding recipients to license patents which they have obtained pursuant to the Act. The "Preference for United States Industry" provision of the Act states:

> Notwithstanding any other provision of this chapter, no small business firms or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.[62]

As previously noted, the provisions of this section have been extended to cover all grants, contracts and cooperative agreements entered into by the government for the performance of research.[63] However, the limitation above may be waived by the government if it determines that "reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible."[64]

Finally, the government retains so-called "march-in" rights to inventions made with full or partial government funding. The government is provided the right to "march-in" and retake title to inventions in those cases where: (1) "action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention;"[65] or (2) "action is necessary to alleviate health or safety needs which are not reasonably satisfied" by the contractor or grantee;[66] or (3) "action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied" by the contractor or grantee;[67] or (4) the contractor or grantee has granted an exclusive license in violation of the "Preference for United States Industry."[68]

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61. *Id.*
62. *Id.* § 204 (1988).
63. *See supra* note 49.
64. 35 U.S.C. § 204 (1988).
65. *Id.* § 203(1)(a) (1988).
66. *Id.* § 203(1)(b).
67. *Id.* § 203(1)(c).
68. *Id.* § 203(1)(d).

E. The Practical Implications of the Bayh-Dole Act

The practical effect of the enactment of the Bayh-Dole Act in 1980 and its subsequent implementation in Executive Order and regulation is that the government now takes title to virtually no inventions created by government contractors and grantees. The inventory of contractor and grantee inventions stockpiled by the government grows no larger and indeed, slowly diminishes as patents in the existing inventory expire. This does not mean, however, that the overall government inventory of patents is shrinking. Inventions made by federal employees are entering the inventory at an increasing rate. The technology transfer challenge, which now faces the government, is to license these government-created, government-owned inventions.

IV. LICENSING OF INVENTIONS OWNED BY THE FEDERAL GOVERNMENT

Government policy as enacted in the Bayh-Dole Act and its related implementing statements leaves ownership of contractor and grantee inventions in the hands of those parties. In theory, these inventions are now being commercialized to the greatest extent possible by their private sector owners. A second technology transfer challenge, however, is the commercialization of inventions created and owned by the government.

A series of legislative actions over the last decade granted government agencies clear authority to license government-owned inventions to the private sector.[69] These actions created financial incentives for government agencies and employees to pursue vigorously such licenses by permitting these groups to use any royalties earned through their grant of licenses.[70] The actions further established a mechanism to facilitate government licensing of its inventions by permitting federal agencies to use third parties, such as other government agencies, to license their inventions.[71] Moreover, government agencies were permitted to enter into cooperative research and development with the private sector and to make agreements, before the work has begun, that give the private sector participants commercialization rights to any resulting technology.[72]

69. 35 U.S.C. § 207 (1988).
70. 15 U.S.C. § 3710(c) (1988).
71. 35 U.S.C. § 207(a)(4) (1988) and 15 U.S.C. § 3710(c)(a)(4) (1988).
72. 15 U.S.C. § 3710(a) (1988).

Each of these new advances in the law is discussed below. The following section first describes the "baseline" situation: the legal mechanism which determines ownership rights to inventions made by government employees.

A. Ownership Rights to Inventions Made by Federal Employees

The determination of government employee rights to inventions made in the course of their official duties follows government-wide policies and procedures. These broad governmental policies are found in three elements of law: (1) Executive Order 10096, "[p]roviding for a uniform patent policy for the Government with respect to inventions made by Government employees and for the administration of such policy;"[73] (2) government-wide regulations entitled "Uniform Patent Policy for Domestic Rights in Inventions Made by Government Employees;"[74] and (3) section 8 of the Federal Technology Transfer Act of 1986.[75]

Executive Order 10096 sets out the basic policy of the federal government concerning ownership of employee inventions:

> The Government shall obtain the entire right, title and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or (3) which bear a direct relation to or are made in consequence of the official duties of the inventor.[76]

The Executive Order, however, contains exceptions to the overall policy:

> In any case where the contribution of the Government, as measured by any one or more of the criteria set forth in paragraph (a) last above, to the invention is insufficient equitably to justify a requirement of assignment to the Government of the entire right, title and interest to such invention, or in any case where the Government has insufficient interest in an invention to obtain entire right, title and interest therein . . . the Government agency concerned . . . shall leave title to such invention in the employee.[77]

The provisions of the Executive Order are supplemented by section 8 of the Federal Technology Transfer Act of 1986, which provides that if the government neither chooses to patent an employee's invention nor intends to otherwise promote commercialization of the invention, the employee must be granted title, subject to a governmental license.[78] The regulations found in the Code of Federal Regulations

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73. Exec. Order No. 10096, 3 C.F.R. 292 (1949-1953), *reprinted in* 35 U.S.C. § 266 app. at 1285-86 (1988).

