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PROPOSED CHANGES TO THE LAWS GOVERNING OWNERSHIP OF INVENTIONS MADE WITH FEDERAL FUNDING

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I. Introduction

Since their enactment in 1980, the Stevenson-Wydler Technology Innovation Act[1] and Bayh-Dole Act[2] have re-shaped the technology transfer landscape for inventions made during the course of federally funded research. Enacted to stimulate "improved utilization of federally funded technology developments by State and local governments and the private sector"[3] and to "ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise,"[4] these acts allowed individuals, industry, and academic and non-profit institutions to elect to retain title (subject to certain conditions and a license to the federal government) to such inventions.

The Stevenson-Wydler Act was amended by the Federal Technology Transfer Act of 1986, which enabled cooperative research and development agreements (so-called "CRADAs") between government owned laboratories, industry, and academia, and the National Competitiveness Technology Transfer Act of 1989, which extended the Stevenson-Wydler Act to government owned, contractor operated federal laboratories,[5] but neither amendment changed this basic scheme of releasing ownership of such inventions to the recipient of federal funds. However, the Emerging Technologies and Advanced Technology Program Amendments Act of 1991[6] created an Advanced Technology Program (ATP), administered by the National Institute of Standards and Technology (NIST), which changed this scheme by mandating ownership of patentable inventions made during activities funded by the ATP Program by the private ***194** sector participant in the Program.[7] In enacting that 1991 legislation, Congress effectively took title to any inventions made by a non-profit institution participating in the ATP Program out of the institution's hands, and according to academia, effectively deprived the institution of participation in the potential long-term economic benefits of the Program. This provision of the Emerging Technologies Act has therefore been criticized by academia as a disincentive to participation in the ATP Program which may have the effect of decreasing the likelihood of innovation which can be transferred to industry.

Now, legislation is being considered[8] which would further change the role of non-profit institutions in the transfer of technology resulting from federally-funded research to industry. This legislation, among other things, would amend the Stevenson-Wydler Act to require a Federal laboratory to transfer title to inventions made in whole or in part by the Federal laboratory during a CRADA to the industrial partner involved in the CRADA without providing for ownership by a non-profit institution involved in the CRADA even if an employee of the institution is a co-inventor of the invention.

To place this proposed legislation in perspective, it is helpful to consider each of the Bayh-Dole and Stevenson-Wydler Acts in more detail. It is also helpful to consider how Texas institutions might be affected by the enactment of such legislation.

II. The Bayh-Dole Act

The Bayh-Dole Act[9] allows a nonprofit or small business firm[10] which makes an invention during a contract, grant, or cooperative agreement with a Federal agency for the performance of experimental, developmental, or research work funded by the Federal Government to elect to retain title to the invention.[11] Retention of title is subject to certain obligations,[12] the most significant being that the contractor make timely disclosure of the invention to the funding agency, file a patent application prior to any statutory bar date,[13] acknowledge the Government's support in the patent application, and grant a non-exclusive, nontransferable, irrevocable, paid-up license to the funding agency to practice the invention for or on behalf of the United States throughout the world. Another limitation on the right of ownership is that the contractor cannot assign or grant an exclusive license to the invention to any person or entity unless products embodying the subject invention (or produced through the use of the invention) are manufactured substantially in the United States. The statute does, however, provide for exceptions to this preference for U.S. industry in certain conditions.[14]

The regulations implementing the Bayh-Dole Act are set out at 37 C.F.R. § 401, *et seq.,* and provide a standard inventions rights clause (to be tailored for each Federal agency's use) having certain basic provisions which track the provisions of the Act summarized above in all funding contracts.[15] There are provisions for modification of those basic provisions, set out in 37 C.F.R. § 401.3(a), the most important being the "exceptional circumstances" provision of § 401.3(a)(2), which allows modification ***195** when the funding agency determines that it "will better promote the policy and objectives of Chapter 18 of Title 35 of the United States Code."[16]

By all accounts, the Bayh-Dole Act has had a significant impact on the transfer of technology from academia to industry. It is difficult to "quantify" technology transfer, but if the number of patent applications filed by universities, the number of license agreements between universities and industry, and the dollar value of such licenses are any indication, Bayh-Dole appears to be a rousing success. According to a survey conducted by the Association of University Technology Managers (AUTM), in fiscal year 1992 the 130 U.S. and Canadian institutions which responded:
1. granted 1731 licenses,

2. received $298 million in gross royalties (when adjusted for double payment, about $260 million),

3. filed 3251 patent applications (on 7604 invention disclosures), and

4. managed 3177 active (royalty-earning) licenses.
Without baselines, this information needs to be assessed with a grain of salt, but there is no denying that it represents significant economic activity and therefore has the potential to benefit the economy just as intended by the Bayh-Dole Act.

