*Federal Technology Transfer and the Human Genome Project*

September 1995

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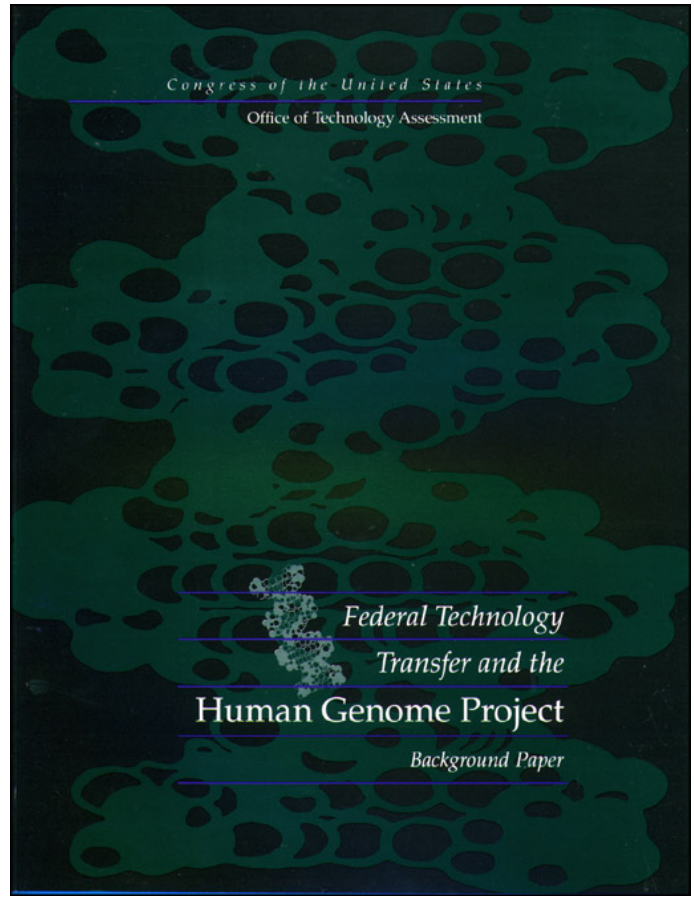

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# Foreword

Technology transfer involves converting scientific knowledge into commercially useful products. As an interest of the U.S. government, technology transfer is not a new issue; the federal government has had laws and policies encouraging innovation dating back to the Patent Act of 1790. Nearly two centuries later, the Bayh-Dole Act of 1980 marked the first in a series of measures enacted by Congress to enhance technology transfer of federally funded research. Today, U.S. preeminence in biomedical research and industrial biotechnology stands, in part, as a striking example of successful technology transfer.

Against this backdrop, the United States and other countries have embarked on an estimated 15-year, $3 billion initiative to map and sequence the entire human genetic blueprint, or genome, and since 1985, Congress has appropriated nearly $1 billion for the Human Genome Project. The project has been undertaken with the expectation that enhanced knowledge about genetic disorders, increased understanding of gene-environment interactions, and improved genetic diagnoses can advance therapies for the 5,000 or so currently recognized human genetic conditions. As with other areas of biomedical research, the expectation is that the results of genome research will yield commercially valuable products of benefit to human health. Given the government's investment in genome research, what role has technology transfer played to date?

*Federal Technology Transfer and the Human Genome Project* analyzes universities', companies', and researchers' experiences and perspectives since enactment of federal laws to enhance technology transfer—especially as it pertains to research funded by the National Institutes of Health and the Department of Energy, the agencies funding U.S. efforts in the Human Genome Project. The background paper was requested by Senator Mark O. Hatfield, Chairman, Committee on Appropriations and Senator Edward M. Kennedy, Ranking Minority, Committee on Labor and Human Resources.

OTA prepared this background paper with the assistance of a panel of advisors and reviewers selected for their expertise and diverse points of view. Additionally, hundreds of individuals cooperated with OTA staff through interviews or by providing written material. These authorities were drawn from government, academia, industry, and professional societies worldwide. OTA gratefully acknowledges the contribution of each of these individuals. As with all OTA reports, however, responsibility for the content is OTA's alone.



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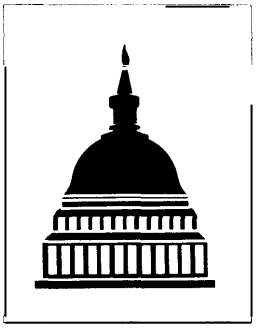
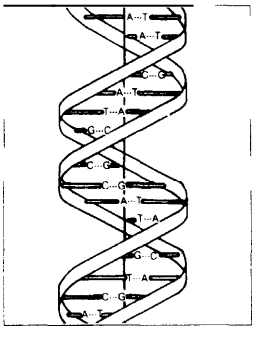
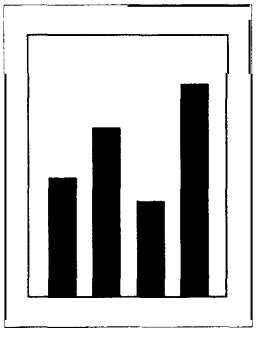






# Executive Summary

For the past 15 years, federal technology transfer has received bipartisan interest, as policymakers sought to enhance the availability of federally supported research for further development by industry. Through the 1980s, Congress enacted a series of laws that encourage commercial development of federally funded research at both universities and federal laboratories. Such laws (chiefly the Bayh-Dole Act of 1980, Stevenson-Wydler Act of 1980, and Federal Technology Transfer Act of 1986; Public Laws 96-517, 96-480, and 99-502, respectively) were not aimed specifically at genome, or even biomedical, research. However, such research and the commercial biotechnology enterprises that surround them clearly have benefited. The success of the biotechnology sector owes much to federal technology transfer and intellectual property policies.

As a commercial enterprise, biotechnology represents billions of dollars of investment, and the engine that drives most investment is intellectual property protection of a venture's research. OTA has consistently reported to Congress that intellectual property protection has played, and continues to play, a critical role in U.S. preeminence in commercial biotechnology. By the late 1960s, advances in biological and genetic technologies had begun to unlock the mysteries of human disease, and in the United States, progress in the biomedical field derived largely from federally funded research. In the 1980s, judicial and legislative policies expressly encouraged moving results from federally supported biomedical research to the marketplace.



Intellectual property and technology transfer continue to play an important role in biotechnology research and development (R&D). The National Institutes of Health's (NIH) 1991 filing of patent applications on thousands of human DNA sequences was

justified, in part, as a means for the federal government to ensure that the public's investment in biomedical research—in this case at a federal laboratory—was optimized through patents that would be attractive to investment by industrial partners.

Such federal-private sector partnerships were made possible under technology transfer legislation enacted in the 1980s. Today, a system of laws, regulations, and policies exists to transfer the fruits of publicly funded research—through grants or contracts at academic research institutions or federal laboratories—to industry. With respect to research conducted under the auspices of the Human Genome Project, the technology transfer policies and practices of NIH and the U.S. Department of Energy (DOE) are key. Additionally, laws and policies outside the scope of legislation designed specifically to facilitate technology transfer also affect federal technology transfer. Indirect forces that affect patent position can influence technology transfer—e.g., licensing and patenting practices in the private sector frequently fall under antitrust scrutiny.

The bulk of technology transfer for life sciences research occurs via the rich academic biomedical infrastructure that is unique to the United States. Universities and research institutions benefit from the level of support provided by the government's sponsorship of basic biomedical science. In return, public investment and technology transfer policies encourage commercial development and have helped make the United States the world's leader in biotechnological development. Both the research base and the progress of dedicated biotechnology companies (DBCs) trace their roots to the growth in federal support of biomedical research since the early 1970s. In fact, the United States is one of few countries with a developed network of university technology transfer offices for DBCs to utilize. Moreover, the initial appearance of DBCs was confined largely to the United States, based in part on the availability of publicly funded biomedical research at universities.

According to a 1993 survey of the Association of University Technology Managers, revenue to U.S. universities from technology licensing agreements grows by 25 percent annually, and in 1992, nearly 1,500 patents were issued to colleges and universities—four times the number issued in 1982. Currently, technology transfer at most institutions is integral to the university's structure and mission, though most do not yet generate income sufficient to support their technology transfer operations.

Cooperative Research and Development Agreements (CRADAs) are one high-profile instrument by which federal laboratories enter into partnerships with the private sector to develop research results into commercial products. With respect to NIH, OTA found that NIH has made extensive use of its authority to enter into CRADAs. However, measuring returns from NIH CRADAs—at least by income—is difficult: Some of NIH's potentially lucrative CRADAs involve therapeutic agents that have not completed the eight to ten years of clinical trials required for market approval by the Food and Drug Administration. Viewed from the private sector, participants at a 1994 OTA workshop who were drawn from a broad spectrum of biotechnology and genome research companies reported some frustration with NIH's CRADA review process, but were supportive of CRADAs per se.

Technology transfer at DOE centers on the national laboratories, and biomedical-related CRADAs reflect DOE-funded research in drug development, diagnostics, therapeutics, and technologies for rapid DNA sequencing. Life science applications are a minority of DOE CRADAs, because most of DOE's technology transfer focuses on its historical role in nuclear weapons and energy research. OTA found that, in general, representatives of national laboratories and company respondents to an OTA survey agree that DOE's CRADA formation process is micromanaged—sometimes to a debilitating degree—by DOE headquarters.

OTA data reveal that CRADAs at NIH and DOE have been a source of negligible income to the agencies. For biotechnology companies responding to the OTA survey, approximately 1.9 percent ($31 million) of gross revenues (e.g., in-

come from goods and services, plus royalty income) associated with all R&D over five years resulted from R&D performed under CRADAs. Likewise, neither NIH nor DOE have realized significant financial return in the form of royalties on CRADA inventions. CRADAs seem most useful for both federal researchers and the partnering company as a mechanism to share resources—i.e., despite the lack of economic payoff to date, CRADAs afford qualitative benefits to all parties.

Data from OTA surveys of selected biotechnology companies and of university technology transfer offices highlight the relative success of implementation of federal technology transfer laws at universities conducting life sciences research supported by NIH and DOE (in comparison with actual technology transfer efforts undertaken by NIH and DOE themselves). Two factors help explain this differential: universities have more experience in transferring technology to industry and the scale of extramural research support at universities is larger than intramural research funding in the case of NIH; DOE spends a substantial component of its human genome research budget intramurally at national laboratories.

Companies report that biomedical CRADAs are useful for sharing basic research resources—especially the materials and equipment available in federal facilities and the expertise of federal personnel. Conversely, companies have provided materials, equipment, expertise, as well as funding for research or the patent application process or compensation for federal researchers. Of companies surveyed by OTA, a minority (13 percent) felt the risks and expenses of CRADAs exceed the benefits.

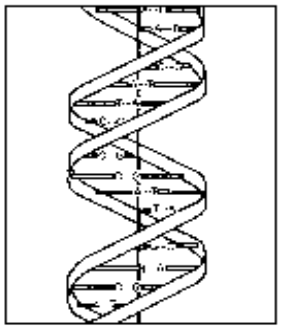
Insofar as patents and publications are viewed as a positive benchmark for federal researchers, the benefit of CRADAs to federal researchers was further quantitatively documented by OTA's examination of patenting and publishing of NIH intramural scientists involved in CRADAs compared to non-CRADA NIH researchers. NIH CRADA researchers obtain more than five times as many patents as non-CRADA scientists. The impact of patents from NIH CRADA researchers versus non-CRADA NIH patentholders also differed: Patents from CRADA scientists are more frequently cited. As measured by publications, CRADA scientists at NIH publish twice as many papers as non-CRADA researchers, though each group publishes equally in influential journals.

Overall then, federal technology transfer related to life sciences research has proved to be beneficial financially to universities and companies, but the principal benefit thus far to industry, academia, and federal laboratories centers on non-income measures. In the context of the Human Genome Project, this effort was launched and is still largely supported by public funding. Nevertheless, private sector interest and investment in genome research has escalated over the past two years, as its federal funders intended. Whether financially measurable benefits exceed qualitative benefits of federal technology laws and policies from the Human Genome Project remains to be seen. There is little question, however, that public, private, and academic partnerships will prove important for the commercialization of genome research.

# Introduction 1

Practical application of federally funded research depends on transferring technology to industry, whose laboratories translate intellectual property into commercial products that benefit the economy and society. This is often, but not always, accomplished through the patenting and licensing of research results (31). Unless guaranteed some measure of market exclusivity via intellectual property protection, most companies are reluctant to invest the millions of dollars and time required to develop and fine tune inventions from federally funded research (1,33,79).

Today, the United States enjoys the economic benefits of an industrial biotechnology sector unmatched worldwide. This success stems from, in part, U.S. patent law and the success of federal technology transfer of biomedical research over the past 15 years (84,85). More recently, scientists around the world have undertaken an estimated 15-year, $3 billion initiative—referred to as the Human Genome Project—to identify and map the components of biological inheritance, called genes (box 1-1). As with other biomedical research, expectations exist that federal technology transfer of human genome research will play a key role in companies' development of new genetic diagnostic and therapeutic products (75,48,17).



This background paper first reviews the development of federal technology transfer legislation and regulations, generally. It discusses the mechanisms and policies of the federal entities responsible for funding the Human Genome Project: the National Institutes of Health (NIH) of the U.S. Department of Health and Human Services and the U.S. Department of Energy (DOE). It examines the role and influence of this matrix on commercialization of life sciences and human genome research funded extramu-

**BOX 1-1: The Human Genome Project**

In humans, as in essentially all forms of life, deoxyribonucleic acid (DNA) contains the entire genetic blueprint for an individual Currently, scientists in the United States and abroad have committed to revealing the details of this blueprint, or genome. In 1985, the Human Genome Project emerged as an ambitious effort to identify the location and composition of the 50,000 to 100,000 human genes (the fundamental units of inheritance) (16) The project has been undertaken with the expectation that enhanced knowledge about genetic disorders, increased understanding of gene-environment interactions, and improved genetic diagnoses can advance therapies for the 5,000 or so currently recognized human genetic conditions, a premise supported by the fact that even prior to formal launching of the project, advances in medical genetics were instrumental in the development of new therapeutic approaches (16,20,62,84).

Progress in understanding human genetics can aid drug development by defining specific subpopulations of patients, thus simplifying the process of ascertaining the efficacy of new drugs Another promising treatment strategy the Human Genome Project might accelerate is gene therapy--deliberately introducing genes into human cells to compensate for aberrant genes that cause genetic disease In the future, DNA itself could serve as a therapeutic agent (87,88).

Still, molecular genetics research constitutes only one of many approaches to alleviate disease (77) Following the trail down to the DNA sequence cannot even fully explain many classical genetic diseases, and clearly genetic factors are just a part of most major diseases. The attraction of the Human Genome Project and genetic approaches to disease, however, is that molecular technologies are so powerful. Most major diseases have been studied for decades. Those more readily explained by traditional approaches have yielded, molecular biology offers a strategy to crack those that have not.

SOURCE Office of Technology Assessment, 1995

rally and intramurally by NIH and DOE. And finally, it reports data from three OTA surveys on: academic research institutions' experiences since enactment of federal laws to enhance technology transfer; industry's experience with collaborative arrangements involving NIH or DOE; and the extent to which partnerships with industry are of benefit-as measured by publications, citations, and patents—to NIH intramural scientists. International technology transfer-either the transfer of technology across borders or the practices of other countries—is beyond the scope of this background paper.

## HISTORICAL PERSPECTIVE

Following World War II, the federal government became the major source of funding for research and development (R&D) in the United States. Today, federal agencies fund nearly half of the nation's R&D, largely to meet public objectives such as national defense, space exploration, improved health, greater food production, and energy conservation. Recently, however, some in industry and government have advocated that the federal government undertake the additional responsibility of supporting the U.S. scientific and technical enterprise to promote economic competitiveness (39).

The notion that the federal government should play a direct and active role in stimulating R&D as it relates to economic growth first came under scrutiny through President Kennedy's Science Advisory Committee's recommendations regarding industrial innovation (8). Subsequent administrations elaborated on these recommendations: President Nixon's Council of Economic Advisors encouraged active partnerships between the public and private sectors in research and technological innovation, and President Carter's Domestic Policy Review explored what steps the federal

government should take to encourage industrial innovation (56). These broad appeals for an activist role of government in stimulating R&D eventually evolved into current technology transfer policies.

Generically speaking, technology transfer is the process by which research results are developed and applied in another area, organization, or commercial sector. However, the term has different meanings in different contexts. It can refer to the legal and administrative process by which the transfer of legal rights--such as the assignment of a patent to a contractor or the licensing of a government-owned patent to a company-is achieved. Or, it can refer to the informal movement of information, knowledge, and skill from a federal laboratory to the private sector through person to person contact or collaboration. One of the most crucial aspects of technology transfer is the use of research to derive a new commercial product or process.

Although the substance of current federal technology transfer has roots in the 1960s, the concept of technology transfer as a federal activity is not new (67). The federal government has laws and policies encouraging innovation, dating back to the Patent Act of 1790 (69). The U.S. Department of Agriculture (USDA) has been transferring technology for over a century, beginning with the establishment of the land grant colleges under the 1882 Merrill Act. The Hatch Act of 1887 created agricultural research stations separate from university systems. The goals of both laws were to improve agricultural productivity through direct education of farmers by providing them with the latest research results and intervening in farming practices to increase yield. Thus, Congress had public interest and commercial motivations (46).

Policymakers in both the executive and legislative branches have favored domestic technology transfer, but never with as much enthusiasm as in the 1980s. During this period, concern grew about the ability of U.S. business to compete in international markets. One sentiment pervaded discussions in Congress, the executive branch, and industry: American "know how''--often generated via public funding-was being transferred




with increasing frequency to foreign nations, only to return to the United States as commercial products (67). Furthermore, few of the inventions for which the U.S. Patent and Trademark Office (PTO) granted the federal government patents each year were ever licensed for commercial use (61). At the same time, U.S. industry was increasingly aware that other nations were challenging its long held position of technological supremacy and that its competitive edge in many sectors was in jeopardy (39,66). A consensus that competitiveness was linked to innovation and that research and technology transfer played a critical role in the nation's ability to compete led some in industry to express increased interest in creating and strengthening its own connections with the scientific community (39).

Congress focused on scientific research conducted in academic laboratories as a key place to improve U.S. technology transfer. University research tended to be more open than research conducted in government laboratories because many federal facilities were created to develop defense technologies and therefore barred unfettered public access. Additionally, because of national security concerns, significant legal barriers had been enacted specifically to prevent technology transfer.

rity concerns, significant legal barriers had been enacted specifically to prevent technology transfer.

In contrast, during the 1970s, policymakers and scholars almost uniformly viewed universities as the fount from which new scientific and technological breakthroughs would improve the U.S. economy. University-industry partnerships were touted as the vehicle through which sustained economic development could be achieved (32,47). Thus, during this decade, new relationships between universities and industry emerged, involving such activities as industrial support of academic research, opportunities for academic consulting, research collaborations, research consortia, shared equipment use, publications, and conferences (68,32). In the 1980s, attention also began to focus on drawing resources of commercial potential out of federal laboratories.

## TECHNOLOGY TRANSFER LEGISLATION

Several laws enacted over the past 15 years encourage technology transfer of results from federally funded research. Early legislation focused on technology transfer of research funded by the government but undertaken at universities and academic research institutions. Other laws arose exclusively from concern about the state of technology transfer to industry from research conducted at U.S. government laboratories.

In particular, three technology transfer laws enacted in the 1980s fundamentally shape today's practices and policies:

- **The Bayh-Dole Act of 1980** (Public Law 96-517) allowed private parties to retain patent rights via a "title in contractor" policy—meaning small businesses and nonprofit organizations, including universities, could retain intellectual property rights to results from federally funded federal research. Prior to Bayh-Dole, such a policy was implemented on an agency-by-agency basis. Amendments to the Act in 1984 brought research contracts with universities that operate DOE's national laboratories within the scope of the title in contractor policy, 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 policy.
- **The Stevenson-Wydler Act of 1980** (Public Law 96-480) required that federal agencies administering research establish an Office of Research and Technology Applications (ORTA) at all government-operated or contractor-operated laboratories with an annual budget greater than $20 million. The Act also provided general guidance for the efforts that the government should take to encourage technology transfer. While acknowledging its value, the legislation provided no means to enforce the requirement for ORTAs. Moreover, Congress withheld much of the funding for the program.
- **The Federal Technology Transfer Act of 1986** (FTTA; Public Law 99-502) amended Stevenson-Wydler; it had become apparent that little technology transfer from federal laboratories was occurring. FTTA shifted the emphasis in federal policy from one permitting technology transfer to one requiring that agencies act vigorously in working with industry to commercialize federally funded research. FTTA's signature feature is the authority of agencies to negotiate Cooperative Research and Development Agreements (CRADAs) and include exclusive licensing terms with CRADA partners—i.e., CRADAs are the administrative and legal mechanism through which commercialization of research performed at federal facilities may be achieved. FTTA also contained provisions specifying federal researchers' rights to royalties and rights to pursue a patent should an agency decline to pursue one.

Appendix A describes these laws in greater detail, as well as two additional laws enacted by Congress to enhance and facilitate domestic technology transfer: the Omnibus Trade and Competitiveness Act of 1988 (Public Law 100-418)

der the jurisdiction of federal laws, regulations, and policies not explicitly designed for oversight of technology transfer processes. Hence, antitrust laws, tax laws, and other policies and initiatives that can affect technology transfer also are briefly outlined in appendix A.

## CONTEXT OF THIS BACKGROUND PAPER

As mentioned earlier, technology transfer of biomedical research has enjoyed visible and commercial success. Molecular biological research and the industrial sector it spawned—biotechnology—are established sources of innovation in pharmaceutical R&D, contributing both production technologies and research tools. Biotechnology is likely to be the principal scientific driving force for the discovery of new drugs as we enter the 21st century, and the impact of biotechnology (including genetic technologies), on the discovery of new therapeutic entities is difficult to overestimate (87).

With the launch of the Human Genome Project in the late 1980s, there was little expectation that results from genome research would not follow a similar path of technology transfer from university and federal facilities to commercial development. Nevertheless, in 1991, technology transfer of human genome research became the subject of intense scrutiny by researchers, universities, industry, and policymakers.

Until summer 1991, as scientific advances in human genetic research incrementally progressed, researchers, universities, and biotechnology companies filed and received a range of human DNA sequence patents on genes and their products—for diagnostic, therapeutic, or research purposes. In June 1991, however, many felt this



Aerial *view of the National Institutes of Health campus in Bethesda, Maryland.*

orderly process, or at least one perceived as orderly, was altered when NIH sought intellectual property protection on more than 6,000 short sequences of human DNA that, by the nature of their isolation method, coded for putative human genes and therefore human proteins, but were themselves incomplete gene sequences.

A swift, and predominantly negative, outcry followed the public disclosure of NIH's maneuver (4,5,6,20,30), which was defended as being required by federal technology transfer laws (1 ,44). That is, the filing of the NIH patent applications was justified, in part, as an attempt by the federal government to ensure that the public investment's in biomedical research-in this case at a federal laboratory-was optimized by seeking intellectual property protection that would be attractive to investment by potential industrial partners.[1]

Thus, OTA sought to examine the impact of technology transfer laws on life sciences research, in particular research funded by the two entities responsible for funding the Human Genome Proj-

[1] In fall 1992, NIH Announced that the U.S. Patent and Trademark Office (PTO) had rejected NIH's applications (as it does for most first applications, which tend to seek the broadest possible scope of coverage.) PTO held the NIH applications lacked novelty, utility, and were obvious. NIH responded to PTO's initial rejection in February 1993, modifying the claims, but the PTO examiner again rejected the applications. A year later in February 1994, facing a deadline to appeal the rejection to the Board of Patent Appeals and Interferences (a review body within PTO) or the Federal courts, NIH withdrew all applications. Nevertheless, their legacy challenged conventional drinking about strategies for seeking patents on human DNA sequences, spotlighted the role of Federal technology transfer in biotechnological innovation, and underscored the perception of the pivotal impact that molecular medicine will play in ameliorating disease.

Thus, OTA sought to examine the impact of technology transfer laws on life sciences research, in particular research funded by the two entities responsible for funding the Human Genome Project—NIH and DOE. What have been universities' experiences since enactment of Bayh-Dole, Stevenson-Wydler, and FTTA? Does industry view collaborative arrangements involving NIH or DOE as one where benefits outweigh risks? And, what has been the impact on federal scientists—NIH researchers, in particular—of evolving federal technology transfer policies? The following chapters analyze these issues in light of data gathered through OTA surveys, interviews, and a 1994 workshop of a wide range of companies involved in genome-related research.