74. 37 C.F.R. § 501 (1990).

75. Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, § 8, 100 stat. 1785.

76. Exec. Order No. 10096, 3 C.F.R. 292 (1949-1953), *reprinted in* 35 U.S.C. § 266 app. at 1285-86 (1988).

77. *Id.*

78. 15 U.S.C. § 3710(d) (1988).

provide the nuts and bolts operation of this policy.[79] Each agency is delegated the authority to make final determinations of employee rights in inventions.[80] The Department of Commerce is made the government-side arbiter of employee appeals of adverse rulings.[81]

B. Licensing of Patents Owned by the Federal Government

Once the government obtains title to an invention made by a federal employee in accordance with the legal structure set out above, the invention enters the government's inventory of inventions that are available for licensing and commercialization. Under provisions of the Bayh-Dole Act, government agencies have the authority to enter into exclusive, partially exclusive and nonexclusive licenses with private organizations to further the commercialization of patents which protect the inventions in the custody of the federal government.[82]

There are several restrictions on the granting of licenses. The person seeking a license must submit a detailed "plan for development and/or marketing of the invention."[83] This information is treated as privileged and confidential and is not subject to disclosure.[84] The licensee must then agree to use the invention "substantially in the United States."[85]

Before an agency may grant an exclusive or partially exclusive license, notice must be published in the Federal Register and an opportunity for filing written objections must be granted.[86] After this period, the agency must conclude that:

1) the public interest will best be served by granting an exclusive or partially exclusive license;[87]
2) the desired application of the license will not be achieved by granting a non-exclusive license;[88]
3) the grant of an exclusive license is a necessary incentive for the required investment risk;[89] and

79. 37 C.F.R. § 501 (1990).
80. *Id.* § 501.4 (1990).
81. *Id.* § 501.8 (1990).
82. 35 U.S.C. § 207(a)(2) (1988).
83. *Id.* § 209(a) (1988).
84. *Id.* (referring to 5 U.S.C. § 552 (1988)).
85. *Id.* § 209(b) (1988).
86. *Id.* § 209(c)(1). This is defined as a "notice and comment period."
87. *Id.* § 209 (c)(1)(A).
88. *Id.* § 209(c)(1)(B).
89. *Id.* § 209(c)(1)(C).

4) the terms and scope of the exclusive license are no broader than necessary to bring the invention to practical application.[90]

The agency must also determine that the granting of a license will not substantially decrease competition or concentrate the related type of technology in a specific geographic area.[91] In issuing licenses, an agency must give first preference to small businesses with the resources to apply the invention.[92] Agencies are also given the authority to grant exclusive or partially exclusive licenses in any invention covered by a foreign patent application. Such a type of license also requires a notice and comment period.[93]

Any grant of a license must contain certain terms and conditions. Licensees are required to report on the utilization of the license, while specifically referring to the plan originally submitted.[94] The agency must also retain the right to terminate the license in various situations. For example, the license may be terminated if the licensee is not proceeding in accordance with the plan originally submitted with the license request;[95] if the licensee is violating an agreement to use the invention substantially in the United States;[96] or if the agency determines that termination of the license is necessary to meet requirements for public use specified by federal regulations issued after the date of the license and if such requirements are not reasonably satisfied by the licensee.[97] Before termination of a license, the federal agency must give written notice to the licensee of its intention to modify or terminate the license. The licensee then has thirty days to remedy the breach of the license or show cause why the license should not be modified or terminated.[98]

Secretary of Commerce Robert Mosbacher, as authorized by the Bayh-Dole Act, has promulgated government-wide regulations, captioned "Licensing of Government Owned Inventions," which implement this authority.[99] The regulations add that all domestic exclusive and partially exclusive licenses shall be subject to the irrevocable, royalty-free right of the government of the United States to practice the invention and have the invention practiced on its behalf and on behalf of any foreign government or international organiza-