There are some figures which help place this information in perspective. For instance, those same 130 survey respondents reported their royalty income in 1981 as about $7 million (total of all respondents). Another statistic which helps is that the 1155 patents granted to U.S. universities in 1990 represented 2.4% of all patents granted in the United States that year. In 1980, the percentage was only about 1%. Perhaps the most telling information for assessing the economic impact of the role of non-profit institutions in technology growth, however, is the report of the Department of Commerce that industry funding of academic research rose from $236 million in 1980 to an estimated $1250 million in 1991.

These increases are consistent with those of the academic institutions located here in Texas. For instance, according to the Office of General Counsel of the University of Texas System, from 1987 -- 1991, the number of patent applications filed by the System rose from 70 (in 1987) to 110 (1991), with the number of patents granted each year rising from 30 to 79. Further, during the period 1985 -- 1992, the System entered into or was negotiating a total of 223 license agreements.

III. The Stevenson-Wydler Act

As amended by the above-described Federal Technology Transfer Act of 1986 and the National Competitiveness Technology Transfer Act of 1989, the Stevenson-Wydler Technology Innovation Act authorizes Federal laboratories to enter into cooperative research and development agreements (CRADAs) with U.S. industry and research institutions. The Federal laboratory contributes personnel, property, and services (but not funds) to a CRADA, while the research institution and private partners can contribute personnel, property, services, and funds. Under the Stevenson-Wydler Act, the directors (or other authorized representatives) of a Federal laboratory can negotiate such an agreement without the need for agency review, significantly streamlining the process. Section 3710a(c)(4) requires the lab director to give special consideration to small business and to give preference to U.S. businesses which agree to manufacture in the U.S. "in deciding what cooperative

research and development agreements to enter into."

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

Like the Bayh-Dole Act, the Stevenson-Wydler Act has had a significant impact on technology transfer. The number of active CRADAs has jumped from 98 in 1988 to about 1300 by the end of 1992. The National Institute of Standards and Technology (NIST) now participates in over 200 CRADAs in over 70 different research areas ranging from materials sciences to biotechnology. Total patent applications filed by Federal agencies increased from 848 to 1936 (1987 to 1991) while the number of inventions disclosed rose from 2662 to over 4200. Likewise, the number of licenses granted by Federal agencies rose from 128 in 1987 to 261 in 1991; license income increased from about $4.9 million in 1987 to over $18 million in 1991. These figures are taken from a January 1993 report of the Secretary of Commerce entitled "Technology Transfer Under the Stevenson-Wydler Technology Innovation Act: The Second Biennial Report," which reports the information as having been gathered by the General Accounting Office from the reports of the agencies involved.

Just as is the case for Texas academic institutions with the Bayh-Dole Act, it appears that the experiences of CRADA participants here in Texas mirrors that experienced nationally. For instance, the Texas A&M System reports that it is currently negotiating one contract involving a federal laboratory and an industry partner to a CRADA and that it is already a participant with another federal laboratory/industry CRADA, the latter having been entered into quite recently. Although the Texas A&M System is not a full participant with the federal laboratory and industry partner in the latter of these two CRADAs, the CRADA was formed to develop inventions owned in part by the Texas A&M System and, if there are royalties from commercialization, that institution will share in those revenues.

IV. Possible Change?

In spite of the apparent success of Bayh-Dole and Stevenson-Wydler, there are critics. For instance, the National Coalition for Universities in the Public Interest, an organization co-founded by Ralph Nader in 1983, points to the Bayh-Dole Act as the major factor in the well-documented increase in college tuitions.[17]