# Technology Transfer and NIH and DOE

2

The federal government's research laboratories—those government owned and government operated (GOGO), as well as those government owned but contractor operated—perform a significant fraction of all research and development (R&D) in the United States. The National Institutes of Health (NIH) and the U.S. Department of Energy (DOE) are among the leading agencies that provide public investment in life sciences research, particularly the Human Genome Project. As pressures to commercialize government-supported research increased, NIH and DOE established and modified the policies and processes governing technology transfer of their research to nongovernment parties.

While the federal technology transfer statutes described provide the authority for the patenting of U.S. government-supported research results, the legal and administrative processes and guidelines developed at each research institution or agency are designed to serve that organization's unique mission. Not surprisingly, implementation by NIH and DOE of federal technology transfer law differs; both have established functional policies that adapt the laws to their organizational focus while reflecting congressional intent and the legal scope and interpretation of the statutes.

This chapter briefly reviews the technology transfer processes for NIH and DOE intramural research; appendix B describes specific elements of NIH's and DOE's processes in greater detail. Additionally, the chapter summarizes technology transfer pertaining to NIH- and DOE-funded projects conducted at universities or research institutions (i.e., technology transfer for extramural research).

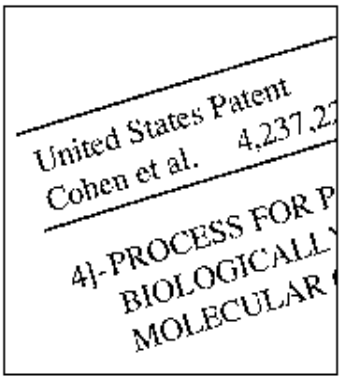

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TABLE 2-1: NIH and DOE Funding for the Human Genome Project

| Source | FY 1992 | FY 1993 | FY 1994 | FY 1995 |
|---|---|---|---|---|
| NCHGR at NIH | $104,800,000 | 106,100,000 | 127,100,000 | 153,000,000 |
| DOE | 61,400,000 | 63,100,000 | 70,000,000 | 89,000,000 |
| Combined Total | 166,200,000 | 169,200,000 | 197,100,000 | 242,000,000 |

Abbreviations DOE=U.S. Department of Energy, NCHGR=National Center for Human Genome Research, NIH=National Institutes of Health

SOURCES Off Ice of Technology Assessment, 1995, based on B Agnew, "NIH Budget War Cry Wait Till Next Year *Journal of NIH Research 643,* 1994, R M Cook-Deegan, "Origins of the Human Genome Project, " presentation for a Franklin Pierce Law Center conference, Concord, NH, July 1993, and Science, "R&D Budget Growth in Hard Times, " 263744, 1994

## SCALE AND SCOPE OF NIH AND DOE RESEARCH

Understanding the scope, role, and nature of technology transfer at NIH and DOE requires a broad overview of the type of research performed at intramural facilities. Additionally, familiarity with research funding provides context for analyzing the impact of technology transfer on NIH and DOE's budget—i. e., could successful technology transfer of basic, intramural, life sciences research return sufficient royalty income to offset current fiscal constraints?

NIH provides the largest federal share of biomedical research funding, including areas such as cancer research, heart disease, drug addiction, and AIDS (acquired immunodeficiency syndrome). More than 70 percent of federal spending on health-related research flows through NIH (96). It funds scientists working within its institutes (intramural research), but the majority of its R&D budget provides extramural support for projects undertaken by researchers at universities and research institutions. NIH extramural funding of individual investigator or program project grants account for a majority of federal biomedical research funding (55). In fiscal year 1994, NIH's budget was $10.9 billion on biomedical research and 1995 appropriations are $11.3 billion. With respect to the Human Genome Project, NIH spent approximately $127 million through the National Center for Human Genome Research in 1994 (NCHGR: table 2-l).

DOE also invests in biomedical research through its Health Effects and Life Sciences Division. In response to the strategic threat from the former Soviet Union after World War II, Congress authorized DOE to establish the national laboratories to develop weapons and technologies. Some of this defense-based research has found application outside of the national security venue-e. g., research on the human genome initially was undertaken by DOE to analyze the genetic effects of radiation poisoning. Currently, laboratories conducting the bulk of DOE life sciences research amenable to technology transfer include Argonne National Laboratory, Brookhaven National Laboratory, Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, and Los Alamos National Laboratory. In 1994, DOE spent $18.7 billion on research, of which $133 million was through the Health Effects and Life Sciences Division (29). In 1994, DOE devoted approximately $70 million for the Human Genome Project (table 2-1 ).

## TECHNOLOGY TRANSFER AT NIH

Historically, technology transfer in biomedical research and biotechnology has been accomplished through patenting and licensing activities, and NIH regards these activities as a legitimate use of federal technology transfer authority (1 ,44,60). Patent protection is viewed as especially necessary—by both NIH and the private sector—to stimulate product development in the pharmaceutical and biotechnology industries, where the demonstration of efficacy and safety is lengthy and expensive.

Whether inventions are patentable can determine whether basic research efforts are accelerated and commercial potential achieved (1). Thus.

much of NIH's technology transfer activities center on establishing cooperative research relationships and pursuing any patents and licenses of potential value. NIH policy specifically states that "NIH/ADAMHA [sic] recognize that under the Federal Technology Transfer Act of 1986 (FTTA; Public Law 99-502) and the patent licensing law to which it refers, Congress and the President have chosen to utilize the patent system as the primary mechanism for transferring government inventions to the private sector" (64).

Currently, the Office of Technology Transfer (OTT) within the NIH Director's office pursues patent protection for intramural NIH research. OTT also manages technology transfer and administers FTTA for the former Alcohol, Drug Abuse, and Mental Health Administration, now the Substance Abuse and Mental Health Services Administration, and for the Centers for Disease Control and Prevention (CDC). Additionally, because FTTA emphasizes a decentralized technology transfer system, each intramural institute or center within NIH maintains a technology transfer office—e.g., the Technology Development Program promotes technology transfer at NCHGR.

OTT (and the other technology transfer units at NIH) receives invention disclosures and processes patent filings for these disclosures in accordance with OTT's determination that such actions are its responsibility under U.S. patent and technology transfer statutes, especially FTTA. OTT's responsibilities include developing policies and procedures related to NIH technology transfer, drafting model agreements, patenting intellectual property, and licensing patented inventions. OTT receives about 300 employee invention reports annually, and approximately 50 percent are processed for patent filing (2).

With respect to licensing, OTT negotiates licenses related to patented inventions and results of Cooperative Research and Development Agreements (CRADAs; box 2-1). As noted in chapter 1, CRADAs, authorized by FTTA, are important legal and administrative means by which companies access research with commercial potential that is performed at federal facilities. OTT coordinates the approval process for all CRADAs (box 2-2) that include exclusive licensing terms, although CRADAs are agreements between the individual institutes and companies—again, consistent with FTTA's emphasis on the decentralization of technology transfer. (Other avenues for technology transfer are available to NIH, but it chiefly uses CRADAs or direct licensing agreements—i.e., NIH generally does not enter into "work for others" or into sponsored research agreements because of statutory constraints and, in part, to avoid the perception that NIH is selling its research services (2).)

A broad range of NIH CRADAs have been negotiated and these represent the spectrum of research conducted by NIH scientists—from gene therapy to products of potential use for heart disease or cancer. According to one CRADA administrator, many companies with NIH CRADAs spend up to $150,000 per year on any one CRADA, but for many, industrial funding amounts to much less, covering travel for a scientist or compensation for a postdoctoral fellow (15).

The number of NIH CRADAs managed by OTT grew from 39 in 1988 to 109 in 1993; there were 16 in 1993 at CDC and 9 at the Food and Drug Administration (FDA) (15). The number of new CRADAs appears to be tapering off to around 25 per year, having peaked at 114 in 1990 (15). These numbers are approximate because they represent the number of CRADAs in existence at a single time point per year, which OTT publishes as an annual list.

OTT has 36 employees, out of a full time equivalent ceiling of 56, but only one is devoted full time to CRADAs (60). Normally, about five percent of OTT's effort is devoted to CRADA issues. In 1994, the Division of Management Policy of NIH evaluated OTT, and out of that process has come a corrective action plan that calls for a total of 58 employees, two of whom would work full time on CRADA issues (15).

As has been noted, NIH has made extensive use of its authority to enter into CRADAs with private firms. However, for a time, controversy over pharmaceutical pricing surrounded NIH's CRADA process (88,98,101), though this issue was re-

## BOX 2-1: What is a CRADA?

As defined and authorized by the Federal Technology Transfer Act of 1986, a Cooperative Research and Development Agreement (CRADA) is an agreement between one or more federal laboratories and one or more nonfederal parties. The government provides personnel, services, facilities, equipment, or other resources (but not funds), and the nonfederal partner(s) provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specific research or development efforts. Under a CRADA, both parties provide resources for specified research and development efforts consistent with the missions of the federal facility.

CRADAS vary in form, depending on the goals of the partners. Most federal agencies, including U S Department of Energy (DOE) and the National Institutes of Health (NIH), have model CRADAs that are used as the basis for negotiation with potential collaborators. A model CRADA contains a statement of work, estimated funding contributions of both parties, terms regarding retainment of property, a product liability article, proprietary reformation clauses, intellectual property and licensing requirements, and reporting requirements. The duration of CRADAs may not exceed four years plus a one-year extension

In general, CRADAs present opportunities for NIH and DOE to gain from collaboration with Industry, According to recent reports from DHHS' Inspector General, most NIH investigators stressed that industry partners made substantial contributions to the collaborative research that would not have been otherwise available (98). A recent General Accounting Office study echoes this point (80)

Likewise, CRADAs present industry with the opportunity to access basic research in order to pursue further development, A recent survey found large, research intensive companies primarily interested in accessing expertise and unique facilities at federal laboratories (70), Interest in forming CRADAs with DOE contractor-operated laboratories in particular has increased in absolute terms. The data implied that the purpose of entering into CRADAs or other collaborate relationships with the laboratories IS less to license anything so developed, than to conduct research enabling further development (60,70)

CRADAs originate in several ways. A facility may initiate a CRADA for development and application of its patented invention. CRADAs also may be investigator-initiated-e. g , beginning with contacts between company and federal researchers at scientific meetings. In such investigator-initiated arrangements, the company might collaborate on any stage from basic preclinical research through development of a product for public distribution and sale, Companies also can originate CRADAs,

To protect the basic nature of the research conducted at the federal laboratory, the U S. government Insists the federal investigator make an intellectual contribution to the joint work as part of the CRADA (This requirement is intended to ensure that companies will not use CRADAs to do research they could do in their own labs and that intramural facilities continue to focus on basic research that makes a fundamental contribution to the scientific knowledge base)

DOE's CRADAs differ somewhat from NIH's because most national laboratories are government-owned but contractor-operated, not government-operated. With such CRADAs, the federal government IS not a signatory, but it retains nonexclusive paid-up royalty-free worldwide rights to CRADA inventions and discoveries, including the right to have products manufactured by another company for the government's use.

SOURCE Off Ice of Technology Assessment, 1995

## BOX 2-2: Technology Transfer at NIH, Step-by-Step

With the passage of the Federal Technology Transfer Act of 1986, the Office of Research and Technology Application and patent functions previously in NIH's Office of Medical Applications of Research were transferred to a new Office of Invention Development, later renamed the Office of Technology Transfer (OTT). Prior to becoming OTT, this office supported the NIH Patent Policy Board and conducted forums to bring NIH scientists and industrial representatives together (78).

Today, OTT's responsibilities include pursuing patent protection for intramural NIH research. (And as mentioned, each institute and center within NIH also maintains a technology transfer off ice.) The process of finding licensees potentially begins as soon as OTT receives an employee invention report, and OTT's licensing efforts include

- promoting technologies at conferences and meetings,
- publishing an annual directory on technology transfer activities at NIH,
- an online abstract of U.S. Public Health Service (PHS) technologies, and
- a database of companies and their interest by technological field for direct marketing of PHS technologies to industry.

In 1987, the NIH Patent Policy Board (recently renamed the NIH Technology Transfer Advisory Committee (60)) was established to develop overall policies for technology transfer. The Committee interacts with oversight committees, such as the PHS Technology Management Board, and also has three Subcommittees

- The CRADA Subcommittee reviews all CRADAs involving exclusive licenses, assesses their appropriateness, and makes recommendations regarding the CRADAs to the Patent Policy Board. As adopted by NIH, a CRADA is a standardized agreement intended to provide an appropriate legal framework for, and to expedite approval of, cooperative research and development projects.
- The Royalty Distribution Subcommittee makes policy recommendations on royalty distribution and on the use of royalty income as an incentive for additional technology transfer.
- The Training Subcommittee develops materials and gives training sessions to educate the intramural community on all aspects of FTTA (64).

Since 1991, OTT has prepared and filed—or contracted for filing—U.S. patents for NIH research (and for results from research at other PHS agencies for which OTT has agreed to perform these functions). Much of the patent preparation and prosecution IS conducted under contract by private law firms (64).

OTT's Division of Technology Development and Licensing markets Inventions to biomedical companies. The technology licensing branch prepares a commercial marketability analysis on each patent filed. Licensing specialists have divided PHS' invention portfollo into categories that reflect market sectors such as AIDS, central nervous system, or cancer-related inventions. Licensing is conducted on a worldwide basis, since most pharmaceutical companies are translational; even domestic biotechnology firms require global patent protection to secure foreign markets. OTT negotiates CRADA-related licenses, but OTT and the National Technical Information Service (NTIS) under the U.S. Department of Commerce both negotiate licenses for technology developed outside the CRADA process (64) (though according to OTT officials. NTIS lacks the staffing to handle licensing negotiations for NIH (2)), OTT reorganized in 1993 to merge its patent and license staffs Into cross-functional teams assigned to jointly manage portfolios and inventions (3).

If any research collaboration between NIH and a company results in royalties, the inventor is eligible to receive 25 percent of the first $50,000 earned, 20 percent of the second $50,000 earned, and 15 percent of any amount in excess of $100,000. The NIH Division of Financial Management receives NIH-generated licensing income, as well as income from the all intramural licensing activities. It then distributes royalty payments to inventors, allocates funds to cover administrative overhead costs, and distributes the remaining royalties to the appropriate Institute, Center, or Bureau (64).

SOURCE Office of Technology Assessment, 1995.

TABLE 2-2: Royalties from Technology Transfer Activities at NIH

| Product | FY 1991 | FY 1992 | FY 1993 | FY 1994 |
|---|---|---|---|---|
| HIV test kit | $11,153,000 | 6,099,000 | 4,742,000 | 4,495,000 |
| All other | 2,131,000 | 3,945$000 | 8,842,000 | 14,159,000 |
| **Combined total** | **13,284,000** | **10,044,000** | **13,584,000** | **18,654,000** |

SOURCE Off Ice of Technology Transfer, National Institutes of Health, 1995

solved in spring 1995 when NIH reversed its policy of including a reasonable pricing clause in CRADAs it negotiates (5 1,60,97).

Another area of concern that has surfaced is so-called "fair access''—i.e., the fairness of a firm getting a boost over its competitors in the marketplace by entering into an NIH CRADA (43,72,98). In fact, some observers suggest that sometimes the technology transfer process operates well enough when government inventions are not uniformly patented nor licensed exclusivel y to one private party (30). According to corporate participants of a 1994 OTA workshop, precedents exist at NIH for limited exclusive licenses to a number of qualified companies—versus exclusivity with one company—and have been successful (43); the extent to which such an arrangement is important for commercializing genome or other biomedical research remains to be seen.

According to NIH, 10 licenses to patented inventions have emerged from CRADAs since NIH established its program in 1986; direct licensing agreements have been the preferred mechanism for technology transfer to the biomedical industry (60). Overall, OTT's technology transfer efforts have yielded neither a glut of marketed commodities (2) nor significant royalty income (e.g., to offset potential budget cuts).

The lack of significant income stems from the fact that most NIH royalties from commercial applications of NIH research lag behind prior inventions and discoveries by other parties, since NIH authority through FTTA was granted six years after Congress initially granted technology transfer rights to recipients of extramural research funds. Moreover, only after eight to ten years of research and clinical trials required by the U.S. Food and Drug Administration does a product enter the market and generate significant revenue for NIH. Nevertheless, NIH receives some royalty income, which totaled slightly more than $18 million in fiscal year 1994 (60; table 2-2). Clearly, income from technology transfer activities for intramural research cannot be expected to significantly supplement NIH's appropriation.

## TECHNOLOGY TRANSFER AT DOE

Technology transfer at DOE and its predecessor agencies—the Atomic Energy Commission and the Energy Research and Development Administration—has a long history. Since enactment of the Atomic Energy Act of 1954 (42 U.S.C. 201 1), DOE has included technology transfer as part of its program efforts (24). In response to the Stevenson-Wydler Act of 1980 (Public Law 96-480), DOE established an R&D Laboratory Technology Transfer Program, managed by the Office of Energy Research, to create an institutional framework for its technology transfer activities.

Although DOE's patent policy had been cited as among the most significant barriers to cooperative relationships with industry and effective technology transfer (92), the technology transfer legislation of the 1980s removed many of these barriers-FTTA and the National Competitiveness Technology Transfer Act of 1989 (NCTTA) in particular. Still, pressure to identify constructive civilian applications of research at the extensive, primarily defense-focused, DOE national laboratories continued to mount. In 1988, DOE's Energy Research Advisory Board offered a set of recommendations for increasing technology transfer: development of a strong policy statement encouraging such activities, development of a high level program to ensure that U.S. firms are aware of opportunities at DOE; improvement of intellectual property and authorization procedures; and encouragement of personnel exchange

activities with the aim of increasing technology transfer (93).

In 1991, the Secretary of Energy further reorganized DOE's technology transfer efforts by establishing the Office of the Science and Technology Advisor. A Director of Technology Utilization is responsible for addressing DOE-wide issues related to technology transfer policies and implementation (94). Like NIH, DOE annually publishes a guide to research, patents, and licensing opportunities of national laboratories (95).

DOE has a network of facilities across the United States where a broad array of intramural research, including life sciences research, is supported. Often referred to as the national laboratories, these institutions—some government operated and some contractor operated—perform about $6 billion annually in R&D (94). As each institute within NIH has its own technology transfer unit, each DOE laboratory has a technology transfer office with authority to use CRADAs and other collaborative agreements to transfer technology to the marketplace.

A model DOE CRADA serves as the basis for initiating individual CRADAs, and field offices can approve CRADAs if they are not substantially different from the model. However, major disparities between the model DOE CRADA and a CRADA submitted by a national laboratory for authorization can slow the approval process, which is conducted through field offices and DOE headquarters in Washington, DC (45).

Specifically, the average time to fund and approve a CRADA exceeds one year, and with the call for proposals once per year, nearly two years can lapse from a project's conception to approval. Representatives from national laboratories report some potential corporate CRADA partners abandon the process because of the process' length (15). Nevertheless, CRADAs administered by DOE recently have increased; biomedical related CRADAs encompass research in drug development, diagnostics, therapeutics, and basic DNA sequencing. In fact, DOE CRADAs overall have grown at a faster pace over fewer years than NIH CRADAs (14). In April 1991, DOE had 12 CRADAs at its laboratories. As of July 1993, DOE CRADAs grew steadily to a total of 465 ongoing CRADAs, including 16 in biomedical research (15).

DOE laboratories and facility contractors often, but not always, retain title to inventions they develop (94). Each laboratory or facility contractor licenses its own patents; DOE headquarters licenses government-owned patents. Each laboratory and facility operator may, within broad guidelines, negotiate terms and conditions for their technology licenses. Mechanisms other than CRADAs available for industry to work with DOE and its contractor operated laboratories include: personnel exchanges, data exchange agreements, use of specialized facilities, cost-shared procurements, cooperative agreements, patent and software licensing, reimbursable-work-for-others agreements, and technical assistance (15, 45,94).

A recent survey examined industry's views of the national laboratories. The survey population was drawn from the corporate membership of the Industrial Research Institute, a private trade association representing 85 percent of industrial research performed in the United States. According to the companies' chief technical officers, national laboratories are a valuable resource for basic research, but few thought that licensing technology already developed and patented from the laboratories was worth the trouble (70). Interactions at the researcher level were viewed favorably: The primary justification given for entering into a relationship with a federal laboratory was to gain access to unique technical and human resources that the company could not afford to reproduce by itself (70). U.S. industries reported they benefited most from a joint research relationship—in the form of technical assistance, a CRADA, or reimbursable work-for-others agreement—with federal laboratories (70).

In contrast to technology transfer at NIH, which is in a nascent stage and hence more difficult to evaluate, DOE's longer history has been scrutinized extensively—especially in the current fiscal climate. Elsewhere, OTA has found that, in the short run, the national laboratories and DOE face an immediate need to streamline the process

of initiating collaborative research, while also adapting to increasingly severe budget constraints. Recently, DOE and the laboratories have tried to improve the technology transfer function at DOE (89). Still, the latent economic value of the national laboratories to the nation remains difficult to quantify, and some industry experts believe DOE has not tapped the laboratories' potential (28,50).

## TECHNOLOGY TRANSFER AT UNIVERSITIES AND RESEARCH INSTITUTIONS

The United States is uniquely endowed with a rich academic biomedical research infrastructure in the form of the nation's public and private universities and nonprofit research institutions. These institutions benefit from the level of federal support for biomedical research, and in return they deliver the world's preeminent body of biomedical research results. Moreover, federal support has built an academic R&D infrastructure for biomedical research that has benefited government, private enterprise, individual citizens, as well as firms and government agencies worldwide. Technology transfer has played, and continues to play, a central role in this success (figure 2-1).

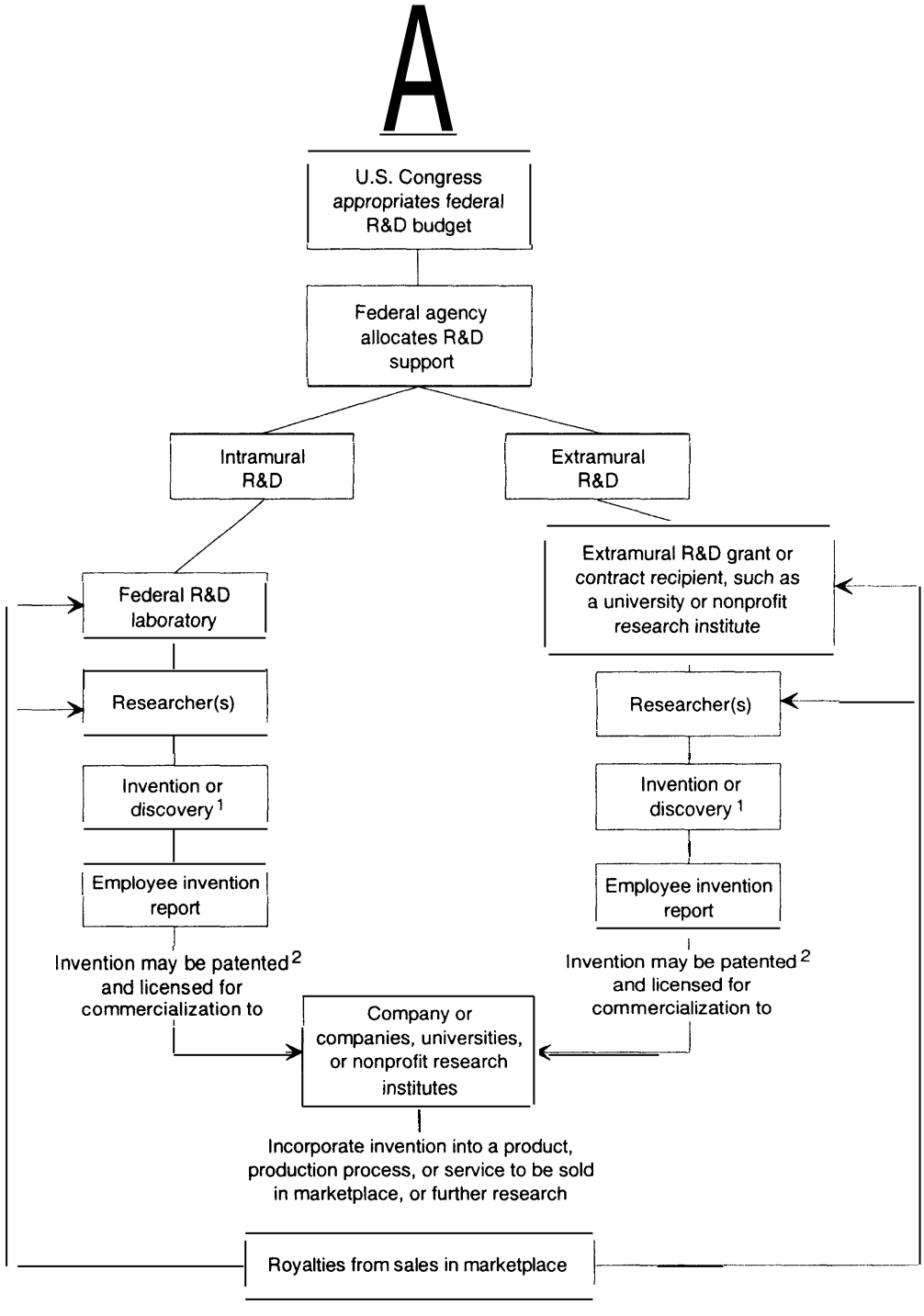
Technology transfer at federal facilities such as NIH and DOE is important, but since the majority of federally funded life sciences and biomedical research is conducted at universities and nonprofit research institutions, the impact of academic-based technology transfer is much greater. In fact, the United States is one of few countries to have a developed network of university technology transfer offices. Moreover, Congress enacted the explicit statutory authority for technology transfer associated with extramural research—the Bayh-Dole Act of 1980 (Public Law 96-517)—six years prior to FTTA, which primarily affects research at federal facilities (i.e., intramural research).

