Appendix A Federal Technology Transfer Legislation

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To enhance private sector development and application of results from federally funded research—at universities, research institutions, and federal facilities—Congress enacted a series of measures during the 1980s. This appendix describes these measures, and also briefly reviews federal laws, regulations, and policies not specific to technology transfer, but that nevertheless exert an impact on the process.

BAYH-DOLE ACT OF 1980

High rates of unemployment and inflation characterized the late 1970s and early 1980s. Policymakers turned to technology transfer to rebuild, in part, what some believed to be a deteriorating industrial science and technology infrastructure. The theme of economic competitiveness influenced most of the politics governing technology transfer during the 1980s. In fact, so far in the 1990s, economic competitiveness and technology transfer have continued to be important issues for federal research and development (R&D) policy.

In 1980, the Bayh-Dole Act (Public Law 96-517) became one of the first in the series of recent congressional attempts to enhance the flow of results from federally funded research to development by the private sector. Based on the belief that the private sector would do a better job than federal agencies of commercializing results of U.S. government funded research, Congress viewed Bayh-Dole as providing a set of broad federal rules governing patent law that would encourage industry to develop federally funded research into marketable, commercial products (72). Previous policies promoted an entirely different concept—i.e., if the public pays for the research, then the results should be available at no cost to taxpayers (46).

Through Bayh-Dole, private parties retain patent rights via a "title in contractor" policy, which means small businesses and nonprofit organizations, including universities, retain title to results from federally funded contracts (71). Prior to Bayh-Dole, some federal agencies allowed contractors to retain title to their inventions, but Bayh-Dole was the first legislation mandating a comprehensive federal implementation of the title in contractor policy.

As originally enacted, Bayh-Dole had some limitations. It did not cover government-owned, contractor-operated (GOCO) facilities. As a result, the law excluded a significant portion of federal research—primarily the U.S. Department of Energy's (DOE) national laboratories and university-operated, DOE-owned facilities. Not until the Bayh-Dole Act was amended in 1984 (Public Law 98-620) could federal agencies include research contracts with universities that operate DOE's national laboratories within the scope of the title in contractor policy (71). The 1984 amendments also provided statutory authority for the government to dispose of patent rights to contractors and made the U.S. Department of Commerce (DOC) the lead federal agency for technology transfer matters (71).

STEVENSON-WYDLER ACT OF 1980

Prior to passage of Bayh-Dole, Congress enacted the Stevenson-Wydler Technology Transfer Act of 1980 (Public Law 96-480; also referred to as the Technology Innovation Act). Stevenson-Wydler established an explicit precedent for the United States to try and capitalize on its massive investments in R&D (72). Stevenson-Wydler codified several policies to ensure that the government had full use of its extensive investments in science and technology, particularly if the use was within the mission of the agency conducting the research. However, Stevenson-Wydler only granted permission to fulfill these functions; it did not state that technology transfer was a statutory requirement (71).

As part of the attempt to leverage federal investment in science and technology, Stevenson-Wydler explicitly stated the U.S. government should transfer technology developed at federal facilities to state and local governments and, wherever appropriate, the private sector. Stevenson-Wydler also required that federal agencies administering research establish an Office of Research and Technology Applications (ORTA) at all government-operated or contractor-operated laboratories with annual budgets greater than $20 million. Under Stevenson-Wydler, federal agencies could spend up to 0.5 percent of their research budgets to support of technology transfer at their ORTAs, but no more.

Stevenson-Wydler also provided general guidance on the measures the federal government should employ to encourage technology transfer. It stated that government's responsibility includes ensuring full use of results derived from federal R&D (71). The law acknowledged the value of technology transfer as an important economic function and legitimized grass roots efforts to transfer technology at the national laboratories, but provided no means for enforcing the provision for ORTAs (40). As a result, few agencies paid attention to the requirement to establish ORTAs or involve industry in cooperative projects. None of this was lost on critics of the law, who said it was ineffective because much of its funding was withheld by Congress, which meant agencies had neither the personnel nor resources to comply (36,76). During 1985 hearings on technology transfer, the chair of the Federal Laboratory Consortium for Technology Transfer testified that of 69 technical facilities supported by government funding, less than half had a full-time person assigned to technology transfer and three-quarters had no stated policy or procedure for encouraging technology transfer (76).