Another criticism, so far directed at the Bayh-Dole Act but equally applicable to the Stevenson-Wydler Act (if it is a valid criticism), is that non-U.S. based industry is accessing the results of federally-funded research as well as U.S. business. In 1989, a House subcommittee criticized certain U.S. universities which were licensing foreign business and instructed the General Accounting Office to survey the technology transfer practices of the thirty-five universities which receive the most federal grant money. That survey was published in May of 1992, and found that 24 of those 35 institutions had dealings with at least one foreign business. That survey also formed part of the basis of an October 1992 report issued by the House Committee on Government Operations which stated that "the benefits of publicly funded research are being sold at bargain basement prices to foreign corporations, and . . . the very programs that were initiated to increase U.S. competitiveness are benefitting our economic competitors instead." Texas may be a microcosm illustrating that this criticism may have some validity. In an article which appeared in the October 19, 1992 issue of Business Week,[18] the authors noted that it is no coincidence that European, Canadian, and Japanese industry has located near some of the ***197** premiere academic institutions in the U.S., citing the location of Fujitsu, Alcatel, and Ericsson (along with U.S.-based Texas Instruments and Northern Telecom) in the so-called "Telecom Corridor" in the Dallas area: "the goal is to harvest ideas and talent from universities or start-ups, a key advantage in a global economy where the first to market wins."

Recently, several research-oriented, non-profit institutions have received inquiries from the National Institutes of Health regarding the transfer of technology to U.S. based business (as compared to foreign industry). Further, the Commerce Department's Assistant Secretary for Technology Policy, Technology Administration held information-gathering public meetings in October and November of 1993 at which input was sought on the preference for U.S. industry. The announcement of the public meetings also asked for comment on the above-described exceptional circumstances provisions of the Bayh-Dole Act (and the regulations at 37 C.F.R. § 401.3(a)). These several criticisms and information gathering efforts, when viewed in conjunction with the provisions mandating ownership of technology by industry as set out in the enabling legislation for the ATP Program and the above-mentioned proposed amendment to the Stevenson-Wydler Act, indicate that there may be a movement afoot to make changes which may restrict or even cut non-profit research institutions out of the process of transferring technology resulting from federal funding to industry.

In this latter regard, at the Commerce Department's October 25, 1993 hearing on the Bayh-Dole Act, at least one representative of academia was strongly critical of the provisions in the above-described Emerging Technologies and

Advanced Technology Program Amendments Act of 1991 requiring mandatory transfer of title to patentable inventions to the private sector.[19] Academia also made its opinion known after publication of the proposed rules implementing that Act on August 2, 1993,[20] and specifically, was highly critical of proposed 15 C.F.R. § 295.8(a) which implements § 278n(d)(11). However, as pointed out in the final rules,[21] NIST is without authority to change § 295.8(a) in response to academia's criticism because of the statutory mandate of § 278n(d)(11). It was also suggested at that October 25, 1993 hearing that the exceptional circumstances provisions of 35 U.S.C. § 202(a) could be used to accomplish much the same result as mandated by 15 U.S.C. § 278n(d)(11) and the rules implementing that legislation.

Although it is contemplated by Congress and NIST that academic and other non-profit institutions would participate in the ATP Program, such institutions are probably more likely to participate in the cooperative research and development agreements enabled by the Stevenson-Wydler Act. However, as noted above, S. 1537 amends section 12 of the Stevenson-Wydler Act[22] to state that a Federal laboratory participating in a CRADA "shall ensure that title to intellectual property arising from the agreement. . . [except intellectual property developed solely by an employee of the Federal laboratory] is assigned to the collaborating party or parties to the agreement in exchange for reasonable compensation to the laboratory . . . . " Although the definition of "collaborating party" is not set out in the Stevenson-Wydler Act or S. 1537, in his remarks introducing S. 1537, Senator Rockefeller made it clear that the term does not include non-profit institutions: "The bill we are introducing today eliminates. . . [the option to claim ownership of intellectual property made by the Federal laboratory under the Stevenson-Wydler Act] by directing Federal laboratories to ensure that the private sector is assigned title to any intellectual property arising from a CRADA."

***198** With the introduction of S. 1537, the provision mandating transfer of title to technology developed under the ATP Program to industry may be about to creep into the Stevenson-Wydler Act such that the ability of non-profit institutions to participate in the potential long-term economic benefits of the transfer of such technology may be threatened. Senator Rockefeller noted that the justification for S. 1537 was that:

> The Stevenson-Wydler Technology Innovation Act currently gives Federal laboratories an option to claim ownership to technology developed jointly by a laboratory and a private research partner under the terms of a cooperative research and development agreement, despite the fact that the private sector partners in most cases provide the majority of the research. I believe that this ability of the Federal Government to claim a right of ownership to intellectual property developed jointly with the American companies has inhibited the establishment of cooperative R&D agreements and has retarded the commercialization of federally-supported technology developments.