90. *Id.* § 209(c)(1)(D).
91. *Id.* § 209(c)(2).
92. *Id.* § 209(c)(3).
93. *Id.* § 209(d).
94. *Id.* § 209(f)(1).
95. *Id.* § 209(f)(2).
96. *Id.* § 209(f)(3).
97. *Id.* § 209(f)(4).
98. 37 C.F.R. § 404.10 (1990).
99. *Id.* § 404 (1990).

tion.[100] Furthermore, the federal agency shall reserve the right to require the licensee to grant sublicenses in the interest of public health and safety.[101]

The Federal Technology Transfer Act of 1986 extended the authority to license patents to individual federal laboratories. With this decentralized authority, laboratories such as the National Institute of Standards and Technology in the Department of Commerce are beginning to license inventions made by their employees, using the procedures found in the Code of Federal Regulations.[102]

C. *Incentives: Distribution of Royalties Received by Federal Agencies*

The legal structure established by Congress for the licensing of government-owned inventions includes incentives for government agencies and employees. Enacted as part of the Federal Technology Transfer Act of 1986, these incentives provide government laboratories and their employees a financial stake in the commercialization of the inventions they create. Agencies are generally permitted to retain and use all of the royalties that they earn in a given year from the licensing of their inventions.[103] The laboratories are required, however, to share these royalties with their employee-inventors.[104]

Government laboratories may retain all royalties they receive from the licensing of inventions made by their employees, up to a maximum of five percent of the laboratory's budget for that year.[105] The laboratory must use the royalties it retains in certain ways specified by law. First, "[t]he head of the agency or his designee shall pay at least 15 percent of the royalties or other income the agency receives on account of any invention to the inventor . . . if the inventor has assigned his or her rights in the invention to the United States."[106] Second, from the remaining royalties it retains, the laboratory is per-

100. *Id.* § 404.7(a)(2)(i).
101. *Id.* § 404.7(a)(2)(ii).
102. *Id.* § 404 (1990).
103. 15 U.S.C. § 3710c(a)(1) (1988).
104. *Id.* § 3710c(a)(A)(i) (1988).
105. *Id.* § 3710c(a)(2) (1988). The same section provides that if any royalties are received by the laboratory in excess of 5 percent of its budget, "75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent may be used [by the laboratory]." *Id.*
106. *Id.* § 3710c(a)(A)(i) (1988). 15 U.S.C. § 3710c(a)(A)(ii) provides that the percentage paid to inventors may be increased by the agency through independent regulations that provide for an alternate program.

mitted to pay for activities "that increase the licensing potential for transfer of the technology of the Government-owned laboratories of the agency," including education and training of employees consistent with the R&D mission of the agency.[107]

D. Centralized Patent Licensing Activities for the Government

In an additional attempt to facilitate government licensing, federal agencies are authorized to use other government agencies to license their inventions. Section 207 of Title 35 of the United States Code, enacted as part of the Bayh-Dole Act, allows federal agencies to "transfer custody and administration, in whole or in part, to another federal agency, of the right, title, or interest in any federally owned invention."[108] The same section authorizes the Secretary of Commerce to "assist Federal agency efforts to promote the licensing and utilization of Government-owned inventions."[109]

The Federal Technology Transfer Act of 1986 also addressed this situation in amendments found in section 3710c(a)(4) of Title 15 of the United States Code. This section controls the royalties received by a federal agency as a result of "invention management services performed for another Federal agency."[110] Such federal agencies may retain royalties to the "extent required to offset the payment of royalties to inventors, . . . the cost of foreign patenting and maintenance for any invention of the other agency," and "for payment of expenses incidental to the administration and licensing of inventions."[111] The remaining royalties must be transferred back to the agency for which the services were performed.[112]

E. Cooperative Research and Development Agreements and the Commercialization of Government Technology

The Federal Technology Transfer Act of 1986 authorizes federal laboratories to make agreements with U.S. businesses concerning the ownership and use of inventions created during joint research programs between the particular laboratory and business.[113] These arrangements are made under so-called "cooperative research and