Bayh-Dole has boosted significantly the technology transfer function at U.S. academic institutions. Licensing of federally supported research results has increased gradually since Bayh-Dole's enactment—especially as technology transfer programs at these institutions have developed and matured. According to the Association of University Technology Managers, gross revenue to U.S. universities from technology licensing agreements is growing by 25 percent annually (25). This growth also is reflected in the increasing number of technology transfer and licensing offices at U.S. universities and the increased number of invention disclosures from faculty conducting research. Almost 1,500 patents were issued in 1992 to universities and colleges in the United States alone—four times as many as issued to U.S. universities in 1982 (25). Moreover, many universities also pursue patent protection in foreign markets.

Academic-based technology transfer is not without controversy. Concern over the transfer of taxpayer supported research results to private interests exists, leading some to express fear of commercial corruption and loss of academic freedom for research performed at U.S. universities and to decry such academic-industry arrangements (49,81). Persistent issues relating to the management of academic-industry relationships still challenge technology transfer at nonprofit research institutions today (13,32). On the other hand, some view technology transfer as auxiliary to, rather than competitive with, the goals of U.S. research universities—education, discovery, and the dissemination of knowledge (63). That is, the primary mission of technology transfer is to foster research and assure that research results are made available to the public in a meaningful and useful form.

Though technology transfer has, over time, become an institutionalized part of most universities' operations, residual controversy surfaces in some circumstances while remaining virtually absent in others. For example, in 1980, Harvard University proposed participating in the establishment of a private corporation to transfer technology to companies in order to profit from its research. Harvard retracted the plan soon after it was aired in public, but in 1992 Harvard was able to resurrect similar plans with little controversy (7). In contrast, the University of California had to

FIGURE 2-1: Summary of Federal Technology Transfer




[1]All federal R&D does not necessarily lead to inventions or discoveries that are suitable for transfer to industry Most federal research is basic science published in scientific journals

[2]Not all inventions or discoveries are patented

SOURCE. Office of Technology Assessment, 1995.

shelve announced plans to establish a technology transfer venture called the University of California Technology Development Company. The University of California abandoned the plans in the face of the outcry from faculty members who complained their academic integrity would be compromised if the venture took shape as planned (41,73).

As noted, technology transfer of biomedical research is viewed as contributing to the growth and development of the nation's commercial biotechnology enterprise. With respect to the Human Genome Project, high expectations also exist. Early funding and progress of this initiative have depended on public investment at universities, which in turn currently serve as key research resources for companies attempting to commercialize human genome research. For example, several biotechnology companies recently reached agreements with U.S. universities in genome-related research. In spring 1995, Amgen announced it would pay Rockefeller University an initial fee of $20 million for licensing rights to a gene closely identified with obesity and is reportedly planning to pay as much as $100 million if the key milestones are attained (42). One noteworthy aspect of this arrangement is its illustration of the high potential market value—at least from the perspective of some companies—placed on some human genome related research despite the fact that the research in question is very basic and not without great risk.

In another case, Myriad Genetics has an ongoing relationship with the University of Utah to search for genes that are involved in causing cancer and heart disease (37). Recently, the university and company filed a joint patent application on the BRCA1 gene for breast cancer; the application was later amended to include federal researchers at NIH (34). The exact terms of the relationship between the University of Utah and Myriad Genetics are proprietary.

## SUMMARY AND CONCLUSIONS

Federal technology transfer of NIH and DOE research—funded extramurally or conducted intramurally—have played, and likely will continue to play, an important role relative to the U.S. biotechnology industry. Cooperative Research and Development Agreements, or CRADAs, foster important collaborative arrangements between federal (intramural) and company scientists, but initial indications are that royalty income to the government will be modest. Rather, an evaluation of the role and function of CRADAs and technology transfer should center on whether congressional intent to foster innovation is being achieved. Hence, the next chapter analyzes results from an OTA survey that was designed to gather qualitative and quantitative data about the positives and negatives of NIH and DOE technology transfer.

Legislation granting intellectual property protection to federally funded research at academic and nonprofit research institutions has played a central role in the development of the U.S. biotechnology sector. Technology transfer, in combination with strong federal support for biomedical research, led to a four-fold increase in patents to universities between 1982 and 1992. Data from an OTA survey of university technology transfer officials (also presented in the next chapter) point out the benefits and downsides of university-based technology transfer of federally funded research.

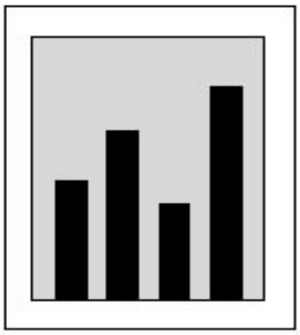
Overall in the biomedical and genome arenas, to the extent that increased patent activity, proliferation of academic technology transfer offices, and multi-million dollar licensing rights are viewed as positive indicators, the Federal Technology Transfer Act of 1986 and the Bayh-Dole Act of 1980 may be perceived to have achieved their aims.

# OTA Survey Results 3

Almost simultaneously with, but not linked to, steep increases during the 1970s and 1980s in federal support for biomedical research, came legislation addressing technology transfer to the private sector. As described in chapter 1 and appendix A, these laws allowed the government, universities, and industry to negotiate patents and exclusive licenses on federally funded research. For industry, exclusivity is particularly important (1,79), and the prior dicta that federal inventions were required to be nonexclusive posed a barrier to commercialization of federally funded research results.

The growth of molecular technologies as tools for the application of basic biological knowledge and the enormous potential for commercial gain from such discoveries—buttressed in part by the new technology transfer laws—set the stage for new institutional arrangements between government, universities, and industry. Fifteen years after Congress began to systematically encourage transfer of federally funded research results, how do industry and university technology transfer officials view the evolution of federal technology transfer? That is:

- What types of collaborative arrangements have proved most useful? What have been university and research institutions' experiences? How much income has been generated? How many patents have been obtained? What measures, if any, could the federal government adopt to improve technology transfer?
- Similarly, what has been industry's experience with agreements involving the National Institutes of Health (NIH) or the U.S. Department of Energy (DOE)? Does industry view them as successful? And from their perspective, what measures, if any, might improve federal technology transfer?



- Finally, what about federal scientists? For example, are scientists at the NIH—which funds the bulk of the federal government's biomedical research—more likely to hold patents, publish more frequently, or have their work more frequently cited if they are involved in formal collaborations with industry? Are NIH scientists who hold patents more, or less, likely to publish or be cited?

OTA examined these questions by conducting several surveys:[1] technology transfer officials at research institutions and universities, biotechnology research and development (R&D) executives, biomedical researchers receiving extramural NIH funding, and a bibliometric and patent survey and analysis of NIH intramural scientists.

## UNIVERSITY AND RESEARCH INSTITUTIONS' PERSPECTIVES ON TECHNOLOGY TRANSFER

Two events primarily influenced university and research institutions' interest in technology transfer related to federally funded biomedical research. First, as mentioned previously, with enactment of the Bayh-Dole Act of 1980 (Public Law 96-517), Congress explicitly sought to encourage commercialization of government-sponsored research. Second, and more importantly for development of products from biomedical research (19,83,84), the U.S. Supreme Court ruled in 1980 that a living composition—in this case an artificially selected oil-eating microorganism—could be considered an invention and therefore patentable (26).

Intellectual property, then, is a critical resource of the biotechnology industry, and much of this knowledge derives from federally funded projects at university and nonprofit research institution laboratories (85). In fact, however, universities and research institutions themselves can realize financial gain from federally funded research. For example, in 1980 Stanford University and the University of California received the so-called Cohen-Boyer patent, which grants exclusive use of a genetic engineering method. To date the Cohen-Boyer patent is one of the most lucrative patents, accruing royalty revenues of $14,660,699 in FY 1992 alone (52). However, is this experience unique?

OTA's survey of universities and academic research institutions focused on NIH and DOE life sciences research (charged by Congress to undertake the Human Genome Project) and, for comparative purposes, all U.S. government-supported research at the same institutions. OTA queried technology transfer officials about qualitative aspects of technology transfer at academic research institutions—e.g., the goals of the technology transfer function; the effectiveness of different methods of technology transfer; the nature and impact of obstacles to technology transfer at these institutions; and several other issues related to academic-based technology transfer. Additional-

[1] To address questions related to technology transfer at universities and academic research institutions, OTA sought data related to the experiences and perspectives of technology transfer officials at these entities. Questionnaires were mailed to institutions that fell within the top 45 in funds (representing a majority of extramural funding for both NIH and DOE) received from either NIH or DOE life sciences or both. For this survey, respondents were asked to provide data based on their institution's fiscal year.

To assess industry's perspectives, OTA surveyed 100 biotechnology firms by telephone to assess their experiences with Cooperative Research and Development Agreements (CRADAs). Firms involved in NIH or DOE life sciences CRADAs were contacted and compared to a sample of firms not involved in CRADAs.

One of the most vocal sectors opposed to the NIH's patent filing was the academic-based researcher. To gauge the attitudes of scientists toward the NIH applications specifically, as well as intellectual property and technology transfer issues generally, OTA surveyed by telephone 253 randomly selected recipients of NIH grants awarded through study sections principally funding grants in human molecular biology. OTA also sought information to assess the impact, if any, of these patents and technology transfer on research practices.

Finally, publication counts and citation analysis are part of the field of bibliometrics, an indicator of research productivity, although it does have limitations (84,86). To explore relationships between publications, citations, patenting, and federal technology transfer activities, OTA conducted a bibliometric and patent analysis of intramural NIH scientists participating in one or more CRADAs compared to NIH scientists not involved in CRADAs. Appendix B contains details of OTA survey methods.

ly, OTA sought quantifiable measures such as income, numbers of patents, and types of licenses.

## Goals

OTA's survey sought respondents' views of the purpose of federal technology transfer. Technology transfer officials were asked to score eight primary factors according to relative importance. These goals, listed below in no particular order, were:

- to promote local or regional economic development;
- to augment the research budget of the institution;
- to augment the discretionary income of the institution;
- to fulfill laws obligating the transfer of federally supported technology to the public;
- to stimulate more commercially applicable research at the institution;
- to help create innovative spinoff companies based on the institution's research;
- to assist staff at the institution in establishing industrial research arrangements; and
- other (list).

Twenty-four institutions cited fulfilling federal technology transfer laws as the most important goal. Eighteen institutions chose "other" as the most important, and all but one wrote in a goal best summarized as "to benefit society through the commercialization of research." One respondent said "to protect faculty inventions" was the chief goal, calling attention to the patenting function in the technology transfer process.

Although subjective, OTA's survey results clearly indicate that federal technology transfer statutes are taken seriously by technology transfer officials at universities and nonprofit research institutions. This finding is consistent with the sampling method for this survey—i.e., the survey population was drawn from institutions where a significant amount of research was funded by the U.S. government and therefore subject to federal law. Interestingly, 43 percent of technology transfer officials (18 of 42) viewed their technology transfer function as part of a university or research institution's larger social mission; such a view is consistent with what nontechnology transfer university officials have stated is the purpose of academic technology transfer function (100). Of the remaining goals, survey respondents said creating innovative spinoff companies based on research performed at the institution was the least important purpose of technology transfer.

## Effectiveness of Different Mechanisms

OTA asked respondents about the effectiveness of common methods of technology transfer, that is: exclusive licensing, nonexclusive licensing, industry-sponsored research agreements, technical assistance, direct investment in licensees, setting up spinoff companies, exchange of personnel, and site visits. Institutions were asked to characterize the methods as not effective, effective, or very effective. All but two institutions responded to this question.

Data reveal that survey respondents view exclusive licensing as the most effective method of transferring technology at these institutions, with all but four institutions responding that it was very effective and only one of those four claiming it was not effective. Industry-sponsored research agreements (see box 3-1) were judged the second most effective mechanism overall: 20 institutions claimed sponsored research was very effective, with two believing it ineffective. Nonexclusive licensing and setting up spinoff companies were both viewed as the next most effective means of transferring technology. And finally, OTA found that 32 institutions viewed direct investment in licensees to be an ineffective technology transfer method (though two institutions judged it to be very effective).

With respect to this last mechanism—direct investment in licensees—opportunities for investing in such licensees, or receiving equity in a small startup as part of a licensing arrangement, are likely to increase in the future if universities continue attempts to set up venture capital funds or incubators to commercialize academic science. Current-

**BOX 3-1: Washington University-Monsanto Sponsored Research Agreement**

Sponsored research agreements present both the corporate sponsor and the research institution with an opportunity to benefit. The key to taking advantage of this opportunity is ensuring that care is taken in the process of reconciling the profit-maximizing goals of the corporation with the academic mission of the nonprofit research institution or university. Moreover, the concerns of the U.S. government must be considered as well because of significant federal support for biomedical research at these institutions, Reconciling disparate institutional goals, sometimes in tension, must be negotiated in advance—especially if the proposed agreement involves large sums of money. Most sponsored research agreements, however, are small and easily managed by all parties involved.

Some agreements, however, are broader, occur for longer periods of time, and involve a significant amount of money. For example, at Washington University, Monsanto is providing about $9 million each year on topics chosen by the research faculty, but that are of interest to Monsanto as well (23). Monsanto funding represents 5 percent of the annual research budget at Washington University, and Monsanto is restricted to research on bioactive proteins and peptides under the agreement (23). Monsanto issues requests for proposals (RFPs) each year, describing areas of specific interest that faculty members may submit proposals for. A joint committee of five senior scientists from Monsanto and five from Washington University review the proposals. Every two years, an independent audit of scientific quality is conducted; several members of the National Academy of Sciences conducted a recent audit (23).

Under the agreement, faculty members receiving Monsanto funds agree to assign their patents to the company and to keep confidential any proprietary information they receive from Monsanto. Manuscripts are reviewed and then released for publication in 30 days or less. No restrictions on collaboration with faculty at other Institutions exist, and the agreement provides a mechanism for sharing research materials based on Monsanto-funded work (23). On occasion, a patentable discovery has been developed with funding from Monsanto and the U.S. government. In such cases, the provisions of federal law are applied to the discovery, Including the Bayh-Dole Act (Public Law 96-517)(23).

Some experts express concerns about sponsored research agreements, particularly those that are large in scale or scope. Among the concerns: agreements excluding rival firms from access to unused R&D, deals allowing companies to excessively control the direction of research and its results, and provisions that restrict the freedom of researchers to publish their work. In the wake of the controversy over a proposed agreement between Scripps Research Institute and Sandoz Pharmaceutical, the National Institutes of Health (NIH) conducted a survey of 375 sponsored research agreements at 100 U.S. research institutions in 1993. The NIH survey revealed that most agreements are small and so presumably raise less concern. Indeed, according to NIH officials, there were no agreements similar to the Scripps-Sandoz agreement (57). Nevertheless, in response to a congressional directive, NIH has drafted guidelines to resolve concerns about the potential for sponsored research agreements and perceived abuse of federal funding at nonprofit research institutions.

SOURCE Office of Technology Assessment, 1995

ly, however, U.S. universities pursue this avenue cautiously because of the controversy it generates (53).

## ■ Barriers

OTA also sought to determine technology transfer officials' perceptions of the most serious obstacles to technology transfer at their institutions. Three institutions did not respond to the question, which asked respondents to rank from one (most significant) to 10 (least significant) the following list of potential obstacles (here, in no particular order):

- cost of patenting discoveries;
- appearance of conflict of interest;

- lack of industry interest;
- lack of researcher or faculty interest;
- compliance with U.S. government technology transfer laws;
- difficulty of attracting skilled technology transfer personnel;
- conflicts between local government and U.S. government requirements;
- industry reluctance to accept nonexclusive licenses;
- industry reluctance to meet royalty demands;
- unproven state of academic technology; and
- other (list).

Twenty-eight institutions believed the unproven state of academic technology was the most significant barrier; another 11 institutions ranked it as the second most significant barrier. On the other hand, three institutions ranked it among the least significant barriers to effective technology transfer.

OTA data reveal that a lack of industry interest was viewed by survey respondents as the second greatest barrier to technology transfer: Twelve institutions ranked the lack of industry interest as the most significant barrier to technology transfer, and 18 claimed lack of industry interest as the second greatest barrier to technology transfer. Four institutions did not view low industry interest as a significant barrier. Patenting costs are viewed as the third most significant barrier, according to survey respondents. Eight institutions claimed patenting costs as their first or second most significant barrier.

Interestingly, one institution claimed conflict of interest issues are the second most significant obstacle, and three others cited conflict of interest as the third most significant obstacle to technology transfer. Three institutions cited "other" and offered that decreased federally funding of research is the most significant obstacle to technology transfer. For three institutions, industry dislike of royalty demands is perceived as an obstacle. One respondent felt the U.S. tax code creates disincentives that amount to the most serious obstacle to technology transfer. Along that vein, university officials propose that the federal government establish a permanent R&D tax credit to encourage greater support by industry of university research (102). OTA's data reveal that for all but two institutions, industry aversion to nonexclusive licensing terms is not viewed as a significant obstacle.

Federal technology transfer laws and regulations, and conflicts between local and federal requirements regarding technology transfer, are viewed as the least significant barriers to technology transfer. Nevertheless, one respondent felt conflicts between federal and local governments impede technology transfer, another respondent viewed federal technology transfer laws as the second most significant obstacle, and four respondents felt federal laws were the third most severe obstacle.

Overall, OTA data concerning obstacles to technology transfer indicate that respondents believe federal laws and regulations do not interfere with technology transfer. The most serious obstacle stems from the (expected) uncertainty about the value of new discoveries and technologies derived from basic academic research. Hence, neither industry nor institutions surveyed are at fault per se for this obstacle: Industry might be tentative about an area of basic research, but the respondents' interface with industry does not appear to be a serious barrier, according to academic technology transfer officials.

With respect to the possibility that specific federal regulations related to technology transfer present a burden, OTA also sought comments on federal regulations that require reporting of invention disclosures for federally funded research. For 26 institutions, the regulations, on balance, had no effect. For 18 institutions, the reporting requirement was burdensome to some degree. However, six institutions commented that the reporting requirements aided the technology transfer process.

## Other Issues

In addition to inquiring about the goals, barriers, and effective mechanisms of federal technology transfer, OTA gathered information about academic institutions' policies and practices in implementing their technology transfer function.

### Flexibility

OTA probed the flexibility of certain negotiated issues or provisions of standard licensing agreements. Areas explored included controls on data access, restrictions on the release of data, payment schedules, structure of royalties and licensing fees, ownership of patent rights, liability issues, dispute resolution, and allocation of patenting costs. Institutions reported themselves as not flexible, flexible, or very flexible for each provision. The level of flexibility carried a numeric weight on the questionnaire that was used to calculate population results.

According to OTA's data, the institutions surveyed are more flexible regarding issues such as royalties, fees, and payment schedules. Somewhat less flexible, but still subject to negotiation, are issues relating to patent cost distribution, dispute resolution, and control over access to scientific data. According to respondents, licensing provisions relating to patent ownership and liability issues are generally not subject to negotiation for companies wishing to license discoveries at academic research institutions. Moreover, seven institutions said they are generally less flexible if the invention in question derived from federally funded research.

### Royalty Distribution

With respect to the distribution of net income from royalties and fees, OTA found a range of practices among the surveyed institutions. Respondents had licensing royalty distribution policies that allocated income to the inventor(s), sometimes to the inventor's laboratory, the inventor's academic department or school, to the institution itself, and sometimes to the office responsible for technology transfer. The proportion of royalty income received by the inventor(s) ranged from 15 to 50 percent. At 13 institutions, the inventor's laboratory received from 10 to 47.5 percent of net income from royalties and fees. The institutions themselves received royalty income ranging from 7.5 to 75 percent. On average, inventor(s) received 32 percent of royalty income, and institutions received an equal share of 32 percent.

Overall, respondents viewed income from royalties or fees as discretionary. One institution reported having no formula for distributing royalty income because it had no licenses or other activities from which any income could accrue. Many institutions claimed that income went into a research or patent fund; in fact, most researchers do not view royalty income to supplement their research or salaries as an important aspect of technology transfer (table 3-1; box 3-2). No differ-

TABLE 3-1: Researchers' Expectations of the Effectiveness of Technology Transfer for Molecular Biological and Biomedical Research (in percent)

| | A lot of effect | Some effect | A little effect | No effect | Not sure[a] |
|---|---|---|---|---|---|
| Promoting public health and helping cure disease | 79% | 17~0 | 2% | o % | 2% |
| Promoting U S economic competitweness abroad | 65 | 25 | 6 | o | 4 |
| Creating Innovative spinoff companies | 51 | 37 | 6 | 12 | 4 |
| Advancing the frontiers of science | 45 | 40 | 13 | 1 | 0.8 |
| Making new discoveries public without losing rights to commercialize them | 21 | 32 | 20 | 10 | 17 |
| Creating opportunities for "hands-on" student learning | 17 | 35 | 33 | 12 | 4 |
| Augmenting funds for one's research | 15 | 39 | 34 | 9 | 4 |
| Augmenting one's salary | 2 | 8 | 26 | 64 | 1 |

[a]percentages may not add to 100 due to rounding

SOURCE Off Ice of Technology Assessment, 1995, based on a 1993 OTA telephone survey of 253 biomedical researchers receiving extramural NIH funds from study sections awarding grants in molecular biology and genetics, broadly defined

## BOX 3-2: Researchers' Attitudes Towards Technology Transfer

To assess the attitudes and practices of academic researchers regarding the commercializatlon of biomedical research, OTA conducted a telephone survey in 1994 of 253 U.S. academic molecular biology researchers receiving grants from the National Institutes of Health. Several questions specifically dealt with the topic of technology transfer in academic institutions.

Ninety-one percent of researchers surveyed by OTA (230 respondents) approved or strongly approved of academic research collaboration with industry in the life sciences. Forty-six percent of these researchers (106 individuals) were personally involved in industry-sponsored collaborations, and 53 percent (122 respondents) were not personally involved in industry-sponsored collaborations

Researchers were generally aware and supportive of technology transfer processes. Eighty-seven percent of researchers (219 respondents) were aware their university had technology transfer policies Sixty-two percent (156 respondents) of researchers surveyed stated that they "are required to disclose possibly patentable inventions to (their) university, " but 28 percent (71 respondents) said they were not required to do so. Seventy percent of researchers who stated that their university had technology transfer policies (153 respondents) also said that these policies had not "frustrated (them) with more paperwork burdens that (they) would rather not deal with. "

OTA found that not only were scientists aware, but a majority had been involved in technology transfer at their institution. Sixty-three percent (159 respondents) of researchers surveyed reported that they or members of their research team had conferred with officials at their institution about technology transfer issues arising from their research Of those who had conferred with officials, 38 percent conferred with them once a year, 20 percent conferred with them once every six months, 18 percent conferred with them once every three months, 16 percent conferred with them once a month, and 3 percent conferred with them once a week or more. Thirty-six percent (91 respondents) claimed that they had not conferred with officials about technology transfer.