FEDERAL TECHNOLOGY TRANSFER ACT OF 1986

When it became apparent that relatively few technologies were being transferred from federal laboratories after enactment of Stevenson-Wydler, Congress amended Stevenson-Wydler with the Federal Technology Transfer Act (FTTA) of

1986 (Public Law 99-502). Legislative hearings and debate prior to passage dwelled on the looming trade imbalance, which by the mid-1980s had extended to key high technology areas, specifically microelectronics (82). A report from the President's Commission on Industrial Competitiveness cited the creation and application of new technology as one of four major ways in which the United States could become more competitive. The Commission recommended that the federal government manage its R&D with more concern for commercial application and economic competitiveness (66). Of primary concern to Congress was how best to share federal R&D resources, including personnel, with commercial entities. FTTA also moved the discussion of technology transfer beyond the patent provisions of Bayh-Dole to more general discussions on how to facilitate cooperative R&D within federal laboratories (66).

FTTA strengthened Stevenson-Wydler and extended the authority to explicitly promote the economic competitiveness of American industry. FTTA altered the emphasis of Stevenson-Wydler from permitting the transfer of research results from federal laboratories to requiring that agencies act vigorously and work more closely with industry for successful technology transfer (40). FTTA detailed specific measures to remedy uncertainties about technology transfer at federal laboratories operated by the government.

The signature feature of FTTA was the authority granted to federal agencies to negotiate Cooperative Research and Development Agreements (CRADAs) with nonfederal parties, provided the joint research falls within the originally chartered mission of the laboratory (71). The initiating and negotiating authority specifically rests with the laboratory's director, with final approval of CRADAs coming from agency headquarters in certain, limited cases (71,45). Once a CRADA is approved, the research may begin, but no federal funds may be used to conduct the research (72,15). FTTA allowed federal agencies, in the CRADA formation process, to negotiate exclusive licensing terms with CRADA partners (15).

FTTA also authorized award programs for federal employees who invented or discovered anything of commercial worth, and specified that royalties from an invention to which the agency retained rights should be shared with the individual employee, up to $100,000 annually (13). When the agencies themselves do not retain ownership or promote any commercialization whatsoever for an invention or discovery at a federal facility, the employee/inventor is free to pursue a patent individually (14,15,31). FTTA mandated that federal agencies conducting R&D allocate a small fraction of their budgets to the Federal Laboratory Consortium (FLC), an interagency group that was first set up by several defense laboratories in 1971 (40). FTTA also established several policies for the laboratories to follow, including:

- technology transfer is a responsibility of each science professional and should be included in a position description as well as an annual performance evaluation;
- each laboratory having 200 or more full-time scientists or engineers must devote at least one full-time career professional to the facility's ORTA; and
- laboratories shall participate, wherever possible, with local, state and regional authorities to promote local economic development (71).

FTTA required the head of each agency conducting research to identify and encourage persons to act as third-party brokers to facilitate technology transfer between a laboratory and a potential user (71). FTTA also established a new technology share program, requiring agency heads to select one or more laboratories as the focal point for using their particular areas of scientific expertise in consortia with university and industry members; laboratories were authorized to contribute up to $5 million annually to each consortium (40).

OMNIBUS TRADE AND COMPETITIVENESS ACT OF 1988

The central goal of the Omnibus Trade and Competitiveness Act (OTCA) of 1988 (Public Law

100-418) was to enhance U.S. economic competitiveness in relation to other nations. Encouraging technology transfer from the federal government to industry was one of several solutions the law offered. OTCA established a technology extension program comprised of several regional centers to transfer manufacturing technologies within DOC. It also changed the name of the National Bureau of Standards to the National Institute of Standards and Technology (NIST) and authorized NIST to administer the Advanced Technology Program (ATP).

NATIONAL COMPETITIVENESS TECHNOLOGY TRANSFER ACT OF 1989

In 1989, Congress enacted the National Competitiveness Technology Transfer Act (NCTTA) (Public Law 101-189) in a further attempt to open up federal laboratories to outside interests and commercialization. NCTTA authorized all DOE facilities to enter into CRADAs with industry, placing contractor-operated national laboratories on equal footing with government-operated laboratories (72). NCTTA gives preference for CRADAs to small businesses, companies manufacturing in the United States, or foreign firms from countries that permit U.S. firms to enter into similar agreements (40). In the case of government-owned, contractor-operated laboratories, NCTTA required that conflict of interest provisions regarding CRADAs be included in the laboratories' operating contracts. NCTTA also amended the Freedom of Information Act (Public Law 89-487) to allow federal laboratories to withhold from public disclosure certain proprietary types of information resulting from cooperative or sponsored research with industry (40).

Large contractor-operated national laboratories, such as Los Alamos, Lawrence Livermore, Oak Ridge, and Argonne, were particularly affected by NCTTA. Researchers from these and other federal facilities increasingly interacted with colleagues at scientific conferences, and many private intermediary organizations have attempted to commercially exploit the federal investment in science and technology since NCTTA became law (40,50).