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107. *Id.* § 3710c(a)(B)(iv).
108. 35 U.S.C. § 207(a)(4) (1988).
109. *Id.* § 207(b)(1). In carrying out this authority, the Department of Commerce operates a patent licensing program within the National Technical Information Service, which licenses to the private sector government-owned inventions transferred to it by other agencies, including the National Institute of Health, the Department of Agriculture, and others. *See* 15 U.S.C. § 3710(d)(1).
110. *Id.* § 3710c(a)(1) (1988).
111. *Id.* § 3710c(a)(4), § 3710c(a)(B)(i).
112. *Id.* § 3710c(a)(4) (1988).
113. *Id.* § 3710a.

development agreements" or "CRDAs."[114]

Under these CRDAs, federal laboratories may accept "funds, personnel, services and property from collaborating parties."[115] Although federal laboratories may not provide funding to collaborating parties, they may provide personnel, services and property.[116] They may grant to a collaborating party a license to an invention made in whole or in part during the conduct of research under a CRDA by a laboratory employee. However, they must "retain a nonexclusive, nontransferable, irrevocable paid up license to practice the invention" on behalf of the federal government.[117] They also may waive any right of ownership which the federal government may have in any invention made solely by employees of collaborating parties in the course of the performance of a CRDA.[118] This waiver is subject to retention by the federal government of an irrevocable right to practice the invention.[119] Additionally, the agencies may permit employees to participate in the commercialization of inventions they made while working for the United States.[120]

Laboratory directors are given some direction to guide their decisions involving cooperative R&D agreements. They are required to give special consideration to small business firms, and to give preference to firms located in the United States.[121] If a foreign company is involved in a cooperative R&D program, the director must "take into consideration whether [the] . . . foreign government permits United States [entities] . . . to enter into [CRDA] agreements."[122]

Contractor-operated laboratories have several requirements imposed upon them in addition to those placed on government-operated laboratories. The contractor operating a laboratory for a particular agency must submit a joint work statement to the agency.[123] The agency then has ninety days to "review and approve, request specific modifications, . . . or disapprove" the statement.[124] "No agreement

114. *Id.* § 3710a(1). This authority reaches to both government-owned, government-operated laboratories ["GOGOs"] and to government-owned, contractor-operated laboratories ["GOCOs"]. *Id.* § 3710a(a), § 3710(a)(1).
115. *Id.* § 3710a(b)(1).
116. *Id.* § 3710a(b)(1).
117. *Id.* § 3710a(b)(2).
118. *Id.* § 3710a(b)(3).
119. *Id.* § 3710a(b)(3).
120. *Id.* § 3710a(b)(5).
121. *Id.* § 3710a(c)(4)(A) and (B).
122. *Id.* § 3710a(c)(4)(B).
123. *Id.* § 3710a(c)(5)(c)(i).
124. *Id.*

may be entered into by a government-owned, contractor-operated laboratory" before the joint work statement is approved.[125] If the agency disapproves the joint work statement, it must submit a "written explanation of [the] disapproval or modification to the director of the laboratory."[126] Also, contractor-operated laboratories participating in CRDAs must prepare a model agreement for the laboratory in order to "standardiz[e] practices and procedures, resolv[e] legal issues and enabl[e] review" of the agreement to be carried out promptly.[127]

V. FEDERAL TECHNOLOGY TRANSFER CASE LAW

An important step forward in the development of federal technology transfer law occurred when the United States Court of Appeals for the Federal Circuit decided *Nutrition 21 v. United States v. Thorne Research, Inc.*,[128] a case involving a claim of infringement against a federally-licensed patent.[129] The patent upon which the claim of infringement was based had been filed by the U.S. Department of Agriculture as a result of technology developed by its staff regarding certain dietary supplements containing essential metal picolinates.[130] The patent had been licensed for the U.S. government through the National Technical Information Service, an agency of the U.S. Department of Commerce.[131] A pertinent provision of the license agreement provided as follows:

> During the exclusive term of the Agreement, *as provided under Paragraph 2.1 above*, LICENSEE is *empowered* pursuant to the provisions of Chapter 29 of Title 35, United States Code of other statutes
>
> (a) *to bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in a Licensed Patent*;
>
> (b) in any such suit, to enjoin infringement and to collect *for*

125. *Id.* § 3710a(c)(5)(C)(i).

126. *Id.* § 3710a(c)(5)(C)(ii).

127. *Id.* § 3710a(c)(5)(C)(iii).

128. Nutrition 21 v. United States, 930 F.2d 862 (D.C. Cir. 1991) (on interlocutory appeal from U.S. District Court for the Western District of Washington State).