OTA also asked researchers about how strongly they expected technology transfer in the life sciences to affect some of the frequently-cited goals of technology transfer (table 3-1) In general, OTA found molecular geneticists receiving NIH funding appear to view technology transfer positively in the context of the societal goals intended by lawmakers.

Seventy-nine percent (199 respondents) expect technology transfer to have "a lot of effect on promoting public health and helping cure disease. " Sixty-five percent (165 respondents) expect technology transfer to have "a lot of effect on promoting U.S. economic competitiveness abroad " Fifty-one percent (130 respondents) expect technology transfer to have "a lot of effect on creating innovative spin-off companies. " Forty-five percent (114 respondents) expect technology transfer to have a lot of effect on "advanclng the frontiers of science. " Researchers felt that technology transfer would have some effect on "making new discoveries public without losing rights to commercialize it, " "creating opportunities for 'hands-on' student learning, " and "augmenting funds for [their] research. " Additionally, a majority of scientists—64 percent (161 respondents)—do not expect technology transfer to augment their salary.

SOURCE Office of Technology Assessment, 1995

ences existed in the distribution of royalty income from federally funded versus that from privately funded research.

### *Timing of Patenting*

Under the premise that it is easier to justify the expense of pursuing patent protection (which, as noted earlier was viewed as a barrier to technology transfer by some respondents) on a discovery if a company interested in licensing has already been identified, OTA's survey explored the timing of the patenting function as part of the technology transfer process at academic institutions. Specifically, questions addressed the proportion of cases where a licensing agreement with a company was sought before pursuing a patent on a discovery, and how often the institution was successful with this approach.

On average, institutions participating in OTA's survey seek potential licensees before pursuing patent protection 53 percent of the time, and they are successful 22 percent of the time. For NIH-funded research in particular, universities and research institutions seek potential licensees prior to patenting in 50 percent of cases and are successful 21 percent of the time. For DOE-funded research, potential licensees are sought before pursuing a patent 29 percent of the time and institutions succeed for 12 percent of cases. Thus, respondents report it is generally easier to find prospective licensees for NIH-funded discoveries than for DOE-funded discoveries.

### *Marketing*

OTA also asked how respondents conduct marketing of new inventions. For an average 48 percent of cases, 47 institutions have the researcher identify potentially interested companies. At 46 institutions, technology transfer officials offered technologies to key firms that the officials know are commercializing related technologies approximately 61 percent of the time. Thirty-seven institutions canvass by mail, telephone, or site visit, local or regional firms for 31 percent of their new inventions. Thirty-three institutions turned to companies already engaged in research at their institutions in an average 16 percent of cases. At 27 institutions, an average 25 percent of technologies are published in a database frequently examined by interested parties. And finally, 20 respondents relinquish the marketing of their technologies to an outside party about 10 percent of the time.

### *Licensing without Patenting*

Another series of questions examined licensing of discoveries without applying for patents. OTA asked institutions if they had ever licensed a discovery (other than software), without ever intending to file for a patent, and whether the research leading up to the discovery was funded by NIH or DOE. In FY 1992, 37 institutions had licensed without patenting for a total of 80 discoveries. An average of 53 percent of those were based on research funded by NIH, and one discovery in FY 1992 was based on research funded by DOE. According to data OTA gathered from follow-up questions, most of these discoveries were biological materials or reagents commonly used for research purposes without filing for a patent.

### *Domestic Manufacturing Preference Clause*

Finally, OTA asked if any potential licensees had declined to license a discovery because the firm objected to a domestic manufacturing preference clause as required by law. Five institutions reported turning away an interested company for this reason, for a total of six scuttled deals in FY 1992. Four of those potential deals involved research funding from NIH, and none involved DOE-funded research. Nearly all the institutions commented that they never had a need to end licensing discussions with a company over the issue of manufacturing in the United States, primarily because licensees' approached had domestic manufacturing operations.

## Income

Income from exclusive and nonexclusive licenses is the main financial indicator of the productivity of NIH- and DOE-funded research at academic institutions. Nevertheless, income is a crude indicator of productivity, lagging behind research re-

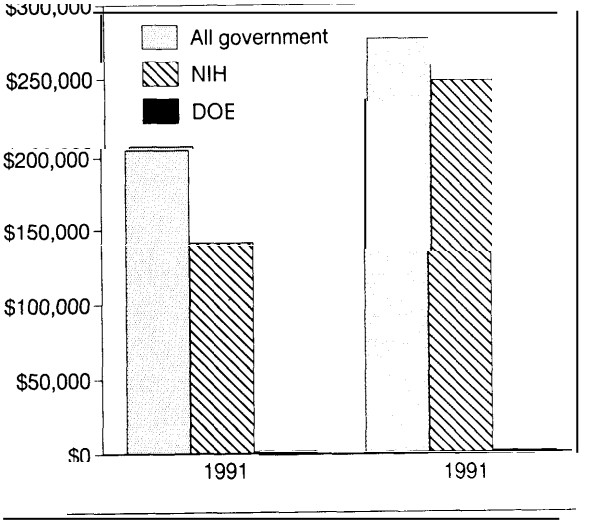
suits that emerge before commercial applications are even found. Income from licensing usually takes months, or even years, to accrue. After years of research, and what can be a time-consuming process to obtain a patent, it can take months or years to find a party interested in licensing the technology. Moreover, even after a licensee is aboard, several years often can elapse, since most biomedical technologies require regulatory approval to reach the marketplace. All of these factors increase the time it takes (in most cases) to realize a financial return on biomedical research and probably account for what some might perceive as a low rate of return from licenses related to NIH- and DOE-supported life sciences research.

Still, analyzing income data can prove instructive. Exclusive licensing income is examined separately from nonexclusive licensing income. OTA's income data (figure 3-1) allow an approximate characterization of both licensing strategies, which could prove useful in assessing the merits of proposals to mandate nonexclusive licensing of federally funded research.

Licensing income, from NIH- and DOE-supported life sciences research at the institutions responding to OTA's survey, ranged from zero to nearly $13 million. For example, 1992 income from exclusive licenses based on NIH-supported research was $12.9 million at the institution reporting the most income, with approximately $3.3 million the next highest response. In 1992, OTA survey respondents had a median income of $102,5OO from exclusive licenses.

OTA found an even greater range for income from nonexclusive licenses. The 1992 income from nonexclusive licenses based on NIH-supported research ranged from zero to nearly $15 million, with five institutions accounting for more than 90 percent of the income reported by survey respondents. The median income in 1992 from nonexclusive licenses based on NIH-supported research was $21,200. The 1992 median total income—from both exclusive and nonexclusive licenses based on NIH supported research-was $248,325.

FIGURE 3-1: Median Income Earned from Licenses to U.S. Government, NIH, and DOE Supported Research for 1991 and 1992




SOURCE: Off Ice of Technology Assessment, 1994

For life sciences research supported by DOE, 1992 income from exclusive licenses ranged from zero to $837,000, with only seven institutions reporting any exclusive licensing income that year. The survey found 1992 income from nonexclusive licenses based on DOE-supported life science research at 46 institutions ranged from zero to just over $90,000, with the other three institutions receiving income of about $11,000 or less. In 1992, only 10 institutions reported some income from licenses based on DOE supported research.

OTA's survey respondents reported a cumulative total for FY 1992 of $87.74 million of income from NIH licenses and almost $1.65 million from DOE licenses. Interestingly, in only one case did an institution receiving significant income from nonexclusive licenses also receive significant income from exclusive licensing agreements. In all other cases, institutions reporting higher than average income from exclusive licenses reported relatively little or no income from nonexclusive licenses.

TABLE 3-2: Summary of Data from OTA Survey of Academic Research Institutions

| Institutional Fiscal Year | All U.S. government | National Institutes of Health | U.S. Department of Energy |
|---|---|---|---|
| Reported Inventions 1991 | 1373 | 822 | 52 |
| Reported Inventions 1992 | 1549 | 889 | 55 |
| Patent filings 1991 | 688 | 496 | 21 |
| Patent filings 1992 | 723 | 518 | 19 |
| Exclusive licenses 1991 | 181 | 135 | 3 |
| Exclusive licenses 1992 | 222 | 169 | 2 |
| Nonexclusive licenses 1991 | 186 | 104 | 2 |
| Nonexclusive licenses 1992 | 174 | 135 | 4 |
| Exclusive license income 1991 | $28,364,646 | $24,081,480 | $ 594,767 |
| Exclusive license income 1992 | $45,197,909 | $32,002,457 | $1,528,105 |
| Nonexclusive license income 1991 | $55,031,692 | $51,318,994 | $ 31,748 |
| Nonexclusive license income 1992 | $60,777278 | $55,738,223 | $ 114,492 |

SOURCE, Off Ice of Technology Assessment, 1995

A few institutions appear to have received significantly more income from exclusive licensing agreements than their peer institutions. Although the Bayh-Dole Act was passed in 1980, it has taken almost a decade for most academic institutions to begin to see royalties emerge from patents on their federally funded discoveries. Even at institutions with mature programs, the technology transfer function is barely self-supporting; as noted earlier, accruing income from licensing usually takes years.

Based on the income data, DOE-supported life sciences research appears significantly less productive for extramural academic research institutions. However, DOE research in the life sciences is more commonly conducted at large, contractor-operated federal laboratories, which were not part of the survey population.

Based on OTA's survey data, a handful of institutions clearly have exploited nonexclusive licensing to yield significant income; the Cohen-Boyer patent, a breakthrough technology, illustrates this point. (OTA's data, however, do not allow for conclusions concerning the nature of research more likely to yield significant income through nonexclusive licensing.) Nevertheless, experts generally agree that however rare they may be, enabling breakthrough technologies are usually appropriate for nonexclusive licensing because they promote broad diffusion. Again, as the Cohen-Boyer patent illustrates, both industry and the patentholder benefited from the many nonexclusive licenses permited. Table 3-2 summarizes data related to income and other quantitative results obtained from the OTA survey of technology transfer officials at universities and nonprofit research institutions.

## ■ Additional Data Analysis

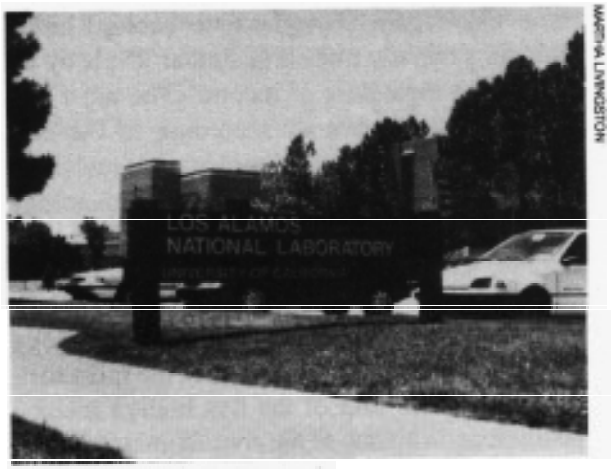
As part of the data analysis, OTA analyzed a few bivariate cross tabulations and performed some ordinary least squares (OLS) regression analyses and associated statistical tests. OTA did not investigate relationships between more than the two variables noted in each case, although there may be such causal relationships or links among more than the variables explored in each cross tabulation. It is important to recognize these correlations say nothing about the likelihood of other, possibly confounding, variables affecting the outcomes of the analyses reported by OTA in this section. Moreover, the sample sizes for some of these analyses were small.

To examine whether a correlation exists between "high" income (defined by OTA as greater than $1 million) and seeking licenses before filing for patents, licensing income data for both NIH and DOE were compared with data from questions

about seeking licenses on discoveries prior to filing a patent application. OTA found no significant difference in behavior between institutions, regardless of income. Some institutions with no license income always attempted to find licensees 'before patent filing. As well, no differences emerge when examining rates for successful licensing prior to patent filing. For NIH-funded research, all but one of the five institutions with high licensing income sought licensees before patent filing 50 percent or more of the time. However, of those institutions, one claimed success 50 percent of the time and four said they were successful 10 percent of the time or less. For DOE, 10 institutions had income; the two institutions with more than $200,000 reported success in licensing discoveries prior to patenting 20 percent of the time or less. OTA analyses, including t-tests of the coefficients, indicated that a causal relationship was extremely unlikely.

Licensing income data for both NIH and DOE research were also crosstabulated with data from questions about the methods used to find potential licensees. Based on this analysis, OTA found no marketing technique unique to institutions that had high licensing income. All respondents use all marketing approaches to about the same extent, regardless of licensing income received. All but one institution reporting high income turned to key companies in the relevant field to try to license discoveries 75 percent or more of the time. Conversely, less than 20 percent of the time, all but one respondent reporting high income published discoveries in an electronic database to which potential licensees have access. For institutions reporting high income, all remaining methods of finding potential licensees tend to be used less than 50 percent of the time. Regression analysis and associated t-tests for this sample showed that any causal bivariate relationship was very unlikely between the level of income and any of the methods used to market inventions.

In addition, licensing income data were compared with data from questions probing the effectiveness of certain methods of technology transfer to determine if any correlation exists between levels of income at the institutions and the perceived effectiveness of those methods. Again, all methods of technology transfer are viewed as effective or not effective to the same extent by the institutions, regardless of income. All high income institutions viewed exclusive licensing as very effective, including the institutions reporting the highest income from nonexclusive licenses. The high income institutions were split on the effectiveness of nonexclusive licensing, just over half viewing it as effective and the remainder claiming it as very effective. One of the high income institutions felt that sponsored research agreements are an ineffective method of technology transfer. Direct investment in licensees was viewed as not effective by all but two of the high income institutions, which viewed it as a moderately effective method of technology transfer. Technical assistance, personnel exchange, site visits, and setting up spinoff companies were all claimed to be generally effective by institutions with high income. Institutions reporting little or no licensing income shared no coherent viewpoint on the effectiveness of these methods of transferring technology. When regression analysis and associated statistical tests are conducted for this survey, no causal relationship appeared between any of the methods and any level of income reported.




The same income data were compared with data from questions examining obstacles to technology transfer at these institutions to determine if a simple correlation exists between the perceived obstacles at the institutions and their in-

come. Once again, obstacles to technology transfer were generally ranked at similar levels by all institutions regardless of income. The most significant obstacle overall according to the survey—unproven state of technology—is ranked as the second most severe obstacle to technology transfer by four of five institutions reporting high income, with one high income institution claiming it as the most significant obstacle. Conversely, a general lack of industry interest in technology transfer at academic institutions is the most serious obstacle for four of the five highest income institutions, with one of the five claiming it as the second most severe obstacle. For all obstacles however, the rankings tended to be similar regardless of income from licenses. Regression analysis and associated statistical tests showed that, among the various reported obstacles to technology transfer, no unique causal relationships to income reported exist for this sample.

Finally, income data from the institutions were crosstabulated with patent filing and licensing data to determine whether a correlation exists between those institutions filing for and licensing patented discoveries and income. One of the five institutions reporting high income filed over 40 patent applications. However two institutions with little or no income also filed for at least 40 patents. On the other hand, one institution reporting about $13 million in licensing income, filed fewer than five patent applications. The number of licenses granted to companies followed the same pattern. In this survey, OTA found no correlation between filing for patents or entering into licensing agreements and income from licenses. It is critical to note, however, that patents and licenses do not immediately yield income, usually not even in the same year that the patent issues or the licensing agreement is signed. Patents and licenses are among the first steps toward building a stream of royalty income derived from sales of a good or service that incorporates the technology invented at an academic research institution. Hence, the income reported by the institutions in this survey is primarily derived from patents and licenses in prior years. Not surprisingly, OLS regression analysis on OTA's data, and associated statistical tests of this bivariate relationship, confirms this conclusion.

## BIOTECHNOLOGY COMPANIES' PERSPECTIVES ON FEDERAL TECHNOLOGY TRANSFER

As defined and authorized by the Federal Technology Transfer Act (FTTA) of 1986 (Public Law 99-502), a Cooperative Research and Development Agreement (CRADA) is an agreement between one or more federal laboratories and one or more nonfederal parties, under which the government provides personnel, services, facilities, equipment, or other resources (but not funds), and the nonfederal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specific research or development efforts. Under a CRADA, these resources are provided toward the conduct of specified research or development efforts consistent with the missions of the laboratory.

Hence, CRADAs are a key mechanism for federal laboratories to share research materials and data and to collaborate on research with industry. CRADAs are intended to be agreements negotiated between individual laboratories or institutes and nonfederal parties, although there is oversight from federal agencies. This section presents results from an OTA survey of selected biotechnology companies' perspectives and experiences with CRADAs they have negotiated with NIH and DOE.

### Profile of Companies Surveyed

Appendix B describes the sample population selection in detail. Briefly, OTA conducted a survey of 100 biotechnology companies in late 1993 and early 1994. A sample of firms, with and without life science CRADAs at DOE or NIH, was drawn and survey questions focused on the value to companies of CRADA collaborations, as well as the nature of the collaboration between the companies and federal laboratories. A total of 75 companies qualified following initial screening and responded to both written questionnaires and telephone interviews. The survey questions were

asked of the vice president for R&D, or other comparable executive for each company.

The demographic characteristics of the survey sample emphasize the scale and scope of the types of companies that the FTTA legislation was intended to assist. Of the 75 responding companies, eight were subsidiaries of other companies, and five are divisions of larger companies; these companies responded with data drawn from the parent company. The median estimated gross revenue for their current fiscal year (1993 or 1994) was $810 million; the median projected life sciences R&D budget was $9 million. The 75 respondents together employ approximately 1,005,000 full-time workers. Over the past five years, respondents reported receiving a total of 1,514 patents from the U.S. Patent and Trademark Office. The 75 companies currently have a combined total of 2,269 health care products on the market, 420 (19 percent) of which required regulatory approval. Interestingly, 23 firms reported not having any product on the market at the time the survey was conducted.




## ■ Experience with and Value of CRADAs

OTA's data provide some general indicators of the value to respondents of research performed under CRADAs. For the 75 companies, 23 reported having CRADAs with NIH and 10 reported having CRADAs with DOE. Three companies had both NIH and DOE CRADAs, and 27 companies had CRADAs with either NIH or DOE, but not both. CRADAs undertaken by these 30 firms, at NIH and DOE, led to 21 patent filings and 15 issued patents over the five-year period 1989 to 1994, though to date only three patented inventions are used in products that have reached the market. The companies reported to OTA that, on average for the 30 firms, 1.9 percent of gross revenues for the five-year period resulted from research performed under CRADAs, totaling approximately $31 million over the past five years. For these companies, royalty income from licenses to which the CRADA contributed were insignificant. These data imply that CRADAs have yet to generate much income for the firms that enter into life science CRADA partnerships with NIH and DOE.

The survey also probed the experiences of the companies with life science CRADAs at NIH and DOE. Of 75 companies, 23 reported having experience with a total of 43 CRADAs at NIH, including ongoing and terminated CRADAs. The 10 companies with DOE CRADAs reported having 14 life science CRADAs, including ongoing and terminated projects. The three companies with both NIH and DOE life science CRADAs were asked if there was any difference between CRADAs at NIH and DOE. One company claimed there was no difference and the two others claimed there was a significant difference. Of these, one claimed that the DOE CRADA application process was too bureaucratic, while the other company stated they have had problems with the pricing provision that was then a part of NIH's CRADAs.

To further examine companies' experiences with CRADAs, one CRADA was randomly selected from a list the respondent provided. Among the issues explored for the specific CRADA were the extent of the companies' and NIH or DOE laboratories' contributions. For the 30 companies with CRADAs at either NIH or DOE:

- 19 companies reported that federal researchers were provided to explore topics of interest to the companies;
- 18 companies reported that their laboratories were provided with U.S. government materials and equipment;
- 10 companies had access to equipment in federal laboratories;
- 16 companies had exclusive licensing provisions in the CRADA agreement;
- 4 companies received exclusive licensing privileges to research that was not conducted under the CRADA;
- 8 companies provided researchers to work in federal laboratories;
- 23 companies provided materials and equipment;
- 9 companies provided access to their equipment for federal researchers;
- 14 companies provided compensation for federal researchers;
- 16 companies provided other funding for federal researchers; and
- 13 companies provided funding for, or otherwise conducted the patent application process.

Clearly, federal laboratories contribute a share of resources to CRADAs, but OTA data reveal that a company's contribution to the CRADA is significant as well. To the extent that companies share the burden of CRADAs, it becomes more difficult to argue they are getting a free ride from the U.S. government (see Box 3-3).

OTA's survey results demonstrate that for the companies willing to invest in life science CRADAs at NIH or DOE, in most cases U.S. government contributions (other than funds) likely will match those of the companies. Overall, six companies felt that the benefits greatly outweigh the risks and expenses of CRADAs, seven felt the benefits somewhat outweighed the risks, and 12 thought the benefits equaled the risks and expenses. There were four companies that felt the risks and expenses of CRADAs exceeded the benefits.

From a qualitative viewpoint, the data from the 30 companies' tend to endorse the general value of CRADAs to the biotechnology industry. For example, 8 companies said that the intellectual contributions of federal researchers were very important, another 15 claimed the contributions to be somewhat important. Fifteen companies felt that government researchers had contributed original research ideas unavailable without the CRADA. Moreover, 18 companies reported that the researchers' technical know-how also would have been unavailable without the CRADA, and 17 companies expect an ongoing working relationship with government CRADA scientists. Nine of these companies intend to pursue another CRADA, and the remaining seven companies expect informal working relationships. A total of 15 companies felt that use of biological materials provided by the federal laboratory was somewhat or very important, and 10 felt that the use of such materials and expenses would be unavailable outside the CRADA. When asked if they would do it over again for all of their CRADAs, 8 companies said that they would do so for all their CRADAs, 8 said they would for most of their CRADAs, 7 said they would for some of their CRADAs, and 6 companies said they would be willing to repeat the experience for only a few or none of their CRADAs.

## Concerns

OTA's survey identified concerns that trouble some companies participating in the survey. Seven companies reported that these concerns caused them to forgo or retreat from a CRADA with NIH or DOE. Eleven companies expressed no concern over the possibility of disclosure of information that they had intended to keep secret. Nine companies felt it was a major concern, and nine felt it was a minor concern. Only three companies reported major concern about government scientists, involved under their CRADA, going to work for a competitor; for 14 other companies this issue was a minor concern.

Fourteen companies had major concerns that the reasonable pricing clause in their NIH CRADA at that time would restrict profitability of products resulting from the CRADA. This result mirrors

## BOX 3-3: Patenting, Publishing, and CRADAs for NIH Scientists

Cooperative Research and Development Agreements (CRADAs) are the mechanism by which industry effects technology transfer with federal scientists. Because of their exposure to industry and its sensitivity to the Importance of intellectual property protection, federal scientists involved in CRADAs might be expected to hold more patents than National Institutes of Health scientists not involved m CRADAs. However, the extent to which CRADA involvement affects the degree to which NIH scientists seek patents is unknown. Similarly, some have raised concern that commercialization of research could lead to Increased secrecy. Hence what effect, if any, do CRADAs have on publication by NIH intramural scientists? To address these issues, OTA performed a bibliometric analysis of possible relationships between CRADAs with patent and publishing characteristics of NIH intramural scientists.

The patents of 199 NIH scientists who participated in CRADAs (before and after they received their CRADAs) were analyzed and compared with a matched control group set of 199 NIH scientists. CRADA scientists get more than five times as many patents (136 in 1986-1993) as the non-CRADA scientists (25 in 1986-1993). In addition, patents from CRADA scientists were considerably more frequently cited than patents of control group scientists—i.e., the impact of the CRADA scientists' patents was higher (1,1 O v. 0.79) for the years examined. The patent rates of the CRADA scientists before and after receiving their CRADAS (defined as more than two years after the CRADA) increased at the same rate as their rate of patenting. From the point of view of patenting, while the CRADA itself does not seem to have a substantial effect on the patenting behavior of scientists, those scientists who enter into CRADAs are more prolific patenters (by almost a factor of 5), than scientists who are not involved in CRADAs That is, CRADA scientists appear to have a different orientation toward patentable biomedical research than non-CRADA researchers.

A second analysis examined the publications of a set of 116 CRADA and 116 non-CRADA researchers, separating the CRADA scientists who received their first CRADA In each of the three years 1988 1989, and 1990, so that "before CRADA" and "after CRADA" publications could be analyzed Based on this analysis, OTA found that researchers involved in CRADAs publish twice as many papers as non-CRADA scientists. Those scientists whose first CRADA was in 1988 were the most prolific, coauthoring more than 12 papers per year.