OTHER LAWS AND POLICIES AFFECTING TECHNOLOGY TRANSFER

Technology transfer is a multifaceted process. U.S. laws and policies not explicitly designed to govern technology transfer affect that process. Currently, the federal government has economic regulations, tariffs, tax laws, subsidies, and other actions that affect federal technology transfer, primarily in response to specific interests. These laws and policies exist without a more formal, coordinated technology policy (69). Examples pertinent to this study include antitrust law, conflict of interest policies, tax laws, and funding initiatives. This section briefly highlights a few factors that affect technology transfer in order to illustrate the range of mechanisms by which the effectiveness of technology transfer efforts might be governed.

Antitrust Laws

Antitrust laws affect both public and private efforts—research consortia, patent pooling, licensing agreements, joint ventures, and other alliances—to commercialize technologies in several sectors, including microelectronics, aerospace, electric vehicles, and biotechnology (38,58). In general, antitrust enforcement has relaxed since the 1960s and 1970s, which theoretically increased flexibility for businesses to pursue strategic objectives. In some cases legislation has been introduced to codify exemptions for cooperative research (58).

With an eye toward investing in the economic competitiveness of the U.S. technology base, several U.S. government sponsored consortia have been established with public and private funds. Most of these consortia are explicitly chartered to conduct research and sponsor development of technologies that U.S. industry can exploit to compete in global markets for high technology products. For example, in the biotechnology sector, the Biotechnology Research and Develop-

ment Corporation, a joint seven company-U.S. Department of Agriculture research consortium in Illinois, spends approximately $4 million per year on biotechnology research with agricultural applications. Individual private sector consortium members have initial rights to negotiate nonexclusive and exclusive licenses from the consortium, in support of technology transfer (58).

Such efforts could be problematic from an antitrust standpoint. To allow these consortia and similar alliances to form without threat of antitrust prosecution, Congress passed the National Cooperative Research Act of 1984 (Public Law 98-462). The most frequently justified exemption from antitrust enforcement under this law is that most research consortia focus on developing precompetitive technologies that are generic and open to application by all U.S. firms in a particular sector. No U.S firms are explicitly excluded from joining the consortium if they invest a minimum amount in projects undertaken by the group. The law even allows consortia to form without the participation of a federal agency, as long as the consortium satisfies the criteria for basic research outlined in the law. Interestingly, companies will sometimes create a consortium for the sole purpose of entering into a CRADA with a federal laboratory (15).

Antitrust laws are intended to promote competition in the markets for goods and services. Because a patent is, in some respects, a legal form of a monopoly, antitrust issues sometimes emerge and affect licensing agreements or joint ventures. Department of Justice (DOJ) guidelines specify nine forms of licensing behavior that qualify for investigation (38), and the federal government has initiated investigations into licensing agreements and alliances in the biotechnology sector.

In one case, a cross licensing agreement between Schering-Plough and Hoffmann-La Roche was investigated by the Federal Trade Commission (FTC) because of allegations that Hoffmann-La Roche had improperly obtained its patent on a method of mass producing a form of the drug interferon. Based on reports that Schering-Plough and Hoffmann-La Roche had agreed not to contest each other's patents by crosslicensing two related patents for producing interferon in a bid to corner the market, the FTC claimed that the patent claims constituted part of a larger plan to restrict entry (38). As of summer 1995, there had been no public court finding on this matter. Moreover, recent activities indicate that DOJ recognizes a market for research tools called the "innovation market." Currently, DOJ is scrutinizing licensing activities that could lead to monopoly power over a research tool in an innovation market, with the potential for investigation of antitrust violations in cases where licenses threaten the competitive nature of these markets (10).

Currently, the role of antitrust law and its effect on technology transfer from a federal agency to industry is unclear. However, where anticompetitive practices result, the possibility of antitrust enforcement could play a role in encouraging transparency and competition.

Conflict of Interest

Conflict of interest issues with respect to technology transfer have emerged as a subject of considerable controversy, particularly the issue of whether conflict of interest issues inhibit technology transfer. In this context, conflict of interest refers to "a clash between public interest and the private pecuniary interest of the individual concerned" (11).

Generically, the concern over conflict of interest in the case of technology transfer arises from a fear that a researcher or administrator responsible for a discovery that a company is interested in licensing might prejudice research results or negotiations based on a financial relationship with the company. Some experts claim that policies and rules governing conflict of interest are too vague and need to be more explicit (12). Others contend that conflict of interest concerns can inhibit the process of transferring research results out of the laboratory and into the marketplace.