129. Nutrition 21 v. Thorne Research, Inc., 130 F.R.D. 671 (D. Wash. 1990).

130. U.S. Patent No. 4,315,927.

131. *See* 51 Fed. Reg. 31,163 (1986). Regulations governing the licensing of Government-owned inventions are found at 37 C.F.R. § 404 (1986). Section 404.7(a)(1)(i) requires that notice of an invention and the name of the prospective license be published in the Federal Register in order to provide the opportunity for the filing of written objections from the public within a 60-day period. No objections were filed in response to the cited Federal Register notice. The National Technical Information Service licenses patents for other agencies of the U.S. Government under authority of 35 U.S.C. 207(a)(4) (1984). *See supra* notes 6 and 99.

> *its use*, damages, profits, and awards of whatever nature recoverable for such infringement; and
> (c) to settle any claim or suit for infringement of the Licensed Patent.
>
> provided, however, *that NTIS [Department of Commerce] and appropriate U.S. Government authorities shall have a continuing right to intervene in such suit.*[132]

The terms of the license that granted Nutrition 21 the power to bring suit in its own name for infringement were based upon an agency interpretation of the statutory provision of the Federal Technology Transfer Act which allows agencies to grant patent licenses "on such terms and conditions, including the grant to the licensee of the right of enforcement . . . as determined appropriate in the public interest."[133] The statutory language purported to fulfill the Congressional interest "to minimize the costs of administering policies in this area," and to promote the commercial exploitation of federally-developed technological research by giving especially exclusive licensees all the rights traditionally associated with an exclusive license, including the right of enforcement independent of the U.S. government.[134]

The United States was surprisingly named as a defendant in Nutrition 21's complaint as a matter of legal strategy.[135] A motion for a preliminary injunction to restrain further infringement accompanied the complaint.

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132. Nutrition 21 v. United States, No. 90-1382, slip op. at 7 (Fed. Cir. Mar. 29, 1991).

133. *See* 35 U.S.C. § 207(a)(2) (1988). NTIS interpreted the statute as empowering federal agencies to grant to private parties an independent right of enforcement to federally licensed technology. *See also* Nutrition 21 v. United States, No. 90-1382, slip op. at 12 (Fed. Cir. Mar. 29, 1991).

The governing regulation, 37 C.F.R. § 404.6(a)(2)(iv), is essentially a restatement of this statutory language. While Nutrition 21's license is by its terms primarily an "exclusive" license, it is also "non-exclusive" with respect to compositions in which one form of picolinate (zinc) is present. With respect to all other picolinates, the license is exclusive for nine years, then reverts to non-exclusive status. *See* Nutrition 21 v. United States, No. 90-1382, slip op. at 6-7 (Fed. Cir. Mar. 29, 1991). The distinction between picolinates and their relative status of exclusivity in the terms in the license agreement is not relevant to this discussion, since this case only involved products included in the exclusive grant.

134. 35 U.S.C. § 200 (1988) ("Policy and Objective" portion of the statute). *See also* S. Rep. No. 662, 98th Cong., 2d Sess. 8 (1984). 35 U.S.C. § 297 (a)(2) authorizes the grant of enforcement rights, however, to "nonexclusive, exclusive or partially exclusive licensees." 35 U.S.C. § 297(a)(2)(1988).

135. Brief for Appellee at 2. Nutrition 21 v. United States, CA FC No. 90-1382, Mar. 29, 1991.

Nutrition 21 justified the action of naming the United States as a defendant in its brief to the Federal Circuit upon its concern that defendant Thorne, Inc. would oppose the infringement action on procedural grounds rather than on the merits.[136] This concern centered on the decision of the United States Supreme Court in *Independent Wireless Telegraph Co. v. Radio Corp. of America*,[137] which held, under then-existing federal statutes, that a patent licensee could not bring an infringement action solely in its own name, but had to do so also in the name of the patent owner.[138] Since the patent owner had declined to join the action voluntarily, the Supreme Court held proper its joinder as an involuntary plaintiff.[139] This step was subsequently adopted in the Federal Rules of Civil Procedure,[140] and is a central consideration in patent and copyright infringement cases.