The bibliometric analysis revealed a slight, but statistically significant, decline in publication rate after an NIH scientist receives a CRADA. How to account for this result, however, is not entirely clear because of the time limitations required to track CRADA scientists over many years. Conversely, the non-CRADA scientists show absolutely no decline in publication pattern. Another comparison between the two populations revealed that the degree of "basicness" of journals in which articles were published was virtually identical between the CRADA and non-CRADA researchers. Finally, CRADA and non-CRADA scientists at NIH also published in equally influential journals.

SOURCES Office of Technology Assessment, 1995, based on F, Narin and K S Hamilton, CHI Research, Inc., Haddon Heights, NJ "Patenting for CRADA and Control Scientists," contract document prepared for D. Blumenthal and N. Causino, Massachusetts General Hospital, Boston, MA, under a contract for the Office of Technology Assessment, U S Congress, Washington, DC, 1994, and F Narin and K S Hamilton, "Publishing for CRADA and Control Scientists, " CHI Research, Inc. , Haddon Heights, NJ, "Publishing for CRADA and Control Scientists," contract document prepared for D Blumenthal and N Causino, Massachusetts General Hospital Boston, MA, under a contract for the Off Ice of Technology Assessment, U S Congress, Washington, DC, 1994

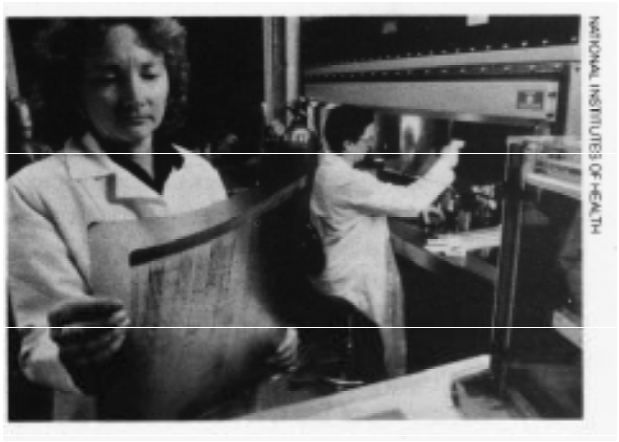
the finding of a 1994 OTA workshop involving a broad range of biotechnology and genome industry representatives, where executives pointed out that their interest in CRADAs was significantly retarded by potential price controls on pharmaceuticals (74).[2] On the other hand, eight companies felt the reasonable pricing clause was a minor concern, and seven others had no such concerns.

Eight of the companies felt it was a major concern that the CRADA language had no guarantee of an exclusive license for unanticipated products developed under the CRADA, and 14 others felt it to be a minor concern. Of the 30 CRADA firms, seven companies had major worries that the government would not honor the terms of the CRADA regarding exclusivity, and 10 other firms had minor concerns over this issue.

In general, OTA's survey results related to concerns of the biotechnology industry with CRADAs echo the findings of a 1993 report by the U.S. Department of Health and Human Services' Inspector General. This report also noted that industry considers the process of establishing CRADAs to be lengthy and complex, thus either discouraging formation or serving as a disincentive to further participation (98). As described in the next section, OTA's survey data show some evidence of this issue as a concern to some in the biotechnology industry, but the data also demonstrate the process is not a concern to others. ,

## ■ Executing CRADAs with NIH and DOE

Another set of questions probed the CRADA formation process from the companies' perspective. Out of 30 firms with NIH and DOE CRADA experience, 22 discovered CRADAs via personal contacts, one reported reading a journal article, one firm was made aware of CRADAs at a professional meeting, four companies reported receiving promotional materials from the U.S. government. According to these data, personal contacts are most effective for forming life science CRADAs at NIH or DOE. Four companies claim




that initial discussions toward forming CRADAs were begun by company officials, and eight report that the discussions were begun by government officials. Sixteen companies claim that discussions began by both federal and company officials equally. Within 20 companies, the research scientists themselves are the most enthusiastic advocates of CRADAs, and in five firms it was the vice president for R&D. Efforts to make industry more aware of CRADAs are seen as very effective by five companies, somewhat effective by 13 companies, somewhat ineffective by nine companies, and very ineffective by two companies. These data suggest that outreach to industry could be improved on the part of federal laboratories.

Relative to applying for life science CRADAs at NIH and DOE, 20 companies said they used a model CRADA application. Of these 20 companies, eight thought it was helpful, five said it was neither helpful nor obstructive, and six firms felt it was obstructive. Nine companies felt that the government's involvement in writing the CRADA application was very helpful, and seven other firms felt it was somewhat helpful. Six companies claimed that federal involvement is neither helpful nor obstructive, and seven companies felt it was obstructive. Twenty-five of the companies said there was a federal official responsible for coordinating the CRADA application process. For those five firms that said there was no such of-

2 In spring 1995, NIH dropped its insistence on a reasonable pricing clause (97).

ficial, they all claimed it would have been helpful if there was a government coordinator. Only six companies felt that such an official neither helped nor obstructed; 19 firms felt that a coordinating official in the application process helped them. Nineteen companies reported that their application was reviewed by a committee, and nine firms claimed that the committee's review took longer than was reasonable. Four companies felt that the committee pointed out ambiguities or problems important to resolve.

### Licensing Provisions

Companies tend to focus on exclusive licensing of results to their CRADAs. A total of 21 companies sought exclusive licensing in the CRADA application for patents that might result from the CRADAs. Concerning the scope of exclusive licenses in the application, 16 companies reported that it was an issue for negotiation. Five companies sought exclusive licenses to government held patents on material used under the CRADA, but not a result of it. However, 22 companies did not actually receive exclusive licenses from the government, despite 16 companies having exclusive licensing provisions in their agreements. Seven companies did obtain exclusive licenses to their CRADA results. It is possible that some of the CRADAs did not result in anything to license exclusively from the 22 companies' perspective, or less likely, the federal laboratory did not honor its agreements.

### Additional Issues

For those companies with no experience with CRADAs, OTA asked about their attitudes and awareness relative to CRADAs. Fourteen of 34 companies had never heard of CRADAs. For the 20 firms that were aware of CRADAs, 17 said they would consider entering into one. Ten of the 20 firms aware of CRADAs had some contact with federal officials or scientists concerning CRADAs, and for two of these companies the contacts were ongoing. Five companies said it would be very likely they would apply for life science CRADAs in the future, eight said it would be somewhat likely they would do so. Seventeen companies said they probably would not be interested in life science CRADAs with NIH or DOE laboratories.

As part of the survey, OTA took the opportunity to inquire about relations between the survey respondents and foreign nonprofit research institutions, with a focus on intellectual property rights resulting from international R&D collaborations. According to the survey, 31 of the 75 companies claimed to participate in collaborative R&D agreements with foreign nonprofit research institutions complete with rights to intellectual property licensed or otherwise obtained from foreign research institutions. These data show the openness of at least 41 percent of the companies to international research collaboration. Only one firm claimed to have licensed technology from a U.S. party that had such rights originally based on an international research collaboration.

In summary, OTA's data show an unevenness of companies experiences with CRADAs. Although most of the companies with CRADA experiences felt the federal laboratory helped them, the fact that most firms did not obtain exclusive licenses to CRADA results belies the more basic or enabling nature of the research collaboration common to CRADAs in the life sciences. In many cases, such a result is not necessarily a problem, but it does point to a possibility of companies' expectations going unfulfilled.

From the U.S. government's perspective, CRADAs can assist federal investigators in many cases, according to an analysis of OTA survey data. This is consistent with the findings from the DHHS Inspector General's investigation (98). A recent report by the U. S. General Accounting Office also found that CRADAs can provide a useful opportunity for federal research agencies to benefit from collaboration with industry, while pursuing research goals consistent with their statutory missions (80).

## SUMMARY AND CONCLUSIONS

Over the past 15 years, Congress enacted legislation to address technology transfer of federally funded research performed at universities and re-

search institutions, as well as technology transfer of intramural research performed at federal facilities. Given the time necessary to implement the laws, however, only now are efforts to evaluate their impacts being undertaken.

Data from OTA's survey indicate that universities and research institutions do not believe federal laws and regulations interfere with technology transfer in most cases. Overall, OTA's survey found that academic technology transfer officials view the Bayh-Dole Act as vital to federal technology transfer. Clearly, academic research institutions successfully transfer some federally supported research to the private sector for commercial development. Significant barriers to academic technology transfer apparently are not a function of U.S. government laws or regulations.

With respect to the biotechnology industry's view of NIH and DOE (life sciences) technology transfer, CRADAs in particular, OTA's survey data found most respondents held positive views—despite the finding that life science CRADAs have yet to become commercially productive for most companies that have them. For companies willing to invest in life science CRADAs with NIH or DOE, U.S. government contributions (other than funds) match those of the companies in most cases. Moreover, six companies felt the benefits greatly outweigh the risks and expenses of CRADAs, seven felt the benefits somewhat outweighed the risks, and 12 thought the benefits equaled the risks and expenses. In contrast, four companies felt the risks and expenses of CRADAs exceeded the benefits.

Thus, beginning in 1980, Congress provided incentives for nonprofit research institutions and universities to license federally funded research, simply by changing the rules of intellectual property ownership. Congress appears to have achieved the intended effect of moving federally supported research to the marketplace without appropriating taxpayer funds for a new R&D program. On the other hand, because the increase in number of products mirrors a period of rapid growth in federal funding for life sciences research, it is impossible to unlink technology transfer from strong federal support for basic biomedical research. Nor did OTA assess the relative contribution of each to the unequaled development growth of the U.S. of the biotechnology sector.

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# Appendix A Federal Technology Transfer Legislation

A

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.

# Appendix B Methods of OTA Surveys

B

This background paper describes data from two surveys conducted by OTA, or by OTA and its contractors. This appendix details the methods used for each survey and also reproduces the survey instruments.

## SURVEY OF UNIVERSITY TECHNOLOGY TRANSFER OFFICIALS

Beginning in summer 1993, OTA surveyed university and nonprofit research institutions about their experiences with technology transfer concerning results from federally funded life sciences research. OTA requested information from technology transfer officials at each institution, under the assumption that technology transfer officials would be a key source for understanding technology transfer and the implementation of federal technology transfer policies, practices, and laws.

OTA's survey of technology transfer programs was designed to elicit quantitative and qualitative data from those officials responsible for carrying out the technology transfer function, generally, and for extramural life sciences research funding from the National Institutes of Health (NIH) and the U.S. Department of Energy (DOE). The questions (survey instrument B-1) focused on technology transfer officials' perceptions of and experiences with the implementation of federal technology transfer legislation, especially the Bayh-Dole Act of 1980 (Public Law 96-517). The survey sought both quantitative and qualitative data. Some questions asked respondents for subjective information, because the firsthand experience of these officials was viewed as important to understanding academic technology transfer; whereas

some questions asked for quantitative data, such as income or number of patents.

OTA compiled the population of institutions to be surveyed by obtaining a list of the 45 largest recipients of funds from either NIH or DOE (life sciences only) for FY 1992 (the year most readily available at that time). Officials at NIH and DOE reported that the list tends not to change from year to year, and so OTA felt confident that the FY 1992 list represented the appropriate target population.

The final number of institutions surveyed was fewer than 90 because some institutions receive significant funding from both NIH and DOE, and therefore appear twice on a composite list. The list also was reduced by excluding all for-profit companies, foreign research organizations, and recipients performing nonscientific functions (e.g., a grant to administer a meeting or provide a service). After exclusions, a total of 62 academic research institutions were surveyed by mail. Regardless of the source of funding, all institutions received identical survey instruments, which were coded for tracking only. Survey respondents were offered the opportunity to remove the coding label and hence anonymize their questionnaire; one respondent removed the label.

A single mailing was executed and follow-up calls were made to increase the survey response. In two cases, the instrument was resent to the institution, but duplication in response by these entitites was avoided through the coding system. By fall 1993, 50 institutions had returned the survey questionnaire by mail following one round of phone calls, and responses from technology transfer officials at these 50 university and research institutions form the basis for the data OTA reports for this survey.

## SURVEY OF BIOTECHNOLOGY COMPANIES

In summer 1993, OTA sought data from selected biotechnology companies about their experience with federal technology transfer, specifically their experiences with life sciences Cooperative Research and Development Agreements (CRADAs) with NIH and DOE—i.e., their views on technology transfer with researchers at NIH and DOE intramural laboratories. The survey population for this effort was senior executives responsible for managing research and development (R&D) at selected biotechnology companies.

Survey questions (survey instrument B-2) focused on companies' perspectives on the implementation of federal technology transfer legislation, particularly the Federal Technology Transfer Act (FTTA) of 1986 (Public Law 99-502). In consultation with OTA, a contractor prepared the survey instrument and constructed the sample of biotechnology companies. A separate contractor administered the instrument and collected the data by telephone interviews.

To derive the final survey sample, a master list was compiled using several sources (14). A published directory of biotechnology firms (35) served as the base population to which other lists were added; the directory was selected as a starting point because it was inclusive, although it included noncommercial, publishing, and financing organizations that were a priori excluded from the master list.

To evaluate whether the master list was comprehensive, it was compared with random samplings from two additional lists (9,21) and against another database in its entirety (27); the full Dibner list was used because it was published in a form that easily could be read by an electronic text-recognition scanner. Eight percent of the BioScan (9) sample of 124 firms and 11 percent of the Coombs and Alston (21) sample of 126 firms did not appear on the master list. For the Dibner list (27), 29 percent of companies were not on the master list—a total of 258 firms. These firms were added to the master list, although some were deleted later because they were units of firms already on the master list. The complete BioScan and Coombs and Alston lists were not used to supplement the master file because the additional resources required to use them would not have been commensurate with the relative increased contribution to the master list.

Finally, firms that the Dibner database (27) indicated were out of business were deleted from the list. And, using information from Dibner and Genetic *Engineering News (35), firms* on the master list reported as merged or as operating under more than one name-or anew name—were combined into single entries as deemed appropriate. A final, stratified, random sample was drawn according to table B-1. A specific contact for each company was identified using directories described earlier (27,35) or from a third corporate directory (22). In general, the title for the individual targeted was Vice President of Research, Director of R&D, or similar constructions.

Other additions to the master list were made. First, firms not already on the master list but with current or recently concluded CRADAs (NIH or DOE life sciences) were added. NIH information initially was obtained from NIH's Office of Technology Transfer (OTT); the OTA contractor identified a few additional companies with CRADAs on the basis of telephone conversations with officials in the technology transfer offices of individual institutes. (Such CRADAs were generally efforts not reviewed by OTT's CRADA subcommittee because they did not include exclusive licensing provisions.) DOE's Office of Technology Utilization provided a list of companies that had DOE life-sciences CRADAs. Second, businesses not already on the master list but receiving U.S. Department of Commerce (DOC) Small Business Research Program awards for life-sciences projects from 1985 through 1992 were also added to the master list. Information about these awards was taken from a DOC publication containing abstracts of the awards (90,91).

TABLE B-1—Sampling Design for Biotechnology Company Survey

| Strata | | Number of Firms |
|---|---|---|
| Non-CRADA Fortune 500 | | 20 |
| | Non-Fortune 500 | 50 |
| CRADA | NIH | 20 |
| | DOE | 10 |
| **Total** | | 100 |

KEY: CRADA = Cooperate Research and Development Agreement; DOE = U.S. Department of Energy, NIH = National Institutes of Health

SOURCE Office of Technology Assessment, 1995, based on D Blumenthal and N. Causino, "Sample of Biomedical and Biotechnology Firms for the U S Congress Office of Technology Assessment Survey About Firms' Involvement m Joint Projects with National Institutes of Health and the Department of Energy of the Study of the Effects of the Federal Technology Transfer Act on the Commercial and Academic Activitiesof Federal Scientists, " Massachusetts General Hospital, Boston, MA, Apr 21, 1993

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| | DOE | 10 |
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SOURCE Off Ice of Technology Assessment 1995 based on D Blumenthal and N Causino, "Sample of Biomedical and Biotechnology Firms for the U S Congress Off Ice of Technology Assessment Survey About Firms' Involvement in Joint Projects with National Institutes of Health and the Department of Energy of the Study of the Effects of the Federal Technology Transfer Act on the Commercial and Academic Activities of Federal Scientists," Massachusetts General Hospital Boston, MA, Apr. 21, 1993

## Survey Instrument B-1—Instrument for OTA Survey of University Technology Transfer Officials

**Office of Technology Assessment**
**United States Congress**
**Washington, D.C. 20510-8025**

**SURVEY OF TECHNOLOGY TRANSFER**

At the request of Congress, the Office of Technology Assessment (OTA) is conducting an assessment of issues relating to patenting human genetic discoveries and inventions. As part of this effort, OTA is surveying research institutions that receive substantial research funding from the National Institutes of Health (NIH) or the Department of Energy (DOE) to examine technology transfer generally, and for human genetic technologies, specifically. Please give your best estimate in those cases where exact data are unknown.

For the purposes of this survey, OTA has adopted the following definitions:

U.S. government funding for research should include **both direct and indirect costs.**

**Exclusive licenses** are licenses to use, further develop, or in any other way commercialize a technology exclusive of any other party. This includes partially exclusive licenses that have any geographic boundary, time restriction (other than the patent protection term), or exclusion of any other party only for a particular, defined use or application of the technology.

**Nonexclusive licenses** are those licenses that do not exclude any other party from entering into a license with the licensor institution under any circumstances.

Statistically, a **licensing option agreement should be considered the same as any licensing agreement.** Therefore, any income derived from an option should be considered the same as income derived from a license

---

1. How much **U.S. government research funding** did your institution receive for the fiscal years indicated?

   1991 _____ 1992 _____

   How many invention disclosures resulted from this **research? 1991** _____ **1992** _____

   How many patent applications filed? 1991 _____ 1992 _____

   How many exclusive licenses granted? 1991 _____ 1992 _____

   How many nonexclusive licenses granted? 1991 _____ 1992 _____

   How much royalty income from exclusive licenses? 1991 _____ 1992 _____

   How much royalty income from nonexclusive licenses? 1991 _____ 1992 _____

   If your institution's fiscal year ends on a date other than June 30, please indicate when:

   _____

2. For the fiscal years indicated, how much **U.S. government research funding from either NIH or DOE did** your institution receive for human genetics research?

   1991 _____ 1992 _____

   How many invention disclosures resulted from this research? 1991 _____ 1992 _____

   How many patent applications filed? 1991 _____ 1992 _____

   How many exclusive licenses granted? 1991 _____ 1992 _____

   How many nonexclusive licenses granted? 1991 _____ 1992 _____

   How much royalty income from exclusive licenses? 1991 _____ 1992 _____

   How much royalty income from nonexclusive licenses? 1991 _____ 1992 _____

## Survey Instrument B-1—Instrument for OTA Survey of University Technology Transfer Officials (Cont'd.)

3. Please rank the following goals in importance for your office (1= most important, 6=least important).

   To promote local or regional economic development

   To augment the research budget of my institution

   To augment the discretionary income of my institution with a steady stream of royalty income

   To fulfill laws obligating my institution to transfer federally funded technology to the public

   To stimulate more commercially applicable research at my institution

   To assist faculty at my institution in establishing industrial research arrangements

4. In approximately what percent of cases does your office seek potential licensees to a technology before pursuing a patent? _____%

5. In approximately what percent of cases does your office seek potential licenses to human genetics inventions/discoveries before pursuing a patent? _____%

6. Are you aware of any cases in which researchers at your institution, at a company's request, agreed to delay publication of research results that involved U.S. government funding?

   _____ No (1)

   _____ Yes (2) If yes, please indicate the reason.

   A sponsor needed time to review the publication for proprietary or patentable data (2.1)

   Time needed to be allowed to prepare and file a patent application (2.2)

   ____ Other (2.3) _____

   How often in the last two fiscal years? 1991 _____ 1992 _____

   How long was the average delay? _____

7. Are you aware of any cases in which researchers at your institution, at a company's request, agreed to **limit public disclosure of research results** that involved U.S. government funding?

   _____ No (1)

   _____ Yes (2) If yes, please indicate the reason.

   The publication would disclose company proprietary information covered in a prior agreement that provided the researchers access to the company's technology or materials (2.1)

   The disclosure held information that could be the basis for a patent application (2.2)

   Other (2.3) _____

   How often in the last two fiscal years? 1991 _____ 1992 _____

8. Does the information supplied in the previous two questions significantly differ for cases of inventions/discoveries based on human genetics research funded by NIH or DOE?

   _____ No (1)

   _____ Yes (2) If yes, please describe the differences in the space below.

## Survey Instrument B-1—Instrument for OTA Survey of University Technology Transfer Officials (Cont'd.)

9. In your judgment, is compliance with **Federal regulations that require** reporting of invention disclosures counterproductive to technology transfer mechanisms used by your office?

_____ No (1)

_____ Yes (2) If yes, for what reason(s)? Please check all that apply.

Writing the reports is a waste of time and money **(2.1)**

**The** process of disseminating the reports is a waste of time and money (2.2)

The continuously updated report of invention disclosures could give an unfavorable impression to potential licensees of inventions that continue to remain unlicensed on a revolving basis (2.3)

____ Other (2.4) _____

10. Does your office have a strictly uniform licensing agreement, a standardized licensing agreement, or is each potential license handled on a case-by-case basis?

_____ Uniform agreement (1)

_____ Standardized agreement (2)

_____ Case-by-case (3)

11. Please describe how royalty income is allocated at your institution.

Is the allocation formula different for federally funded research?

_____ No (1)

_____ Yes (2) If yes, how is it different?

12, Of all licenses granted in the last two fiscal years, how much time elapsed from your office's initial involvement with an invention/discovery to the final signing of a licensing agreement, excluding time allowed for receiving a patent? Please indicate how many cases for each timeframe.

_____ Less than 1 week

_____ 8-30 days

_____ 31-90 days

_____ 91-180 days

_____ 181-365 days

_____ Over 1 year

_____ Over 2 years

## Survey Instrument B-1—Instrument for OTA Survey of University Technology Transfer Officials (Cont'd.)

**13.** How **do you market** your institution's technologies to potential licensees? Please estimate percentage of cases where each of the following mechanisms are used at your institution (percentages may add up to more than 100%).

_____% Rely on database of invention disclosures to attract licensing interest

_____% Contact several key firms that you know are commercializing related technology

_____% Canvas local or regional firms by mail, telephone, or visit

_____% Turn over the marketing aspect to an outside party

_____% Rely on inventor to assist your office in finding a suitable firm

_____% Rely on firms already engaged in research projects or sponsored research agreement

_____% Other _____

**14.** In your judgment, what are the most effective methods of technology transfer from your institution to industry? For each of the following please indicate degree of effectiveness.

| | not effective | effective | very effective |
|---|---|---|---|
| Exclusive licensing | 1 | 2 | 3 |
| Nonexclusive licensing | 1 | 2 | 3 |
| Sponsored research agreements | 1 | 2 | 3 |
| Technical assistance | 1 | 2 | 3 |
| Personnel exchanges | 1 | 2 | 3 |
| Site visits | 1 | 2 | 3 |
| Other _____ | 1 | 2 | 3 |

**15.** Has your office ever licensed an invention/discovery without ever intending to file for a patent'?

_____ No (1)

_____ Yes (2) If yes, how many times in the last two fiscal years? 1991_____ 1992 _____

What percentage were based on human genetics research funded by NIH or DOE?

1991 _____% 1992 ___%

**16.** Has your office ever turned away an interested firm from licensing an invention/discovery because the firm did not agree to a domestic manufacturing preference clause?

_____ No (1)

_____ Yes (2) If yes, how many times in the last two fiscal years? 1991_____ 1992 _____

What percentage involved human genetics research funded by NIH or DOE?

1991 _____% 1992 _____%

**17.** In your opinion, what are the primary challenges or obstacles to effective technology transfer from your institution to industry? Please designate in rank order 1-9 (1 =most significant, 9=least significant).

