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National Technology Transfer Center
Training, Marketing and Economic Development

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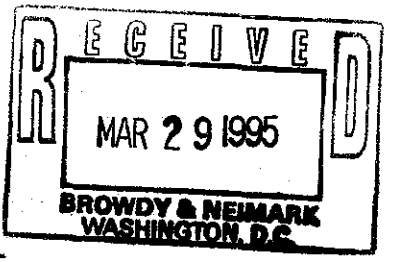

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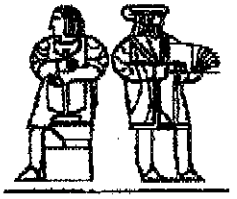

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

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COMMENTS: Joe: A lot of this language is taken directly from the Federal Labs bill (Rockefeller) that didn't get through last year.

-- Karen

AMENDMENT

(Clarifying patent title ownership under the Advanced Technology Program)

Section 28(d)(11) of the National Institute of Standards and Technology Act (15 U.S.C. 278n(d)(11)) is amended by adding thereto the following new subsection (D):

"(11)(D) Nothing in this paragraph shall be construed to take precedence over the application of Section 202 (a) and (b) of title 35 of the United States Code to intellectual property conceived or first actually reduced to practice in the course of projects awarded under this Program by United States universities and nonprofit independent research organizations qualifying under such Section, provided that such university or nonprofit independent research organization shall grant to one or more United States businesses participating on a project, by license or assignment, or an option thereto, in any intellectual property made jointly or solely by its employees, an exclusive right to practice or have practiced the intellectual property in any field of use, on terms that are reasonable under the circumstance, including reasonable compensation to the university or nonprofit independent research organization and a reasonable plan to commercialize the intellectual property."

ANALYSIS:

The 1991 Amendments to the Advanced Technology Program (ATP) (P.L. 102-245) added a provision to the enabling legislation for the ATP (the U.S. Trade and Competitiveness Act of 1988. P.L. 100-418) requiring title to patentable inventions to be held by companies incorporated in the United States. The intent of this provision was to ensure that patented technology developed under the Program would not come under the control of foreign corporations. The Amendment was silent on the disposition of patent title for universities and nonprofit organizations which, under the original enabling statute, were entitled to retain patent title as provided by laws and regulations applicable to Federal Assistance Programs, namely, Public Law 96-517, the Presidential Memorandum on Government Patent Policy Dated February 18, 1983, Public Law 98-620, 37 CFR 401 and DOC regulations governing patents.

Recognizing the overall interest of Congress in establishing the ATP as a program to foster rapid commercialization of advanced technology with minimal government intrusion, this amendment will clarify a treatment of intellectual property developed by universities and nonprofit independent research organizations authorized to participate under the Program, which is consistent with Congressional perspective that the goals of the ATP program will more likely be achieved by industrial participants receiving a preference for commercial rights to intellectual property developed by nonprofit participants. While this amendment maintains statutory consistency with other federally funded programs by clarifying the applicability of Public Law 96-517 (Bayh-Dole) for inventions made by universities and nonprofit independent research organizations, it also recognizes a primary Congressional interest in facilitating effective commercialization by one or more industrial companies participating under the Program.

UNIVERSITIES, PATENT RIGHTS, AND THE ADVANCED TECHNOLOGY PROGRAM

In 1980, Congress enacted Public Law 96-517, the Bayh-Dole Act. This legislation permitted nonprofit institutions, including universities, to retain title to patentable inventions developed in whole or in part with financial support from the Federal government. The legislation was designed to permit these inventions to be licensed directly by the inventing organization to the industrial sector in anticipation of more quickly introducing new products and new jobs into the national economy. Prior to 1980, the government retained rights to any intellectual property arising from federally funded research and provided, at best, generally nonexclusive licenses to industry. As a result, the innovative discoveries of the academic community simply sat on the shelf. By 1978, the Federal government owned 28,000 patents and only 5% had ever been licensed to industry. There was just no incentive for private industry to invest in these new patented technological discoveries.

The Bayh-Dole Act has been tremendously successful in changing that picture. It provided the incentive for creative minds within the university community to bridge the gap between academia and industry. Inventors were encouraged to stay involved during the crucial early stages of the transformation process from innovation to useful product. Thousands of new products have been patented, licensed and commercialized under its provisions. Encouraged by the success of Bayh-Dole, Congress in 1986 passed the Federal Technology Transfer Act (Public Law No. 99-502) to prompt federal laboratories to enter into cooperative research projects with private industry and to promote commercial development of the laboratories' technology through licensing. Further, in 1988, Congress moved to encourage greater industry participation by establishing the Advanced Technology Program ("ATP") (Public Law No. 100-418). The Advanced Technology Program provided for direct federal assistance to businesses or joint ventures (comprised of collaborating businesses, universities and independent research organizations) to develop new and promising technologies for commercial use. During the last decade, Congress has involved the Federal government, universities, independent research organizations, federal laboratories and industry in a common effort to develop new technology in order to bolster the position of the United States in the world economy. The thrust throughout this period has been to provide incentives for cooperation among all of those institutions capable of making a contribution.