The second factor that influenced Nutrition 21's strategy was the Department of Commerce's own regulations. The Department of Commerce is statutorily responsible for establishing regulations governing the implementation of 35 U.S.C. § 207, which appear at 37 C.F.R. Part 404. Section 407(a)(2)(i) includes a reservation of rights for the government in agreements with licensees. The United States retains the right to practice the patent on its own behalf, or on behalf of foreign governments or international organizations, or to require a licensee to grant sublicenses when public health or safety so demands.[141] This reservation is usually intended to give the United States "march-in" rights in the event that an important technology is licensed and is not subsequently exploited by the licensee, such that the public interest is adversely affected. Such a reservation, including a "government use" right, could theoretically be considered harmful to Nutrition 21's assertion of an independent right to enforcement when viewed from the perspective of traditional, non-governmental commercial licensing law. As expressed in the case of *Goldhaft v. Morrhouse*,[142] the law had traditionally recognized three types of patent licenses: exclusive licenses; partially exclusive licenses and non-exclusive licenses.[143] An exclusive license means

136. *Id.*
137. 269 U.S. 459 (1926).
138. *Id.* at 475.
139. *Id.*
140. *See* FED. R. CIV. P. 19(A).
141. *See supra* note 91. There is no *statutory* requirement that the government obtain a royalty-free license on its own behalf from its exclusive and partially exclusive licenses, when those licenses are granted under the authority of the Bayh-Dole Act pertaining to the ownership of inventions made with government funding, found at sections 202 through 204 of title 35 of the United States Code, which includes a requirement that the government obtain a royalty-free use license to any invention created in whole or part with government funding. 35 U.S.C. §§ 202-204 (1988).
142. 306 F. Supp. 533 (D. Minn. 1969).
143. *Id.* at 535.

that the owner of the patent will not grant other licenses covering the subject matter of the license and will not reserve for itself certain rights. An exclusive license in traditional application is intended to convey a complete power of enforcement to the licensee.[144] Nutrition 21's concern in maintaining its infringement action was that defendant Thorne Research would be able to avoid liability for the alleged infringement by asserting that Nutrition 21's license was, despite its terms, a non-exclusive license. This non-exclusivity could be based upon the government retention of limited rights and the idea that jurisdiction would not be proper if the United States was not joined as a party, notwithstanding the untested statutory and regulatory provisions to the contrary.[145]

Nutrition 21 subsequently moved to make the United States a party plaintiff in order to comply with the procedure outlined in *Independent Wireless*.[146] The United States moved for an order to dismiss itself as a party, arguing that sovereign immunity had not been waived, and that joinder as an involuntary party plaintiff would violate 28 U.S.C. § 516, which grants the Attorney General the power to conduct all litigation to which the United States is a party.[147]

The district court ordered the United States realigned as an involuntary plaintiff, finding that as the patent owner, the United States was an indispensable party under the Federal Rules of Civil Procedure.[148] However, recognizing the importance of the case as one of first impression, the court immediately certified an interlocutory appeal to the Federal Circuit for determination of the existence of a potentially controlling question of law as to which there is substantial ground for difference of opinion, the answer to which may advance the ultimate determination of an ongoing patent infringement litigation.[149] The certified question before the court was whether Nutrition 21, as an "exclusive" licensee of a patent owned by the federal government, could, under the circumstances of the case, maintain a suit without the United States as a party when the United States had authorized Nutrition 21 to sue for infringement in its own name and

144. *Id.*

145. *See supra* notes 45, 117 and 118 and accompanying text.

146. Independent Wireless Telegraph Co. v. Radio Corp. of America, 269 U.S. 459, 468-69. The interlocutory appeal was certified under 28 U.S.C. § 1292(b). Nutrition 21 v. United States, No. 90-1382, slip. op. at 1 (Fed. Cir. Mar. 29, 1991).

147. *Nutrition 21*, 130 F.R.D. at 672, 14 U.S.P.Q. 2d at 1245.

148. *Id.*

149. *Id.*

on its own behalf.[150]

On appeal, Judge Rich, writing for the federal circuit, framed the issue as whether the maintenance of an infringement action without the government as a party was supported by statutory authority and the explicit terms of the particular license.[151] The court found the provision at 35 U.S.C. § 207(a)(2), which permits an agency to "grant to the licensee the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest," somewhat ambiguous in that the "right of enforcement" was undefined and did not explicitly address whether the right included the ability to bring an infringement action without naming the government as a co-party.[152] Application of such a definition would cut directly against the venerable *Independent Wireless* decision. However, that case could be distinguished because the case did not involve a government-owned patent, and Congress had since changed the law as applicable to federal technology licensing.