_____ Cost of patenting inventions/discoveries (1)

_____ Appearance of conflict of interest before the public (2)

_____ Lack of industry interest (3)

_____ Lack of researcher or faculty interest (4)

_____ Complying with Federal policies, laws, or regulations regarding technology transfer (5)

_____ Attracting skilled personnel to staff your office (6)

_____ Conflicts between local or U.S. government requirements (7)

_____ Industry reluctance to meet royalty demands (8)

_____ Other (9)_____

## Survey Instrument B-1—Instrument for OTA Survey of University Technology Transfer Officials (Cont'd.)

18. At your institution, is the inventor(s) involved in the licensing process?

___ Yes (1)

_____ No (2) if no, why not? Please check one of the following:

Conflict of interest concerns (2.1)

To increase the level of objectivity in licensing negotiations (2.2)

inventor chooses not to be involved (2.3)

Other (2.4) _____

Attached below is a peel-off identification number that will be removed by OTA on receipt of the completed survey. This is the only link between the institutions that are being sampled and the surveys returned, and is for tracking and follow-up purposes. We would prefer that you leave the identification number on the survey when you return it so we can avoid repeated followup, but if you are uncomfortable with this procedure please remove the label prior to returning the survey.

Thank you very much for your cooperation in completing this survey. We would also like to give you an opportunity to give us any other opinions, concerns, or suggestions related to technology transfer that you feel our questions did not sufficiently address. These comments will be strictly anonymous but may be incorporated in our report to Congress. Feel free to use the reverse side or attach extra sheets, if necessary.

Please return the completed survey **by July 23, 1993** in the enclosed self-addressed stamped envelope. In the event that the envelope is lost please return the survey to:

Mike Snyder
U.S. Congress
Office of Technology Assessment
Biological and Behavioral Sciences Program
Washington, DC 20510-8025

If you have any questions or comments, please feel free to call Mike Snyder at (202) 228-6676.

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies

Questionnaire name: 6191BS 12/14/93 - 2:27 PM Page: 1

```
***QUESTION 1 ***
*Schulman Ronca & Bucuvalas, Inc.  444 Park Ave. South, NY, NY
Study #619lB Technology Transfer and DNA Patenting: Business Screener

SAMPLE READ_IN: COMPANY PHONE NUMBER 10 DIGITS
                GO TO QUESTION #2 ===> < 1> [01]###
-- ANSWER REQUIRED --

*** QUESTION # 2 ***
*SAMPLE READ-IN: SAMPLE TYPE
  GO TO Q. # 3 '===> < 1 > *NIH/CRADA
  GO TO Q. # 3 ====> <  2 > *DOE/CRADA
  GO TO Q. # 3 ====> <  3 > *FORTUNE/NON-CRADA
  GO TO Q. # 3 ====> <  4 > *NON-FOR UNE/NON-CRADA
  GO TO Q. # 3 ====> <  5> [13]###  "

*** QUESTION # 3 ***
*SAMPLE READ-IN: COMPANY NAME  45 COLS.
  GO TO Q. # 4 ====> <  1> [04]###
-- ANSWER REQUIRED --

*** QUESTION # 4 ***
*SAMPLE READ-IN: ADDRESS 1 35 COLS.
  GO TO Q. # 5 ====> <  1 > [05]###
-- ANSWER REQUIRED --

*** QUESTION # 5 ***
*SAMPLE READ-IN: ADDRESS 2 30 COLS.
  GO TO Q. # 6 ====> <  1 > [06]###
-- ANSWER REQUIRED --

*** QUESTION # 6 ***
*SAMPLE READ-IN: CITY 25 COLS.
  GO TO Q. # 7 ====> < 1 > [07]###
-- ANSWER REQUIRED --

*** QUESTION # 7 ***
*SAMPLE READ-IN: STATE 2 COLS.
  GO TO Q. # 8 ====> < 1 > [08]###
-- ANSWER REQUIRED --

*** QUESTION # 8 ***
*SAMPLE READ-IN: ZIP CODE 10 COLS.
  GO TO Q. # 9 ====> < 1 > [09]###
-- ANSWER REQUIRED --

*** QUESTION # 9 ***
*SAMPLE READ-IN: CONTACT NAME 30 COLS.
  GO TO Q. # 10 ====> < 1 > [lO]###
-- ANSWER REQUIRED --

*** QUESTION # 10 ***
```

Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

```
Questionnaire name: 6191BS            12/14/93 - 2:27 PM            Page:    2

*SAMPLE READ-IN CONTACT PHONE 15 DIGITS
  GO TO Q. # 11 ====> < 1 > [12]###
-- ANSWER REQUIRED --

*** QUESTION # 11 ***
*SAMPLE READ-IN: CONTACT TITLE 50 COLS.
  GO TO Q. # 12 ====> < 1 > [11]###
-- ANSWER REQUIRED --

*** QUESTION # 12 ***
*SAMPLE READ-IN CLIENT ID 4 DIGITS
  GO TO Q. # 13 ====> < 1 > [02]###
-- ANSWER REQUIRED --

*** QUESTION # 13 ***
*SAMPLE READ-IN SAMPLE ID 3 DIGITS
  GO TO Q. # 14 ====> < 1 > [03]###
-- ANSWER REQUIRED --

*** QUESTION # 14 ***
*SAMPLE READ_IN REPLICATE 2 DIGITS
  GO TO Q. # 15 ====> < 1 > [14]###
-- ANSWER REQUIRED --

*** QUESTION # 15 ***
*DUMMY QUESTION 15
  GO TO Q. # 16 ====> < 1 > #hold
  GO TO Q. # 16 ====> < 2 > #hold
  GO TO Q. # 16 ====> < 3 > #hold

*** QUESTION # 16 ***
!SWITCHBOARD INTRO:
Hello, may I speak to [lO]###
[11] ###

(IF NECESSARY:) I'm [I]### from SRBI,
the national research organization in New York City. We are calling on
behalf of the Office of Technology Assessment (OTA of the United States
Congress.  We are conducting a survey  of biotechnology company's views
on technology transfer and its impact on their R&D efforts.
  GO TO Q. #24 ====>  < 1 > CONTINUE  INTERVIEW
 DISP CODE # 1 ====>  < 2 > No answer
 DISP CODE # 12 ====>  < 3 > Answering  machine
 DISP CODE # 2 ====>  < 4 > Busy signal
 DISP CODE # 9 ====>  < 5 > Initial Callback
 DISP CODE # 13 ====>  < 6 > Away for duration
 DISP CODE # 6 ====>  < 7 > Initial Refusal
 DISP CODE # 3 ====>  < 8 ) Disconnected  phone/NIS
 DISP CODE # 8 ====>  < 9 > Language  barrier
 DISP CODE # 14 ====>  < 10 > Gatekeeper Refusal
 DISP CODE # 15 ====>  < 11 > Call cannot be completed
 DISP CODE # 16 ====>  < 12 > Second refusal
  GO TO Q. # 18 ====>  < 13 > ENTER  REFERRAL  INFORMATION
 DISP CODE # 18 ====>  < 14 > Company out of business
 DISP CODE # 19 ====>  < 15 > Company  not  in  biotechnology
```

Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

```
Questionnaire name: 6191BS          12/14/93 - 2:27 PM          Page: 3

   GO TO Q. # 17 ====> < 16 > Other reason terminating call

*** QUESTION # 17 ***
(INTERVIEWER:  THIS QUESTION WILL ELIMINATE THIS PHONE NUMBER FROM THE
          IF THIS NUMBER CAN BE DIALED AGAIN, BACK-UP AND CHOOSE ANOTHER
.CODE TO THE PREVIOUS QUESTION.  IF THIS NUMBER CAN NOT BE DIALED AGAIN,
.ENTER THE REASONS WHY BELOW TO EXIT.)
 DISP CODE # 20 ====> < 1 > Open end to disp code
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 18 ***
!REFERRAL INFO
Who is the Research & Development Director or equivalent in your
company?

(ENTER NAME OF R&D DIRECTOR OR EQUIVALENT HERE)
  GO TO Q. # 19 ====> < 1 > Open end single mention
-- ANSWER REQUIRED --

*** QUESTION # 19 ***
At what phone number can I reach [Q18]###?

(ENTER PHONE NUMBER EVEN IF NO CHANGE)
' GO TO Q. # 20 ====> < 1 > Open end single mention
-- ANSWER REQUIRED --

*** QUESTION # 20 ***
May I speak to [Q18]###?
  GO TO Q. #24 ====> < 1 > Yes, transferred to new respondent TO INTRO)
 DISP CODE # 17 ====> < 2 > No, not available now (ARRANGE CALLBACK)
 DISP CODE # 14 ====> < 3 > No,  gatekeeper refusal
 DISP CODE # 14 ====> < 4 > *hold

*** QUESTION # 21 ***
*DUMMY QUESTION IF NEEDED
  GO TO Q. #22 ====> < 1 > #hold
  GO TO Q. #22 ====> < 2 > #hold
  GO TO Q. #22 ====> < 3 > #hold

*** QUESTION # 22 ***
*DUMMY QUESTION IF NEEDED
  GO TO Q. #23 ====> < 1 > #hold
  GO  TO Q. # 23 ====> < 2 > #hold
  GO TO Q. #23 ====> < 3 > #hold

*** QUESTION # 23 ***
*DUMMY QUESTION IF NEEDED
  GO TO Q. #24 ====> < 1 > #hold
  GO TO Q. # 24 ====> < 2 > #hold
  GO TO Q. #24 ====> < 3 > #hold

*** QUESTION # 24 ***
!INTRO:
COMPANY NAME: [04]###
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

Questionnaire name: 6191BS 12/14/93 - 2:27 PM Page: 4

COMPANY PHONE: 01 ###
CONTACT NAME: [ 10 ##
CONTACT PHONE: [12 ###

Hello, I'm [I]### from SRBI,
the national research organization in New York City. We are callin on behalf of the Office of T echnology Assessment (OTA) of the United States Congress. The OTA is conducting a national assessment of the impact of tech nology transfer programs on research and development efforts in the life sciences. As part of this assessment we are conducting a survey of biotechnology company's views on technology transfer and its impact on their R&D efforts.
GO TO Q. #25 ====> < 1 > CONTINUE INTERVIEW
DISP CODE # 9 ====> < 2 > Initial Callback
DISP CODE # 21 ====> < 3 > Respondent Refusal
GO TO Q. # 18 ====> < 4 > Wrong person/enter referral info
DISP CODE # 19 ====> < 5 > Company not involved in biotechnology
GO TO Q. # 17 ====> < 6 > Other reason terminating call

*** QUESTION # 25 ***
-S1- First, just a few back round questions about your company.
Could you tell me which of the following categories best describes

Are you an independent company, a division of a larger company or a subsidiary of a larger company?
GO TO Q. # 30 ====> < 1 > Independent
GO TO Q. #26 ====> < 2 > Division
GO TO Q. #26 ====> < 3 > Subsidiary
GO TO Q. #26
====> < 5 > (VOL) Refused

*** QUESTION # 26 ***
-Sla- Did the larger company acquire your company within the past twelve months?
GO TO Q. # 30 ====> < 1 > Yes
GO TO Q. #27 ====> < 2 > No
GO TO Q. #27 ====> < 3 > (VOL) Not sure
GO TO Q. #27 ====> < 4 > (VOL) Refused

*** QUESTION # 27 ***
-Sib- What is the name of your parent company?

(TYPE IN NAME OF PARENT COMPANY BELOW)
GO TO Q. #28 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 28 ***
-Sic- Would you say that [04]###'s
ties to this parent company are very close, somewhat close, not very close or not at all close?
GO TO Q. #29 ====> < 1 > Very close
GO TO Q. #29 ====> < 2 > Somewhat close
GO TO Q. #29 ====> < 3 > Not very close
GO TO Q. # 29 ====> < 4>Not at all close

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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  GO TO Q. # 29 ====> < 5 > (VOL) Not sure
  GO TO Q. #29 ====> < 6 > (VOL) Refused

*** QUESTION # 29 ***
-Sld- How much direct influence does your parent company have over

 life sciences R&D activities? (READ LIST
  GO TO Q. #30 ====> < 1 > A GREAT DEAL.
  GO TO Q. #30 ====> < 2 > QUITE A BIT,
  GO TO Q. #30 ====> < 3 > SOME OR
  GO TO Q. #30 ====> < 4 > NOT VERY MUCH
  GO TO Q. #30 ====> < 5 > (VOL) Not sure
  GO TO Q. #30 ====> < 6 > (VOL) Refused

*** QUESTION # 30 ***
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q# 25 EQ CODE S 2,3                    CONDITIONAL # 1
   AND Q# 29 EQ CODE S 1,2                    CONDITIONAL # 2
   THEN SHOW CODES 2
    AND HIDE CODES 1
*FOR READ_IN
  GO TO Q. #31 ====> < 1 > your company
  GO TO Q. #31 ====> < 2 > your parent company

*** QUESTION # 31 ***
We would like to get some basic information about the characteristics
of [Q30]###.

~S2- Is [Q30]### conducting or funding research,
either internally or in conjunction with other organizations on...

(ENTER TWICE TO CONTINUE)
  GO TO   . #32 ====> < 1 > Text screen
  -- TEXT SCREEN --

*** QUESTION # 32 ***
-S2a- (Is [Q30] ### conducting or funding research,
either internally or in conjunction with other organizations on...)

DNA SEQUENCING OR GENETIC MAPPING OF THE HUMAN GENOME?
  GO TO Q. #33 ====> < 1 > Yes
  GO TO Q. #33 ====> < 2 > No
  GO TO Q. #33 ====> < 3 > (VOL) Not sure
  GO TO Q. #33 ====> < 4 > (VOL) Refused

*** QUESTION # 33 ***
-S2b- (Is [Q30] ### conducting or funding research,
either internally or in conjunction wit h  other organizations on...)

DNA SEQUENCING OR GENETIC MAPPING OF A MODEL ORGANISM GENOME:
MOUSE FRUIT FLY, ROUNDWORM, YEAST?
  GO TO O. #34 ====> < 1 > Yes
  GO TO Q. # 34 ====> < 2 > No
  GO TO Q. #34 ====> < 3 > (VOL)  Not sure
  GO TO Q. #34 ====> < 4 > (VOL)  Refused
```

Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

```
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*** QUESTION # 34 ***
-S2c- (Is [Q30] ### conducting or funding research,
either internally or in conjunction with other organizations on...)

~SOFTWARE OR DATABASE DESIGN TO SUPPORT GENETIC MAPPING OR DNA
SEQUENCING?
  GO TO Q. #35 ====> < 1 > Yes
  GO TO Q. #35 ====> < 2 > No
  GO TO Q. #35 ====> < 3 > (VOL) Not sure
  GO TO Q. #35 ====> < 4 > (VOL) Refused

*** QUESTION # 35 ***
-S2d- (Is [Q30] ### conducting or funding research,
either internally or in conjunction with other organizations on...)

OTHER TECHNOLOGY TO SUPPORT GENETIC MAPPING OR DNA SEQUENCING?
  GO TO Q. # 36 ====> < 1 > Yes
  GO TO Q. #36 ====> < 2 > No
  GO TO Q. #36 ====> < 3 > (VOL) Not sure
  GO TO Q. #36 ====> < 4 > (VOL) Refused

*** QUESTION # 36 ***
-S2e- (Is [Q30] ### conducting or funding research,
either internally or in conjunction with other organizations on...)

OTHER RESEARCH INVOLVING GENE SPLICING, GENE CLONING, MONOCLINAL
ANTIBODIES, ENZYMOLOGY OR FERMENTATION?
  GO TO Q. # 37 ====> < 1 > Yes
  GO TO Q. # 37 ====> < 2 > No
  GO TO Q. # 37 ====>  < 3 > (VOL) Not sure
  GO TO Q. # 37 ====>  < 4 > (VOL) Refused

*** QUESTION # 37 ***
-S2f- (Is [Q30] ### conducting or funding research,
either internally or in conjunction with other organizations on...)

OTHER AREAS OF LIFE SCIENCE RESEARCH?
  GO TO Q. # 38 ====> < 1 > Yes
  GO TO Q. # 38 ====> < 2 > No
  GO TO Q. # 38 ====>  < 3 > (VOL) Not sure
  GO TO Q. # 38 ====>  < 4 > (VOL) Refused

*** QUESTION # 38 ***
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q# 32 EQ CODE S 1                    (CONDITIONAL #  3)
    OR Q# 33 EQ CODE S 1                    (CONDITIONAL #  4)
    OR Q# 34 EQ CODE S 1                    (CONDITIONAL #  5)
    OR Q#35 EQ CODE( S 1                    (CONDITIONAL #  6)
    OR Q# 36 EQ CODE S 1                    (CONDITIONAL #  7)
    OR Q# 37 EQ CODE S 1                    (CONDITIONAL #  8)
   THEN GO TO Q.# 42 E SE GO TO Q.# 38.
!IF ANY "YES" IN S2a-f SKIP TO S4 ELSE S3a
-S3a- Was [04]###
ever involved in life science research?
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)



```
  GO TO Q. # 39 ====> < 1 >Yes
  GO TO Q. # 41 ====> < 2 >No
  GO TO Q. #41 ====> < 3 > (VOL)  Not sure
  GO TO Q. #41 ====> < 4 > (VOL)  Refused

*** QUESTION # 39 ***
-S3b- Has that life science research has been reassigned to another
division, etc. of [Q30]###?
  GO TO Q. #40 ====> < 1 > Yes
  GO TO Q. #41 ====> < 2 > No
  GO TO Q. #41 ====> < 3 > (VOL)  Not sure
  GO TO Q. #41 ====> < 4 > (VOL)  Refused

*** QUESTION # 40 ***
-S3c- What is the name of that unit/division?

(TYPE IN NAME OF UNIT/DIVISION BELOW)
  GO TO Q. #41 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 41 ***
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q# 39 EQ CODE(S) 1                    (CONDITIONAL # 9)
   THEN SHOW CODES 2
    AND HIDE CODES 1
   << CONDITIONAL ASSOCIATED WITH TH IS QUESTION >>
    IF Q# 39 NE CODE(S) 1                    (CONDITIONAL # 10)
   THEN SHOW CODES 1
    AND HIDE CODES 2
!SCREEN-OUT QUESTION
Thank you for your assistance. The study will focus on organizations
that are currently conducting or funding research in the areas that I
just described, so I won't have to ask you any more questions, but
thank you for all your help.

(ENTER CODE BELOW TO EXIT)
               ====> < 1 > Screen-out/No life science research
 DISP CODE # 23 ====> < 2 > Screen-out/Life science research reassigned
 DISP CODE # 22 ====> < 3 > *hold

*** QUESTION # 42 ***
-S4- Your organization a pears to be conducting the types of life
science research in which we are interested.

We need to know who would be the best person in your organization to
talk to about technology transfer and the type of R&D in life sciences
that you have been supporting. Would that be you or someone else?
  GO TO Q. # 43 ====> < 1 > Respondent
  GO TO Q. #43 ====> < 2 > Someone else

*** QUESTION # 43 ***
-S5- Some of the questions we'd like to ask may require you to check
your files or con fer with others in your office. So, we'd like to
send you a one-page worksheet which includes those questions which
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)



might be hard to answer off the top of your head. In the cover letter we would also explain a little more about the project. Then, we will call you back in about a week and you could read us your answers from the form, as well as answer some questions about your experience and attitudes about technology transfer in the life sciences.
answers will be confiden tial and never attributed to you or our organization. Can I confirm that the mailing address I should send this to is. .. (CONFIRM ADDRESS)

COMPANY NAME: 04 ###
ADDRESS: 05 # #
ADDRESS: 06 ###
CITY: [07 ]##
STATE: 08 ###
ZIP CODE : 09 ###

Is that correct?
GO TO Q. #49 ====> < 1 > Yes, correct
GO TO Q. #44 ====> < 2 > No. not correct
GO TO Q. #44 ====> < 3 > (VOL) Refused

*** QUESTION # 44 ***
Let me correct the information I have. Let's start with the correct company name.

(ENTER COMPANY NAME BELOW)
GO TO Q. #45 ====> < 1 > Open end single mention
-- ANSWER REQUIRED --

*** QUESTION # 45 ***
And the correct street address?

(ENTER STREET ADDRESS BELOW)
GO TO Q. #46 ====> < 1 > Open end single mention
-- ANSWER REQUIRED --

*** QUESTION # 46 ***
The correct city?

(ENTER CITY BELOW)
GO TO Q. #47 ====> < 1 > Open end single mention
-- ANSWER REQUIRED --

*** QUESTION # 47 ***
The correct state?

(ENTER STATE BELOW)
GO TO Q. #48 ====> < 1 > Open end single mention
-- ANSWER REQUIRED --

*** QUESTION # 48 ***
The correct zip code?

(ENTER ZIP BELOW)
GO TO Q. # 49 ====> < 1 > Open end single mention

Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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-- ANSWER REQUIRED --

*** QUESTION # 49 ***
!ASK ALL
To whose attention should I sent the letter?

(ENTER NAME BELOW)
GO TO Q. #50 ====> < 1 > Open end single mention
-- ANSWER REQUIRED --

*** QUESTION # 50 ***
And what is [Q49]###'s title?

(ENTER TITLE BELOW)
====> < 1 > Open end single mention
-- ANSWER REQUIRED --

*** QUESTION # 51 ***
!CLOSING
Thank you so much for your help. We will be sending you a letter right away and we will be back in touch about a week later. Thank You for all of your help. That completes the interview.

/ENTER YOUR INITIALS TO COMPLETE)
' GO TO Q. #52 ====> < 1 > Open end single mention
-- ANSWER REQUIRED --

Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

## WORKSHEET FOR THE U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT SURVEY OF BIOMEDICAL AND BIOTECHNOLOGY FIRMS

**PLEASE PROVIDE THE FOLLOWING INFORMATION.**

A1. Which of the following categories best describes your company? *(Please circle one)*

INDEPENDENT .....1
DIVISION-----.---...-..ti .....2
SUBSIDIARY...-.-...---.-.-3

IF YOUR COMPANY IS A DIVISION OR SUBSUDIARY OF A PARENT COMPANY, PLEASE ANSWER THE FOLLOWING QUESTIONS FOR YOUR PARENT COMPANY IF INFORMATION IS KNOWN.

IF YOUR COMPANY IS AN INDEPENDENT OR IF PARENT COMPANY INFORMATION IS UNKNOWN, PLEASE ANSWER THE FOLLOWING QUESTIONS FOR YOUR OWN COMPANY.