In 1991, Congress amended the Advanced Technology Program by passing the American Preeminence Act (Public Law 102-245). A major focus of the 1991 amendments was to limit the benefits any foreign entity could receive under the Program. In so doing, Congress utilized the word "company" and among other things stated that "title to any intellectual property [patents] arising from assistance provided in this section shall vest in a company or companies incorporated in the United States." 15 U.S.C. §278n(d)(11) (Law. Co-op. Supp. 1993). In interpreting the amendments, NIST has taken the position that the word "company" means a "for-profit" business and thereby has prohibited nonprofit institutions participating in subsequent ATP projects from holding title to their own inventions. While recognizing that the ATP is aimed at industry-led projects, nothing in the ATP legislative history suggests that Congress intended to deviate from Bayh-Dole and deprive universities and other nonprofit research organizations from the right to retain ownership of their intellectual property. There is only the single use of the word "company" in relation to patent ownership, seized upon by NIST.

According to Webster's, the term "company" is not restricted to for-profit organizations. On the contrary, a company is defined as a "group associated for some purpose." Webster's New World Dictionary 283 (3rd ed. 1988). Clearly, universities which are duly incorporated and registered to do business as corporations are "companies." Just as clearly, an interpretation that would include private incorporated universities, but exclude

state chartered institutions makes no sense, and neither does the NIST interpretation which, if applied throughout the amendments, would exclude participation by foreign businesses because they are companies, but would allow participation by foreign universities because they are not companies. Additionally, while NIST reads the requirement of U.S. company ownership as all-inclusive, it may just as well be read as inclusive only of companies in the traditional sense, but exclusive of universities and nonprofit organizations which were known to be subject to Bayh-Dole.

Perhaps of greater importance than the selective application of NIST's definition is the fact that it directly contravenes Section 210 of the 35 U.S.C. (Bayh-Dole) which states that Bayh-Dole shall "take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act." Since Bayh-Dole applies to any grant, contract, or cooperative agreement for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government and NIST's own definition of an ATP "award" is "Federal financial assistance made under a grant or cooperative agreement" (15 CFR Part 295.2 (a)), surely Bayh-Dole should be applied to the ATP, unless Congressional intent to the contrary was clearly expressed. We believe this is a threshold not properly met by a highly debatable Agency interpretation. It is well-established that the rules of statutory interpretation are to give harmonious effect to all acts on a subject where reasonably possible. Baines v. the City of Danville, Virginia, 337 F.2d 579, 590-591 (4th Cir. 1964).

Further, a repeal by implication may be found only if "(1) provisions in two acts are in irreconcilable conflict or (2) it is clear that an earlier act was intended to be replaced by a subsequent act completely covering the same subject." Gov't of Virgin Islands v. Mills, 935 F.2d 591 (3rd Cir. 1991). Moreover, "in either case, the intention of the legislature to repeal must be clear and manifest." Posados v. Nat'l City Bank, 296 U.S. 497, 503 (1936); and Kremer v. Chem Constr. Corp., 456 U.S. 461, 468 (1982). See also, United States v. Barnett, 837 F.2d 933 (10th Cir. 1988); Radzanover v. Touche Ross & Co., 426 U.S. 148 (1976); and Muller v. Lujan, 928 F.2d 207 (6th Cir. 1991). Such clear intent is surely not present in this case.

Over the strenuous objections of the university community, NIST issued final ATP rules implementing its interpretation in early 1994. The application of the interpretation to the 1993, 1994, and 1995 ATP solicitations has had a chilling effect on university participation. It has resulted in some universities not participating, thereby depriving industry of essential base technology. Other universities have withheld use of certain technology or participated only where the likelihood of invention is low. Despite the obvious taxpayer benefit from combining ATP funding with other federal assistance programs, universities have been discouraged from attempting to do so because of the irreconcilable inconsistency between Bayh-Dole and the ATP rules on patent ownership.

While the ATP was meant to encourage industry-led research and development, Congress clearly intended to permit industry to enlist the participation of nonprofits and universities. The policy objective has been to harness all resources to promote the development of new technology and its commercialization. Under the incentives of Bayh-Dole, the universities have demonstrated tremendous creativity in developing new and useful technologies and in working with private industry to commercialize it, witness the growth of the bio-technology industry. The unfortunate choice of words in the 1991 Amendment calling into question the applicability of Bayh-Dole should be immediately rectified. It is surely in the national interest to stem any further loss of participation by this country's world class universities and to provide U.S. industry with an opportunity to access the most advanced technology the universities have to offer.