Academic-industry-government relationships in the context of biomedical research can be controversial and complicated by conflict of inter-

est issues. The mere appearance of conflict of interest can inhibit technology transfer, particularly in the biotechnology sector (12).

Conflict of interest restrictions seek to prohibit or deter conflicts between official public duties of a government employee and the employee's personal financial interests (18 U.S.C 208). These provisions seek to serve the public's interest by prohibiting or regulating possible influences upon a public official that might arise from the personal financial holdings, dealings, or ownerships of the government employee or his or her immediate family, or from current or prospective employment in the private sector (59).

Provisions relating to conflict of interest for federal employees are based on federal laws and regulations (59). DOJ is responsible for investigating conflict of interest cases and enforcing all federal conflict of interest laws. As required by Office of Personnel Management regulations, agencies promulgate their own regulations and prescribe additional standards of ethical conduct as needed because of the special activities of that agency (99). Each agency is instructed to provide ethics counseling, guidance, and advice to its employees, and to keep its employees informed of ethical requirements and current standards of conduct.

Government conflict of interest regulations also apply to nongovernment institutions. The Public Health Service (PHS) has published proposed guidelines for recipients of extramural research grants (18), which, as a condition of funding, must be embodied in each grantees' conflict of interest policy. At a scientific conference in early 1993, one DOE official blamed some of the difficulty of dealing with the bureaucracy involved in administering technology transfer on the fear of conflict of interest regulations in general, along with the potential for vigorous DOJ investigation coupled with congressional oversight (54).

Tax Laws and Policies

Fiscal policy, embodied in U.S. tax law, can play an important role in technology transfer in several ways. In 1954, the Internal Revenue Service began to affect commercial innovation when it implemented a rule that allowed businesses to treat R&D expenditures as current business expenses for tax purposes (69). Regularly renewed by Congress since enactment, the Economic Recovery Tax Act of 1981 (ERTA; Public Law 97-34) provides tax credits for R&D within the company or under contract to another organization, such as a university. In a 1985 survey of biotechnology companies, 20 percent reported that they had benefited from ERTA. Survey respondents claimed that ERTA was important in promoting their support of university research (15). Industrial support for research frequently augments federal funding for research at a university and inventions become eligible for technology transfer under Bayh-Dole (23).

Proposed tax credits also can affect the flow of money to research, and hence, potentially to technology transfer processes. Part of a corporation's financial planning for future expenditures and resource allocation involve the use of R&D tax credits. All other things being equal, if R&D expenses can be deducted from federal tax payments, R&D likely will be stimulated—either in a corporate laboratory or the university where the firm sponsors the research. Again, the potential then exists to create a larger research base that offers greater opportunities for technology transfer and commercialization. However, no guarantee exists that such a tax credit will directly enhance opportunities for technology transfer per se.

Guidelines exist for federal government licensing professionals. These guidelines illustrate the significant federal income tax consequences for both parties involved in an intellectual property transaction (65). For example, the licensee to any technology may claim a federal tax deduction for payments made to the licensor as a business expense. In addition, there may be tax advantages, depending on the specific nature of the transaction, to the licensor. If the intellectual property transaction meets certain threshold qualifications, the transfer is treated as a sale. In this case, the seller may deduct the unamortized capital costs of the

technology being transferred, and also claim capital gains tax treatment (65). Moreover, the cost of a patent may be amortized over the patent term. The transfer of technology to foreign entities also can create tax advantages, depending on the characteristics of the transfer.

The tax code can thus be used to encourage technology transfer, whether through licensing or the assignment of patent rights. However, any consideration of tax codes as an instrument of technology transfer policy must also balance the potential costs of any changes, such as bureaucratic complexity and unintended loophole effects. Nonprofit research institutions also risk jeopardizing their tax exempt status, depending on the nature of cooperative research relationships with industrial partners.

Funding Initiatives

Funding for technology transfer and commercialization occurs at the national, state, and local levels. Federal funding for the FLC is earmarked from each large U.S. government laboratory's budget. Congress appropriates most funding for technology transfer based on research at federal laboratories. An example of a specific federal funding initiative, administered through NIST, is ATP.

ATP is designed to help U.S. companies bring innovative technologies to civilian applications in the marketplace. Through ATP, NIST awards funds to successful applicants and then provides development and technology transfer assistance to help companies get closer to commercializing their work. ATP is generally viewed as a successful government initiative by some industry observers and participants (50). However, under the initial ATP rules, rights to intellectual property emerging from ATP consortium R&D were automatically assigned to the industrial partner, even if a university participates in the R&D process. Currently, universities are concerned that this could erode their rights—granted under Bayh-Dole—to title of federally funded inventions arising from research performed at universities.