A3B. When was your [parent] company incorporated? **19**_____

**A4.** What is your [parent] company's projected gross revenue for your current fiscal year? $_____

**A4a.** What is your [parent] company's projected total dollar volume of sales for ALL products and services for your current fiscal year? **$**_____

A4b. What is your [parent] company's projected royalty revenue for your current fiscal year? **$**_____

A5. What is your [parent] company's projected total R&D budget for your current fiscal year? *Please include both continuing and new projects.* $_____

A6. What is your [parent] company's projected R&D budget for life sciences for your current fiscal year? **$**_____

A7. How many employees does your [parent] company have? *(Please estimate full time equivalents.)* _____ # of Employees

A8. Approximately how many life sciences patents has your [parent] company APPLIED for in the past five year(s)? _____ # of Patents

A9. Approximately how many life sciences patents has your [parent] company OBTAINED in the past five year(s)? _____ # of Patents

A1O. How many life sciences products does your [parent] company have on the market? _____ #of Products

AII. How many of these life science products required regulatory review prior to marketing? _____ # of Products

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

**A12.** Approximately how many life sciences products does your [parent] company have currently undergoing federal regulatory review (FDA, EPA, USDA) prior to marketing?
_____ # of Products

**B4.** Has your [parent] company had life science CRADAs (Cooperative Research and Development Agreements) with any of the National Institutes of Health or the Department of Energy?
YES.....1 *Continue with* E9.
NO.....2 *Skip to End of Form*

E9. How many life sciences patents obtained by your [parent] company in the last five years have been based fully or partially on work done in your [parent] company's CRADA(s)?
_____ # of Patents

E10. How many of the life sciences patents applied for in the last five years by your [parent] company have been based fully or partially on work done in the company's CRADA(s)?
_____ # of Patents

**E11.** How many of the life sciences products marketed by your [parent] company have been based fully or partially on work done in the company's CRADA(s)?
_____ # of Products

**E12.** How many products does your [parent] company have undergoing federal regulatory review prior to marketing that have been based fully or partially on the company's CRADA(s)?
_____ # of Products

E13. Over the last five years, approximately what percent of your [parent] company's total gross revenues from all sources including royalties from licenses was derived from products based fully or partially on the company's CRADA(s)?
_____ % of Gross Revenues

E13a. For the past five years, what was your [parent] company's total gross revenue from these products?
$_____ Gross Revenue

**E14.** For the past five years, what is your [parent] company's total gross sales revenue from products based fully or partially on the company's CRADA(s)?
$_____ Gross Revenue

E15. Over the last five years, approximately what percent of your [parent] company's total gross revenues was derived from royalty income for products based fully or partially on the company's CRADA(s)?
_____ % of Gross Revenues

E15a. For the past five year(s), what is your [parent] company's royalty income from licenses to which the CRADA contributed?
$_____ Royalty Income

**AFTER COMPLETING THIS FORM, PLEASE RETAIN IT UNTIL SRBI CALLS TO COLLECT THE INFORMATION.**

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

Questionnaire name: 6191B 12/15/93 - 11 :41 AM Page: 1

```
*** QUESTION # 1 ***
*Schulman Ronca & Bucuvalas, Inc. 444 Park Ave. South, NY NY
Study #6191B Survey of Biomedical and Biotechnology Firms Involvement
in Patenting Human DNA Sequences - Business

SAMPLE READ-IN: COMPANY PHONE NUMBER
                ====> < 1 > #hold
  GO TO Q: # 2  ====> < 2 > [01]###

*** QUESTION # 2 ***
*SAMPLE READ-IN: COMPANY NAME
  GO TO Q. # 3 ====> < 1 > #hold
  GO TO Q. # 3 ====> < 2 > [??]###

*** QUESTION # 3 ***
*SAMPLE READ-IN: ADDRESS 1
  GO TO Q. # 4 ====> < 1 > #hold
  GO TO Q. # 4 ====> < 2 > [??]###

*** QUESTION # 4 ***
*SAMPLE READ-IN: ADDRESS 2
  GO TO Q. # 5 ====> < 1 > #hold
  GO TO Q. # 5 ====> < 2 > [??]###

*** QUESTION # 5 ***
*SAMPLE READ-IN: CITY
  GO TO Q. # 6 ====> < 1 > #hold
  GO TO Q. # 6 ====> < 2 > [??]###

*** QUESTION # 6 ***
*SAMPLE READ-IN: STATE
  GO TO Q. # 7 ====> < 1 > #hold
  GO TO Q. # 7 ====> < 2 > [??]###

*** QUESTION # 7 ***
*SAMPLE READ-IN: ZIP CODE
  GO TO Q. # 8 ====> < 1 > #hold
  GO TO Q. # 8 ====> < 2 > [??]###

*** QUESTION # 8 ***
*SAMPLE READ-IN: CONTACT NAME
  GO TO Q. # 9 ====> < 1 > #hold
  GO TO Q. # 9 ====> < 2 > [??]###

*** QUESTION # 9 ***
*SAMPLE READ-IN: CONTACT PHONE
  GO TO Q. # 10 ====> < 1 > #hold
  GO TO Q. # 10 ====> < 2 > [??]###

*** QUESTION # 10 ***
*SAMPLE READ-IN: CONTACT TITLE
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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```
  GO TO Q. # 11 ====> < 1 > #hOld
  GO TO Q. # 11 ====> < 2 > [??]###

*** QUESTION # 11 ***
*SAMPLE READ-IN: ORGANIZATION NUMBER
  GO TO Q. # 12 ====> < 1 > #hold
  GO TO Q. # 12 ====> < 2 > [??]###

*** QUESTION # 12 ***
*SAMPLE READ-IN: Respondent NUMBER FROM SCREENER
  GO TO Q. # 13 ====> < 1 > #hold
  GO TO Q. # 13 ====> < 2 > [??]###

*** QUESTION # 13 ***
SAMPLE READ-IN: SAMPLE TYPE
  GO TO Q. # 14 ====> < 1 > *NIH/CRADA
  GO TO Q. # 14 ====> < 2 > *DOE/CRADA
  GO TO Q. # 14 ====> < 3 > *FOR TUNE/NON-CRADA
  GO TO Q. # 14 ====> < 4 > *NON-FOR T UNE/NON-CRADA
  GO TO Q. # 14 ====> < 5 > [??]###

*** QUESTION # 14 ***
*SAMPLE READ-IN: FOR WORDING
  GO TO Q. # 15 ====> < 1 > *your company
  GO TO Q. # 15 ====> < 2 > *your parent company
  GO TO Q. # 15 ====> < 3 > [??]###

*** QUESTION # 15 ***
*DUMMY QUESTION 15
  GO TO Q. # 16 ====> < 1 > #hold
  GO TO Q. # 16 ====> < 2 > #hold

*** QUESTION # 16 ***
*DUMMY QUESTION 16
  GO TO Q. # 17 ====> < 1 > #hold
  GO TO Q. # 17 ====> < 2 > #hold

*** QUESTION # 17 ***
*DUMMY QUESTION 17
  GO TO Q. # 18 ====> < 1 > #hold
  GO TO Q. # 18 ====> < 2 > #hold

*** QUESTION # 18 ***
*DUMMY QUESTION 18
  GO TO Q. # 19 ====> < 1 > #hold
  GO TO Q. # 19 ====> < 2 > #hold

*** QUESTION # 19 ***
*DUMMY QUESTION 19
  GO TO Q. #20 ====> < 1 > #hold
  GO TO Q. #20 ====> < 2 > #hold

*** QUESTION # 20 ***
!SWITCHBOARD INTRO:
Hello, may I speak to
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

```
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 [??]###

 (IF NECESSARY:) I'm [1]### from SRBI,
 the national research organization in New York City. We contacted you
 two weeks ago about the study we are conducting for the U.S. Congress
 Office of Technology Assessment about technology transfer and Research
 and Development in biotechnology
   GO TO Q. # 27 ====>  < 1 > CONTI NUE INTERVIEW
  DISP CODE # 1         < 2 > No answer
  DISP CODE # 12 ====>  < 3 > Answering machine
  DISP CODE # 2 ====>   < 4 > Bus signal
  DISP CODE # 9 ====>   < 5 > Initial Callback
  DISP CODE # 13 ====>  < 6 > Away for duration
  DISP CODE # 6 ====>   < 7 > Initial Refusal
  DISP CODE # 3 ====>   < 8 > Disconnected phone/NIS
  DISP CODE # 8 ====>   < 9 > Language barrier
  DISP CODE # 14 ====>  < 10 > Gatekeeper Refusal
  DISP CODE # 15 ====>  < 11 > Call cannot be completed
  DISP CODE # 16 ====>  < 12 > Second refusal
  DISP CODE # 17 ====>  < 13 > No such person/doesn't work here
  DISP CODE # 18 ====>  < 14 > Company out of business
   GO TO Q. # 21 ====>  < 15 > Other reason terminating call

 *** QUESTION # 21 ***
 (INTERVIEWER:  THIS QUESTION WILL ELIMINATE THIS PHONE NUMBER FROM THE
          IF THIS NUMBER CAN BE DIALED AGAIN, BACK-UP AND CHOOSE ANOTHER
 .CODE TO THE PREVIOUS QUESTION.  IF THIS NUMBER CAN NOT BE DIALED AGAIN,
 .ENTER THE REASONS WHY BELOW TO EXIT.)
  DISP CODE # 19 ====> < 1 > Open end to disp code
 -- MULTI-PUNCH --
 -- ANSWER REQUIRED --

 *** QUESTION # 22 ***
 *DUMMY QUESTION IF NEEDED
   GO TO Q. #23 ====> < 1 > #hold
   GO TO Q. #23 ====> < 2 > #hold

 *** QUESTION # 23 ***
 *DUMMY QuESTION IF NEEDED
   GO TO Q. #24 ====> < 1 > #hold
   GO TO Q. #24 ====> < 2 > #hold

 *** QUESTION # 24 ***
 *DUMMY QUESTION IF NEEDED
   GO TO Q. #25 ====> < 1 > #hold
   GO TO Q. #25 ====> < 2 > #hold

 *** QUESTION # 25 ***
 *DUMMY QUESTION IF NEEDED
   GO TO Q. #26 ====> < 1 > #hold
   GO TO Q. # 26 ====> < 2 > #hold

 *** QUESTION # 26 ***
*DUMMY QUESTION IF NEEDED
   GO TO Q. # 27 ====> < 1 > #hold
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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GO TO Q. # 27 ====> < 2 > #hold

***QUESTION # 27 ***

COMpANY NAME: [?? ###
COMPANY PHONE: [? ###
CONTACT NAME: [.? ##
CONTACT PHONE: [?]###

Hello, I'm [I]### from SRBI,
the nationa/ research organization in New York City. We contacted YOU two weeks ago about the study we are conducting for the U.S. Congress Office of Technology Assessment about technology transfer and Research and Development in biotechnology companies.

GO TO Q. # 28 ====> < 1 > CONTINUE INTERVIEW
DISP CODE # 1 ====> < 2 > No answer
DISP CODE # 12 ====> < 3 > Answering machine
DISP CODE # 2 ====> < 4 > Busy signal
DISP CODE # 22 ====> < 5 > Respondent Callback
DISP CODE # 21 ====> < 6 > Respondent Refusal
DISP CODE # 16 ====> < 7 > Second refusal
DISP CODE # 17 ====> < 8 > Wrong person/doesn't work here
GO TO Q. # 21 ====> < 9 > Other reason terminating call

*** QUESTION # 28 ***

-A1-"Last week we mailed you a letter about this project asking you to fill out some information about [Q14]### on a recordin form.
Have you had an opportunity to complete the recording form that we sent you?

GO TO Q. #34 ====> < 1 > Yes
GO TO Q. #32 ====> < 2 > No
GO TO Q. #29 ====> < 3 > No, never got form

*** QUESTION # 29 ***

I'm sorry you never got the form. Can I have your name and fax number so I can fax you thatas soon as possible? First, your name...

(ENTER CONTACT NAME HERE)
GO TO . #30 ====> < 1 > Open end single mention
-- ANSWER REQUIRED --

*** QUESTION # 30 ***

And your fax number. . .

(ENTER FAX NUMBER HERE)
GO TO Q. # 31 ====> < 1 > Open end single mention
-- ANSWER REQUIRED --

*** QUESTION # 31 ***

We'll fax you a copy as soon as possible. Thank you for your time.

(ENTER CODE BELOW TO EXIT.
DISP CODE # 20 ====> < 1 > Fax worksheet
DISP CODE # 20 ====> c 2 > *hold
DISP CODE # 20 ====> < 3 > *hold

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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```
*** QUESTION # 32 ***
-A2- It is very important that your organization be incl uded in
this study.  Could I contact you later this week and co llect your
information?
  GO TO Q. #33 ====> < 1 > Yes
 DISP CODE # 21 ====> < 2 > No, refused interview

*** QUESTION # 33 ***
-A3- When could I contact you to collect this  informatio n?

(ENTER CODE BELOW)
 DISP CODE # 22 ====> < 1 > Arrange  callback
 DISP CODE # 22 ====> < 2 > *hold
 DISP CODE # 22 ====> < 3 > *hold

*** QUESTION # 34 ***
!WORKSHEET INFO
-A4- Let's go over the recording sheet now.

(ENTER TWICE TO CONTINUE)
  GO TO Q. #35 ====> < 1 > Text screen
  -- TEXT SCREEN --

*** QUESTION # 35 ***
Starting with question A1, what is your answer to the question. . .

~A1- Which of the following categories best describes your company?
(READ LIST)
  GO TO Q. #36 ====> < 1 > INDEPENDENT
  GO TO Q. #36 ====> < 2 > DIVISION
  GO TO Q. #36 ====> < 3 > SUSIDIARY

*** QUESTION # 36 ***
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q# 35 EQ CODE(S) 1                          (CONDITIONAL # 1)
   THEN SHOW CODES 1
    AND HIDE CODES 2
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q# 35 EQ CODE(S) 2,3                        (CONDITIONAL # 2)
   THEN SHOW CODES 2
    AND HIDE CODES 1
*FOR WORDING . IF A1=INDEPENDENT. SHOW 1 HIDE 2
IF A1=DIVISION OR SUBSIDIARY, SHOW 2 HIDE 1
  GO TO Q. #37 ====> < 1 > your company
  GO TO Q. #37 ====> < 2 > your parent company

*** QUESTION # 37 ***
-A3b- When was [Q36]### incorporated?

~ENTER LAST 2 DIGITS OF YEAR BELOW. NOT SURE=98 REFUSED=99)


  GO TO Q. # 38 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS           .              99---
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

```
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 -- ANSWER REQUIRED --

 *** QUESTION # 38 ***
 -A4- What is [Q36] ###'s projected gross revenue
 for your current fiscal year?

 (ENTER ANSWER IN MILLIONS.       9998=DON'T KNOW    9999=REFUSED
 .    1=$1 MILLION OR LESS    9997=$9 BILLION 997 MILLION OR MORE)
   GO TO Q. #39 ====> < 1 > Numeric open end range 0-9999
 -- NUMERIC OPEN END - RANGE IS          0. THRU       9999---
 -- ANSWER REQUIRED --

 *** QUESTION # 39 ***
 -A4a- What is [Q36]###'s projected total dollar volume
 of sales of ALL products and services for your current fiscal year?

 (ENTER ANSWER IN MILLIONS.       9998=DON'T KNOW    9999=REFUSED
 .    1=$1 MILLION OR LESS    9997=$9 BILLION 997 MILLION OR MORE)
   GO TO Q. #40 ====> < 1 > Numeric open end range 0-9999
 -- NUMERIC OPEN END - RANGE IS           .            9999---
 -- ANSWER REQUIRED --

 *** QUESTION # 40 ***
 -A4b- What is [Q36]###'s projected royalty revenue for your
 current fiscal year?

 (ENTER WHOLE NUMBER BELOW.    NONE=0    8=DON'T KNOW    9=REFUSED)
   GO TO Q. #41 ====> < 1 > Numeric open end range 0-9999999
 -- NUMERIC OPEN END - RANGE IS           .               .--
 -- ANSWER REQUIRED --

 *** QUESTION # 41 ***
 -A5- What is [Q36] ###'s projected total R&D budget
 for your current fiscal year?  Please include both continuing and
 new projects.

 (ENTER ANSWER IN MILLIONS.       9998=DON'T KNOW    9999=REFUSED
 .    1=$1 MILLION OR LESS    9997=$9 BILLION 997 MILLION OR MORE)
   GO TO         ====> < 1 > Numeric open end range 0-9999
 -- NUMERIC  OPEN END - RANGE IS           .               .--
 -- ANSWER REQUIRED --

 *** QUESTION # 42 ***
 -A6- What is [Q36]###'s projected R&D budget for
 life sciences for your current fiscal year?

 (ENTER ANSWER IN MILLIONS.       9998=DON'T KNOW    9999=REFUSED
 .    1=$1 MILLION OR LESS    9997=$9 BILLION 997 MILLION OR MORE)
   GO TO Q. #43 ====> < 1 > Numeric open end range 0-9999
 -- NUMERIC OPEN END - RANGE IS           .               .--
 -- ANSWER REQUIRED --

 *** QUESTION # 43 ***
 -A7- How many employees does [Q36]### have?
 Please estimate fulltime equivalents.
```

Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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(ENTER NUMBER BELOW. 999998=DON'T KNOW 999999=REFUSED
====> < 1 > Numeric open end range 0-999999
-- NUMERIC OPEN END - RANGE IS . .--
-- ANSWER REQUIRED --

*** QUESTION # 44 ***
-A8- Approximately how many life sciences patents has
[Q36]### APPLIED for in the past five years?

(ENTER NUMBER BELOW. 97=97 OR MORE 98=DON'T KNOW 99=REFUSED)
GO TO Q. #45 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS 0. THRU 99---
-- ANSWER REQUIRED --

*** QUESTION # 45 ***
-A9- Approximately how many life sciences patents has
[Q36]### OBTAINED In the past five years?

(ENTER NUMBER BELOW. 97=97 OR MORE 98=DON'T KNOW 99=REFUSED)
GO TO Q. #46 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION # 46 ***
-A10- How many life sciences products does [Q36]###
have on the market?

{ENTER NUMBER BELOW. 97=97 OR MORE 98=DON'T KNOW 99=REFUSED)
GO TO Q. #47 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION # 47 ***
-All- How man of these life science products required regulatory
review prior to marketing?

(ENTER NUMBER BELOW. 97=97 OR MORE 98=DON'T KNOW 99=REFUSED)
====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION # 48 ***
-A12- Approximately how many life sciences products does
[Q36] ### have currently undergoin federal
regulatory review (FDA, EPA, USDA prior to marketing?

{ENTER NUMBER BELOW. 97=97 OR MORE 98=DON'T KNOW 99=REFUSED)
GO TO Q. #49 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION # 49 ***
-B4- Has [Q36] ### had life science CRADAs
(Cooperative Research and Development Agreements) with any of the

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)



National Institutes of Health NIH)?
GO TO Q. # 50 ====> < 1 > Yes
GO TO Q. # 50 ====> < 2 > No

*** QUESTION # 50 ***
-65- Has [Q36] ### had life science CRADAs
Cooperative Research and Development Agreements) with the
Department of Energy (DOE)?
GO TO Q. # 51 ====> < 1 > Yes
GO TO Q. #51 ====> < 2 > No

*** QUESTION # 51 ***
-E9- How many life sciences patents obtained by [Q36]###
in the last five ears have been based fully or partially on work done
in [Q36]###'s CRADA(s)?

(ENTER NUMBER BELOW. 97=97 OR MORE 98=DON'T KNOW 99=REFUSED)
GO TO Q. # 52 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION # 52 ***
-E10- How man of the life sciences patents applied for in the last five
years by [Q36 ### have been based fully or partially
on work done In the company's CRADA(s)?

(ENTER NuMBER BElOw. 97=97 OR MORE 98=DON'T KNOW 99=REFUSED)
GO TO Q. # 53 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS 0. THRU 99---
-- ANSWER REQUIRED --

*** QUESTION # 53 ***
-En- How many of the life sciences products marketed by
[Q36]### have been based fully or partially
on work done in the company's CRADA(s)?

(ENTER NUMBER BELOW. 97=97 OR MORE 98=DON'T KNOW 99=REFUSED)
GO TO Q. #54 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION # 54 ***
-E12- How many products does [Q36]### have
undergoing federal regulatory review prior to marketing that have been
based fully *or* partially on the company's CRADA(s)?

(ENTER NUMBER BELOW. 97=97 OR MORE 98=DON'T KNOW 99=REFUSED)
GO TO Q. #55 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION # 55 ***
-E13- Over the last five years, approximately what percent of
[Q36]###'s total gross revenues from all sources
Including royalties from licenses was derived from products based fully

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)



or partially on the company's CRADA(s)?

(ENTER PERCENTAGE BELOW. ALL=100 101=DON'T KNOW 102=REFUSED)
GO TO Q. #56 ====> < 1 > Numeric open end range 0-102
-- NUMERIC OPEN END - RANGE IS 0. THRU 1o2---
-- ANSWER REQUIRED --

*** QUESTION # 56 ***
-E13a- For the past five years, what was [Q36]###'s
total gross revenue from these products?

~ENTER ANSWER IN MILLIONS. 9998=DON'T KNOW 9999=REFUSED
. 1=$1 MILLION OR LESS 9997=$9 BILLION 997 MILLION OR MORE)
GO TO Q. #57 ====> < 1 > Numeric open end range 0-9999
-- NUMERIC OPEN END - RANGE IS 0. THRU 9999---
-- ANSWER REQUIRED --

*** QUESTION # 57 ***
-E14- For the past five years, what is *[Q36]###'s*
total gross sa/es revenue from products based fully or partially on the
company's CRADA(s)?

{ENTER ANSWER IN MILLIONS. 9998=DON'T KNOW 9999=REFUSED
. 1=$1 MILLION OR LESS 9997=$9 BILLION 997 MILLION OR MORE)
GO TO Q. # 58 ====> < 1 > Numeric open end range 0-9999
-- NUMERIC OPEN END - RANGE IS 0. THRU 9999---
-- ANSWER REQUIRED --

*** QUESTION # 58 ***
-E15- Over the last five years, approximately what percent of
[Q36 ###'s total gross revenues was derived from
royalty income for products based fully or partially on the company's
CRADA(s)?

(ENTER PERCENTAGE BELOW. ALL=100 101=DON'T KNOW 102=REFUSED)
GO TO Q. #59 ====> < 1 > Numeric open end range 0-102
-- NUMERIC OPEN END - RANGE IS 0. THRU 1o2---
-- ANSWER REQUIRED --

*** QUESTION # 59 ***
-E15a- For the past five years, what was [Q36] ###'s
royalty income from licenses to which the CRADA contributed?

{ENTER ANswER iN MILLIONS. 9998=DON'T KNOW 9999=REFUSED
. 1=$1 MILLION OR LESS 9997=$9 BILLION 997 MILLION OR MORE)
GO TO Q. # 60 ====> < 1 > Numeric open end range 0-9999
-- NUMERIC OPEN END - RANGE IS . 9999---
-- ANSWER REQUIRED --

*** QUESTION # 60 ***
Now, I would like to ask you a few more general questions about
[Q36]###, the types of research it supports,
and your experience in obtaining any CRADA.

(PROMPT, IF NECESSARY:) CRADA stands for "Cooperative Research

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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and Development Agreement". CRADAs are legal instruments whereby .a company and a government entity agree to work together to promote specific applications of government research.

(ENTER TWICE To CONTINUE)
GO TO Q. # 61 ====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION # 61 ***
<< CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
IF Q# 49 EQ CODE S 1 CONDITIONAL # 3
OR Q# 50 EQ CODE S 1 CONDITIONAL # 4
THEN GO TO Q.# 65 E SE GO TO Q.# 61.
!SECTION B: COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS (CRADAs)
!IF YES IN B4 OR B5 FROM WORKSHEET, GO TO B2 ELSE B1
-B1- Has [Q36]### ever applied for any CRADA?

(PROMPT, IF NECESSARY:) CRADA stands for "Cooperative Research and Development Agreement". CRADAs are legal instruments whereby .a company and a government entity agree to work together to promote specific applications of government research.
GO TO Q. # 62 ====> < 1 > Yes, your company
GO TO Q. #62 ====> < 2 > Yes, parent company
GO TO Q. #62 ====> < 3 > Yes, both
GO TO Q. #175 ====> < 4 > No
GO TO Q. #175 ====> < 5 > (VOL) Not sure
GO TO Q. #175 ====> < 6 > (VOL) Refused

*** QUESTION # 62 ***
-Bla- Has [Q36] ### ever entered into a CRADA?
====> < 1 > Yes, your company
GO TO Q: #63 ====> < 2 > Yes, parent company
GO TO Q. #63 ====> < 3 > Yes, both
GO TO Q. # 64 ====> < 4 > No
GO TO Q. #64 ====> < 5 > (VOL) Not sure
GO TO Q. #64 ====> < 6 > (VOL) Refused

*** QUESTION # 63 ***
-Blb~ Were any of these life sciences CRADAs?
GO TO Q. #64 ====> < 1 > Yes, your company
GO TO Q. #64 ====> < 2 > Yes, parent company
GO TO Q. #64 ====> < 3 > Yes, both
GO TO Q. #64 ====> < 4 > No
GO TO Q. #64 ====> < 5 > (VOL) Not sure
GO TO Q. # 64 ====> < 6 > (VOL) Refused

*** QUESTION # 64 ***
-Blc- Has [ 36 ### ever applied for a life sciences CRADA?
GO TO Q. 6 ====> < 1 > Yes, your company
GO TO Q. #65 ====> < 2 > Yes, parent company
GO TO Q. #65 ====> < 3 > Yes, both
GO TO Q. #182 ====> < 4 > No
GO TO Q. #182 ====> < 5 > (VOL) Not sure
GO TO Q. #182 ====> < 6 > (VOL) Refused

*** QUESTION # 65 ***

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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<< CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
IF Q# 49 EQ CODE(S) 1 (CONDITIONAL # 5)
THEN GO TO Q.# 66 ELSE GO TO Q.# 65.
!IF YES IN B4 SKIP TO B3
-B2- Has [Q36]### ever applied to the
National Institutes of Health NIH)?
GO TO Q. #66 ====> < 1 >Yes
GO TO Q. #80 ====> < 2 > No
GO TO Q. #80 ====> < 3 > (VOL) Not sure
GO TO Q. #80 ====> < 4 > (VOL) Refused

*** QUESTION # 66 ***
-B2al- To which institute at NIH was your most recent application?

(ENTER NAME OF INSTITUTE BELOW
GO TO Q. #67 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 67 ***
-B2bl- In which year was this application made?