The Federal Circuit felt that little guidance was available within the legislative history and governing regulations. The circuit concluded, however, that public policy supported a statutory construction that allowed maintenance of an infringement suit without the United States as a party.[153] It based its conclusion on the overall objectives of the statute,[154] coupled with the government's own interpretation of the statute as expressed in the terms of the license, which granted an independent right of enforcement, and the need to "minimize the costs of administering" policies in this area.[155]

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150. *Id.*

151. Nutrition 21 v. United States, No. 90-1382, slip op. at 8 (Fed. Cir. Mar. 29, 1991).

152. *Id.* at 10-11.

153. *Id.* at 12.

154. *Id.*

155. The court stated:

> Turning to public policy concerns underlying passage of legislation that included 35 U.S.C. 207(a)(2), we conclude that they support maintenance of this infringement suit without the U.S. as a party. Congress passed Pub. L. No. 96-517 in response to, inter alia, growing concerns regarding the effective private sector commercialization of inventions resulting from government-financed research .... We believe that *these objectives, particularly the last one of cost minimization - presumably to the taxpayers - would be undermined* if the U.S. as patent owner were required to make its limited litigation resources available any time on of its licensees sought to sue for patent infringement. The vigorous efforts of the Department of Justice *not to be involved* in this case are eloquent evidence to that effect .... we defer to the Commerce Department's interpretation of its authority ... we view the Commerce Department's empowerment of Nutrition 21, pursuant to the plain terms of paragraph 7.2 of the license agreement (quoted supra), to maintain this infringement action without the participation of the U.S. as a reasonable interpretation of the authority granted to federal agencies under 35 U.S.C. 207(a)(2)."

Nutrition 21 v. United States, No. 90-1382, slip op. at 10-12 (Fed Cir. Mar. 29, 1991) (emphasis added) (citations omitted).

Given the increasing number of licensing agreements between the United States and the private sector, the decision in *Nutrition 21* is a welcome relief to current licensees, potential licensees and government lawyers alike. A different decision would have entangled the federal bureaucracy so deeply into the management of licensed technology that the system quickly would have become unattractive. The decision will embolden federal agencies to grant licensees a meaningful independent right of enforcement and should go quite far in assuring the private sector that federally licensed technology can be effectively protected from infringement.

VI. CONCLUSION

In the post World War II era, privatization of government-owned technology was not an immediate concern. The United States was preeminent in the global marketplace and therefore policy-makers felt no sense of urgency to develop a legal framework to speed the transfer of federally owned or funded technology to the private sector. This complacency was evident in the disjointed federal patent system that existed through the 1960s and 1970s.

Increased economic competition and the new threat of strong foreign competition to the U.S. business community led analysts to look more closely at the U.S. competitiveness problem. As technical innovation, R&D investment and technology transfer each affect the health of the nation's economy, Congress realized the need to take the proactive role in streamlining the law to enhance the ability of the government to transfer the technology developed in its labs and through its funding to the private sector.

The evolving laws on technology transfer are reducing barriers to the commercialization of the government's annual investment of tens of billions of dollars for research and development. The Bayh-Dole Act, the Federal Technology Transfer Act of 1986 and the various regulations and policy statements surrounding those statutes are the keys that United States industry may use to unlock government technological developments and contribute to the improvement of our nation's technological competitiveness. This legal framework provides incentives, such as royalty sharing, to government scientists and those working on projects backed with government funds to create commercially viable technology. Opportunities exist for the private sector to enter into cooperative research and development agreements with government laboratories, and to commercialize directly

their own inventions made with full or partial government funding. These laws have also made it easier for the government to license federally owned technology to the private sector. The licensing of a generic form of AZT, which was discussed in the beginning of this Article, is one of many examples pointing to the benefit of federal technology transfer. Recent changes in the case law further advance that effort. For example, the decision in the *Nutrition 21* case keeps the government out of the management of licensed technology in the hands of the private sector.

In sum, all of these elements are currently working toward the goal of making government-owned technology more accessible to the private sector. The effective use of these laws will enhance the competitiveness of the United States, and through the creation of new technologies and commercial products, help accomplish President Bush's stated technology policy goal to ensure that the United States will continue to be a strong force in technology development and in the global marketplace.