Without ownership and the opportunity to participate in the economic benefits of such agreements, such legislation is surely even more of a concern to non-profit institutions than the 1991 ATP Program legislation complained of at the October 25, 1993 hearing and the newly promulgated implementing regulations discussed above. Indeed, if the next legislation to be changed in the manner in which S. 1537 changes the Stevenson-Wydler Act is the Bayh-Dole Act, the non-profit research institutions (which, according to Congress itself, are so important to the economic competitiveness of the United States) may be in jeopardy of losing some or all of its $298 million income from the licensing of technology.

S. 1537 may also be susceptible to criticism on other fronts. For instance, a criticism of the Bayh-Dole Act is, as noted above, that the technology is being sold at "bargain basement prices." Because S. 1537 gives the Federal laboratory no alternative but to transfer ownership of the intellectual property to the private sector,[23] the laboratory has little or no bargaining power. In apparent contemplation of this criticism, Senator Rockefeller called attention to the "reasonable compensation" provision of S. 1537, but without any choice but to accomplish the transfer, the laboratory lacks the ability to "sell" the technology at market prices. Industry will therefore likely be a strong proponent of S. 1537, and consistent with that expectation, industry testimony at the hearing held on S. 1537 by the Senate Subcommittee on Science, Technology and Space on October 26, 1993 was very favorable.[24]

One might also wonder about the potential for conflict between the provisions of the Bayh-Dole Act and an amended Stevenson-Wydler Act. For instance, one could envision a CRADA in which the participating Federal laboratory contracted with an academic institution and a patentable invention results from that contract. The contract between the laboratory and the academic institution would, at least under current law, be governed by the federal acquisition regulations (FAR) which incorporate the standard inventions rights clause of 37 C.F.R. § 401.14(a) and provide (in accordance with Bayh-Dole) for the release of title to the invention to the academic institution. However a Stevenson-Wydler Act that has been amended by S. 1537 would apparently conflict with those terms by requiring that title to such an invention, if made during performance of the CRADA contract, be assigned to the industry partner involved in the CRADA. It would appear that Federal laboratories, academic and research institutions, and industry in the State of Texas all have a potentially large stake in this proposed legislation.

Footnotes

[a1] Vaden, Eickenroht, Thompson, Boulware & Feather, L.L.P.

[1] 15 U.S.C. § 3701, *et seq.* (Supp. 1992).

[2] 35 U.S.C. § 200, *et seq.* (Supp. 1992).

[3] 15 U.S.C. § 3702(3) (Supp. 1992).

[4] 35 U.S.C. § 200 (Supp. 1992).

[5] Both Acts were amendments to 15 U.S.C. § 3701, *et seq.*

[6] P.L. 102-245.

[7] 15 U.S.C. § 278n(d)(11) (Supp. 1992).

[8] Senate Bill 1537, Rockefeller, and its House counterpart, H.R. 3590, Morella.

[9] P.L. 96-517, as amended in 1984 by P.L. 98-620.

[10] Defined as a "contractor" by 35 U.S.C. § 201 (Supp. 1992).

[11] 35 U.S.C. § 202(a) (Supp. 1992).

[12] 35 U.S.C. § 202(c) (Supp. 1992).

[13] *See* 35 U.S.C. § 102 (Supp. 1992).

[14] 35 U.S.C. § 204 (Supp. 1992).

[15] 37 C.F.R. 401.14(a) (1993).

[16] 35 U.S.C. § 200, *et seq.* (Supp. 1992).

[17] E. Negin, *Education: Why College Tuitions Are So High,* 271 THE ATLANTIC 32 (March 1993).

[18] Pages 80-88.

[19] 15 U.S.C. § 278n(d)(11) (Supp. 1992).

[20] 58 Fed. Reg. 41069.

[21] 59 Fed. Reg. 663 (Jan. 6, 1994).

[22] 15 U.S.C. § 3710a (Supp. 1992).

[23] The language of the legislation is “shall” as compared to “may” as currently set out in 15 U.S.C. § 3710a.

[24] *See* 46 PAT., TRADEMARK & COPYRIGHT J. (BNA) 560 (October 28, 1993).