(ENTER LAST 2 DIGITS OF YEAR BELOW. DON'T KNOW=98 REFUSED=99)

19
GO TO Q. # 68 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99.--
-- ANSWER REQUIRED --

*** QUESTION # 68 ***
An others?
GO TO Q. # 69 ====> < 1 > Yes
GO TO Q. # 80 ====> < 2 > No

*** QUESTION" # 69 ***
-B2a2- To which institute at NIH was your next most recent application?

(ENTER NAME OF INSTITUTE BELOW
GO TO Q. #70 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 70 ***
-B2b2- In which year was this application made?

(ENTER LAST 2 DIGITS OF YEAR BELOW. DON'T KNOW=98 REFUSED=99)

19
GO TO Q. #71 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION # 71 ***
Any others?
GO TO Q. # 72 ====> < 1 > Yes

Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)



GO TO Q. # 80 ====> < 2 >No

*** QUESTION # 72 ***
-B2a3- To which institute at NIH was your next most recent application?

(ENTER NAME OF INSTITUTE BELOW
GO TO Q. # 73 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 73 ***
-B2b3- In which year was this application made?

(ENTER LAST 2 DIGITS OF YEAR BELOW. DON'T KNOW=98 REFUSED=99)

19
GO TO Q. #74 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION # 74 ***
Any others?
GO TO Q. #75 ====> < 1 > Yes
GO TO Q. #80 ====> < 2 > No

*** QUESTION # 75 ***
-B2a4- To which institute at NIH was your next most recent application?

(ENTER NAME OF INSTITUTE BELOW
GO TO Q. #76 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 76 ***
-B2b4- In which year was this application made?

(ENTER LAST 2 DIGITS OF YEAR BELOW. DON'T KNOW=98 REFUSED=99)

19
GO TO Q. #77 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION # 77 ***
Any others?
GO TO Q. #78 ====> < 1 > Yes
GO TO Q. #80 ====> < 2 > No

*** QUESTION # 78 ***
-B2a5- To which institute at NIH was your next most recent application?

(ENTER NAME OF INSTITUTE BELOW
GO TO Q. # 79 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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```
*** QUESTION # 79 ***
-B2b5- In which year was this application made?

(ENTER LAST 2 DIGITS OF YEAR BELOW.   DON'T KNOW=98 REFUSED=99)


  GO TO Q. #80 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS          0. THRU         99---
-- ANSWER REQUIRED --

*** QUESTION # 80 ***
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q# 50 EQ CODE(S) 1                        (CONDITIONAL # 6)
   THEN GO TO Q. # 81 EL SE GO TO Q.# 80.
!IF YES IN B5 SKIP TO CHECKPOINT
-B3- Has [Q36]### ever a lied to the
Department of Energy (DOE) ?
  GO TO Q. # 81 ====> < 1 > Yes
  GO TO Q. # 95 ====> < 2 > No
  GO TO Q. # 95 ====> < 3 > (VOL) Not sure
  GO TO Q. # 95 ====> < 4 > (VOL) Refused

*** QUESTION # 81 ***
-B3al- To which DOE laboratory was your most recent appl ication?

(ENTER NAME OF LABORATORY BELOW)
  GO TO Q. # 82 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 82 ***
-B3bl- In which year was this application made?
.
(ENTER LAST 2 DIGITS OF YEAR BELOW. DON'T KNOW=98 REFUSED=99)

  19
  GO TO Q.#83 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS          0. THRU         99---
-- ANSWER REQUIRED --

*** QUESTION # 83 ***
Any others?
  GO TO Q. # 84 ====> < 1 > Yes
  GO TO Q. #95 ====> < 2 > No

*** QUESTION # 84 ***
-B3a2- To which DOE laboratory was your next most recent application?

(ENTER NAME OF Laboratory BELOW)
  GO TO Q. # 85 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 85 ***
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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-B3b2- In which year was this application made?

(ENTER LAST 2 DIGITS OF YEAR BELOW. DON'T KNOW=98 REFUSED=99)

GO TO Q. # 86 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS 0. THRU 99---
-- ANSWER REQUIRED --

*** QUESTION # 86 ***
An others?
GO TO Q. #87 ====> < 1 > Yes
GO TO Q. #95 ====> < 2 > No

*** QUESTION # 87 ***
-B3a3- To-which-DOE laboratory was your next most recent application?

(ENTER NAME OF LABORATORY BELOW)
GO TO Q. #88 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 88 ***
-B3b3- In which year was this application made?

(ENTER LAST 2 DIGITS OF YEAR BELOW. DON'T KNOW=98 REFUSED=99)

19
GO TO Q. #89 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS 99---
-- ANSWER REQUIRED --

*** QUESTION # 89 ***
Any others?
GO TO Q. #90 ====> < 1 > Yes
GO TO Q. #95 ====> < 2 > No

*** QUESTION # 90 ***
-B3a4- To which DOE laboratory was your next most recent application?

(ENTER NAME OF LABORATORY BELOW)
GO TO Q. # 91 ====> < 1 > open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 91 ***
-B3b4- In which year was this application made?

(ENTER LAST 2 DIGITS OF YEAR BELOW. DON'T KNOW=98 REFUSED=99)

19
GO TO Q.#92 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS 99---
-- ANSWER REQUIRED --

*** QUESTION # 92 ***

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)



```
Any others?
  GO TO Q. #93 ====> < 1 > yes
  GO TO Q. #95 ====> < 2 > No

*** QUESTION # 93 ***
-B3a5- To which DOE laboratory was your next most recent application?

(ENTER NAME OF LABORATORY BELOW)
  GO TO Q. #94 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 94 ***
-B3b5- In which year was this application made?

(ENTER LAST 2 DIGITS OF YEAR BELOW. DON'T KNOW=98  REFUSED=99)

. 19
  GO TO  . # 95 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS .  99.--
-- ANSWER REQUIRED --

*** QUESTION # 95 ***
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>  CONDITIONAL # 7
    IF Q# 62 EQ CODE S 4-6                          CONDITIONAL # 8
    OR Q# 63 EQ CODE S 4-6
   THEN GO TO  Q.#151 E SE GO TO Q.# 95.
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>  (CONDITIONAL # 9)
    IF Q# 49 EQ CODE(S) 1
   THEN GO TO  Q.# 95 E SE GO TO Q.#103.
!IF NO/NOT SURE/ REFUSED IN B1a OR B1b SKIP TO F1a ELSE B4
!IF YES TO B4 FROM WORKSHEET ASK B4 ELSE B5
-B4- Earlier you said [Q36] ### had
life science CRADAs with the National Institutes of Health (NIH).

(ENTER CODE BELOW TO CONTINUE)
  GO TO Q. # 96 ====> < 1 > CONTINUE
  GO TO Q. #96 ====> < 2 > *hold

*** QUESTION # 96 ***
-B4a- How many CRADAs has [Q36]### had with NIH,
including those now ongoing?

(ENTER NUMBER BELOW.     NOT SURE=98 REFUSED=99)
  GO TO Q. #97 ====> < 1 > Numeric open end range 1-99
-- NUMERIC OPEN END - RANGE IS .  99.--
-- ANSWER REQUIRED --

*** QUESTION # 97 ***
   <C CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q# 96 EQ          1 TO          97          (CONDITIONAL # 10)
   THEN GO TO Q.# 97 ELSE GO TO Q.#102
!IF B4a=l-97
-B4bl- With which institute at NIH do you have the first CRADA?
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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(ENTER NAME OF INSTITUTE BELOW
GO TO Q. #98 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 98 ***
<< CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
IF Q# 96 EQ 2 TO 97 (CONDITIONAL # 11)
THEN GO TO Q.# 98 ELSE GO TO Q.#102.
!IF B4a=2-97
-B4b2- With which institute at NIH do you have the second CRADA?

(ENTER NAME OF INSTITUTE BELOW
GO TO Q. #99 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION # 99 ***
<< CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
IF Q# 96 EQ 97 (CONDITIONAL # 12)
THEN GO TO Q.# 99 ELSE GO TO Q.#102
!IF B4a=3-97
-B4b3- With which institute at NIH do you have the third CRADA?

(ENTER NAME OF INSTITUTE BELOW
GO TO Q. #100 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION #100 ***
<< CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
IF Q# 96 EQ 97 (CONDITIONAL # 13)
THEN GO TO Q.#100 ELSE GO TO Q.#102
!IF B4a=4-97
-B4b4- With which institute at NIH do you have the fourth CRADA?

(ENTER NAME OF INSTITUTE BELOW
GO TO Q. #101 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION #101 ***
<< CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
IF Q#96 EQ 97 (CONDITIONAL # 14)
THEN GO TO Q.#101 ELSE GO TO Q.#102
!IF B4a=5-97
-B4b5- With which institute at NIH do you have the fifth CRADA?

(ENTER NAME OF INSTITUTE BELOW
GO TO Q. #102 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION #102 ***
-B4c- In what year did [Q36]### first receive an

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)



NIH CRADA?

(ENTER LAST 2 DIGITS OF YEAR FIRST RECEIVED A NIH CRADA)

(DON'T KNOW=98 REFUSED=99)

19
GO TO Q. #103 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION #103 ***
<< CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
IF Q# 50 EQ CODE(S) 1 (CONDITIONAL # 15)
THEN GO TO Q.#103'ELSE GO TO Q.#113.
!IF YES TO B5 FROM WORKSHEET ASK B5 ELSE B6a
-B5- Earlier you said Q36 ### had
life science CRADAs with the Department of Energy (DOE).

(ENTER CODE BELOW TO CONTINUE)
GO TO Q. #104 ====> < 1 > CONTINUE
GO TO Q. #104 ====> < 2 > *hold

*** QUESTION #104 ***
-B5a- How man life sciences CRADAs has [Q36]### had
with DOE, including those now ongoing?

(ENTER NUMBER BELOW. NOT SURE=98 REFUSED=99)
GO TO Q. #105 ====> < 1 > Numeric open end range 1-99
-- NUMERIC OPEN END - RANGE IS . 99---
-- ANSWER REQUIRED --

*** QUESTION #105 ***
<< CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
IF Q#104 EQ 97 (CONDITIONAL # 16)
THEN GO TO 0.#105 ELSE GO TO Q.#110.
!IF B5a=l-97 '
-B5bl- With which DOE laboratory do you have the first CRADA?

(ENTER NAME OF LABORATORY BELOW)
GO TO Q. #106 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION #106 ***
<< CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
IF Q#104 EQ (CONDITIONAL # 17)
THEN GO TO Q.#106 ELSE GO TO Q.#lIO.
!IF B5a=2-97
-B5b2- With which DOE laboratory do you have the second CRADA?

(ENTER NAME oF LABORATORY BELOW)
GO TO Q. #107 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION #107 ***

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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```
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q#104 EQ          3 TO          97          (CONDITIONAL # 18)
   THEN GO TO Q.#107 ELSE GO TO Q.#110.
!IF B5a=3-97
-B5b3- With which DOE laboratory do you have the third CRADA?

(ENTER NAME OF LABORATORY BELOW)
  GO TO Q. #108 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION #108 ***
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q#104 EQ          4 TO          97          (CONDITIONAL # 19)
   THEN GO TO Q.#108 ELSE GO TO Q.#110.
!IF B5a=4-97
-B5b4- With which DOE laboratory do you have the fourth CRADA?

(ENTER NAME OF LABORATORY BELOW)
  GO TO Q. #109 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION #109 ***
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q#104 EQ          5 TO          97          (CONDITIONAL # 20)
   THEN GO TO Q.#109 ELSE GO TO Q.#110.
!IF B5a=5-97
-B5b5- With which DOE laboratory do you have the fifth CRADA?

(ENTER NAME OF LABORATORY BELOW)
  GO TO Q. #110 ====> < 1 > Open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION #110 ***
-B5c- In what year did [Q36]### first receive a
DOE CRADA?

(ENTER LAST 2 DIGITS OF YEAR FIRST RECEIVED A DOE CRADA)

              (DON'T KNOW=98 REFUSED=99)
  19
  GO TO Q. #111 ====> < 1 > Numeric open end range 0-99
-- NUMERIC OPEN END - RANGE IS                99---
-- ANSWER REQUIRED --

*** QUESTION #ill ***
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q# 49 EQ CODE S 1                        CONDITIONAL # 21
   AND Q# 50 EQ CODE S 1                        CONDITIONAL # 22
   THEN GO TO Q.#111 E SE GO TO Q.#113.
!IF YES TO B4 AND B5 ASK B6a ELSE Cl
-B6a- Have there been any significant differences in your experiences
under NIH and DOE CRADAs?
```

Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

```
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   GO TO Q. #112 ====> < 1 > Yes
   GO TO Q. #113 ====> < 2 > No
   GO TO Q. #113 ====> < 3 > (VOL) Not sure
   GO TO Q. #113 ====> < 4 > (VOL) Refused

 *** QUESTION #112 ***
 -B6b- How have they differed?

 (ENTER RESPONSES ON SAF NEXT TO B6b, THEN,
 .ENTER TWICE TO CONTINUE)
                 ====> < 1 > Text screen
   -- TEXT"SCREEN --

 *** QUESTION #113 ***
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q# 49 NE CODE S 1                          CONDITIONAL # 23
    AND Q# 50 NE CODE S 1                          CONDITIONAL # 24
    THEN GO TO Q.#151 E SE GO TO Q.#113.
 *IF NO TO BOTH B4 AND B5 SKIp TO Fla ELSE ASK THIS QUESTION
   GO TO Q. #114 ====> < 1 > Eligible for Sections C-E
   GO TO Q. #114 ====> < 2 > #ho ld

 *** QUESTION #114 ***
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q# 13 EQ CODE(S) 1,2                       (CONDITIONAL # 25)
    THEN GO TO Q.#115 ELSE GO TO Q.#114.
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q# 13 EQ CODE S 3,4                        CONDITIONAL # 26
    AND Q# 49 EQ CODE S 1                          CONDITIONAL # 27
    AND Q# 50 EQ CODE S 1                          CONDITIONAL # 28
    THEN GO TO  .#l16 E SE GO TO Q.#l14.
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q# 13 EQ CODE S 3,4                        CONDITIONAL # 29
    AND Q# 49 E CODE S 1                           CONDITIONAL # 30
    AND Q# 50 N CODE S 1                           CONDITIONAL # 31
    THEN SHOW CODES 1
     AND HIDE CODES 2
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q# 13 E CODE S 3,4                         CONDITIONAL # 32
    AND Q# 49 N CODE S 1                           CONDITIONAL # 33
    AND Q# 50 EQ CODE S 1                         ICONDITIONAL # 34
    THEN SHOW CODES 2
     AND HIDE CODES 1
 *TYPE OF CRADA NON-CRADA SAMPLE
 IF NON-CRADA SAMPLE AND RESP SAYS BOTH NIH & DOE, ASK RANDOMIZE
 IF NON-CRADA SAMPLE BUT RESP SAYS CRADA, GO WITH B4 OR B5 RESPONSE
   GO TO Q. #115 ====>  <  1  >  NIH  "
   GO TO Q. #115 ====> < 2 > DOE

 *** QUESTION #115 ***
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q# 13 EQ CODE(S) 3,4                       (CONDITIONAL # 35)
    THEN GO TO Q.#117 ELSE GO TO Q.#115.
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q# 13 EQ CODE(S) 1                         (CONDITIONAL # 36)
```

Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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```
   AND Q# 49 EQ CODE S  1                          CONDITIONAL  # 37
   AND Q# 50 EQ CODE S  1                          CONDITIONAL  # 38
   THEN SHOW CODES 1
    AND HIDE CODES 2
   << CONDITIONAL ASSOC IATED WITH THIS QUESTION >>
    IF Q# 13 EQ CODE S                             CONDITIONAL  # 39)
   AND Q# 49 EQ CODE S  1                          CONDITIONAL  # 40)
   AND Q# 50 EQ CODE S  1                          CONDITIONAL  # 41)
   THEN SHOW CODES 2
    AND HIDE CODES 1
   << CONDITIONAL ASSOC IATED WITH THIS QUESTION >>
    IF Q# 13 EQ CODE S  1                          CONDITIONAL  # 42
   AND Q# 49 NE CODE S  1                          CONDITIONAL  # 43
   AND Q# 50 EQ CODE S  1                          CONDITIONAL  # 44
   THEN SHOW CODES 2
    'AND HIDE CODES 1
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q# 13 EQ CODE S 1                           CONDITIONAL  # 45)
   AND Q# 49 EQ CODE S 1                           CONDITIONAL  # 46)
   AND Q# 50 N CODE S 1                            CONDITIONAL  # 47)
   THEN SHOW CODES 1
    AND HIDE CODES 2
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q# 13 E CODE S 2                            CONDITIONAL  # 48
   AND Q# 49 N CODE S 1                            CONDITIONAL  # 49
   AND Q# 50 EQ CODE S 1                           CONDITIONAL  # 50
   THEN SHOW CODES 2
    AND HIDE CODES 1
   << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
    IF Q# 13 EQ CODE S 2                           CONDITIONAL  # 51
   AND Q# 49 EQ CODE S 1                           CONDITIONAL  # 52
   AND Q# 50 NE CODE S 1                           CONDITIONAL  # 53
   THEN SHOW CODES 1
    AND HIDE CODES 2
*TYPE OF CRADA CRADA SAMPLE
IF CRADA SAMPLE AND RESP SAYS BOTH GO WITH SAMPLE
IF CRADA SAMPLE CONTRADICTED BY B4/B5 RESPONSE GO WITH B4/B5 RESPONSE
  GO TO Q. #117 ====> < 1 > NIH
  GO TO Q. #117 ====> < 2 > DOE

*** QUESTION #116 ***
*TO RANDOMLy pICK ONE TypE OF CRADA
SHUFFLE ALL ANSWERS
  GO TO Q. #117 ====> < 1 > NIH
  GO TO Q. #117 ====> < 2 > DOE
-- SPECIAL FEATURE * SHUFFLING ANSWERS
   ALL ANSWERS --

*** QUESTION #117 ***
*GRID SHOW ANSWERS TO pREVIOUS TYpE OF CRADA QUESTIONS
  GO TO Q. #118 ====> < 1 > NIH
  GO TO Q. #118 ====> < 2 > DOE

   THIS QUESTION IS IN A GRID --
   DISPLAY ANSWERS ALREADY MENTIONED IN QUESTIONS:
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)



114,115,116

*** QUESTION #118 ***
!SECTION C: TERMS OF LIFE SCIENCES CRADA
Has [Q36]### agreed to provide any of the
following under the terms of its [Q117]### CRADA(s)?

{ENTER TwIcE TO coNTINuE)
GO TO Q. #119 ====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION #119 ***
-Cla- (Has [Q36]### agree to provide. ..)

iNDUSTRy scientists To WORK IN GOVERNMENT LABS

(under the terms of its [Q117]### CRADAs?)
GO TO Q. #120 ====> < 1 > Yes
GO TO Q. #120 ====> < 2 > No
GO TO Q. #120 ====> < 3 > (VOL) Not sure
GO TO Q. #120 ====> < 4 > (VOL) Refused

*** (QUESTION #120 ***
-Clb~ (Has [Q36]### agree to provide. ..)

BIOLOGICAL SAMPLES, BIOMATERIALS, OTHER MATERIALS OR EQUIPMENT TO
GOVERNMENT

(under the terms of its [Q117]### CRADAs?)
====> < 1 > Yes
GO TO Q: #121 ====> < 2 > No
GO TO Q. #121 ====> < 3 > (VOL) Not sure
GO TO Q. #121 ====> < 4 > (VOL) Refused

*** QUESTION #121 ***
-Clc- (Has [Q36]### agree to provide. ..)

GOVERNMENT USE OF EQUIPMENT IN [Q36]###'S LABS

(under the terms of its [Ql17]### CRADAs?)
GO TO Q. #122 ====> < 1 > Yes
GO TO Q. #122 ====> < 2 > No
GO TO Q. #122 ====> < 3 > (VOL) Not sure
GO TO Q. #122 ====> < 4 > (VOL) Refused

*** QUESTION #122 ***
-Cld- (Has [Q36]### agree to provide. ..)

COMPENSATION FoR GOVERNMENT SCIENTISTS

(under the terms of its [Q117]### CRADAs?)
GO TO Q. #123 ====> < 1 > Yes
GO TO Q. #123 ====> < 2 > No
GO TO Q. #123 ====> < 3 > (VOL) Not sure

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  GO TO Q. #123 ====> < 4 > (VOL) Refused

*** QUESTION #123 ***
-Cle- (Has [Q36]### agree to provide. ..)

OTHER FUNDING FOR GOVERNMENT SCIENTISTS

(under the terms of its [Ql17]### CRADAs?)
  GO TO Q. #124 ====> < 1 > Yes
  GO TO Q. #124 ====> < 2 > No
  GO TO Q. #124 ====> < 3 > (VOL) Not sure
  GO TO Q. #124 ====> < 4 > (VOL) Refused

*** QUESTION #124 ***
-Clf- (Has [Q36]### agree to provide. ..)

DID [Q36] ### AGREE TO UNDERTAKE, MANAGE OR
PROVIDE FUNDING FOR PATENT PROSECUTION (PATENT APPLICATION PROCESS)

{under the terms of its [Q117]### CRADAs?)
  GO TO Q. #125
  GO TO Q. #125 ====> < 2 > No
  GO TO Q. #125 ====> < 3 > (VOL) Not sure
  GO TO Q. #125 ====> < 4 > (VOL) Refused

*** QUESTION #125 ***
Did the government agree to provide any of the following
under the terms of [ Q36]###'s
[Ql17]### CRADA(s)?

(ENTER TWICE TO CONTINUE)
  GO TO Q. #126 ====> < 1 > Text screen
  -- TEXT SCREEN --

*** QUESTION #126 ***
-C2a- (Did the government agree to provide. ..)

SCientists TO WORK ON PROJECTS OF INTEREST TO [Q36]###

{under the terms of the [Q117]### CRADA?)
  GO TO Q. #127 ====> < 1 > Yes
  GO TO Q. #127 ====> < 2 > No
  GO TO Q. #127 ====> < 3 > (VOL) Not sure
  GO TO Q. #127 ====> < 4 > (VOL) Refused

*** QUESTION" #127 ***
-C2b- (Did the government agree to provide. ..)

BIOLOGICAL SAMPLES, BIOMATERIALS, OTHER MATERIALS OR EQUIPMENT TO
[Q36]###'S

(under the terms of the [Ql17]### CRADA?)
                ====> < 1 > Yes
  GO TO Q: #128 ====> < 2 > No
  GO TO Q. #128 ====> < 3 > (VOL) Not sure
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)



GO TO Q. #128 ====> < 4 > (VOL) Refused

*** QUESTION #128 ***
-C2C- (Did the government agree to provide. ..)

YOUR USE OF EQUIPMENT IN GOVERNMENT LABS

(under the terms of the [Ql17]### CRADA?)
GO TO Q. #129 ====> < 1 > Yes
GO TO Q. #129 ====> < 2 > No
GO TO Q. #129 ====> < 3 > (VOL) Not sure
GO TO Q. #129 ====> < 4 > (VOL) Refused

*** QUESTION #129 ***
-C2d- (Did the government agree to provide. ..)

EXCLUSIVE LICENSING OF GOVERNMENT PATENTS RESULTING FROM THE CRADA

(under the terms of the [Ql17]### CRADA?)
GO TO Q. #130 ====> < 1 > Yes
GO TO Q. #130 ====> < 2 > No
GO TO Q. #130 ====> < 3 > (VOL) Not sure
GO TO Q. #130 ====> < 4 > (VOL) Refused

*** QUESTION #130 ***
-C2e- (Did the government agree to provide. ..)

EXCLUSIVE LICENSING OF GOVERNMENT PATENTS RESULTING FROM RESEARCH
THAT IS NOT PART OF THE CRADA

(under the terms of the [Ql17]### CRADA?)
GO TO Q. #131 ====> < 1 > Yes
GO TO Q. #131 ====> < 2 > No
GO TO Q. #131 ====> < 3 > (VOL) Not sure
GO TO Q. #131 ====> < 4 > (VOL) Refused

*** QUESTION #131 ***
!SECTION D: CONCERNS ABOUT FORMING CRADAs
In considering whether or not to pursue or continue a CRADA, how much concern have the following issues caused [Q36]###?

(ENTER TWICE TO CONTINUE)
====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION #132 ***
-Dla- Has concern that...

THE REVIEW PROCESS MAY LEAD TO DISCLOSURE OF INFORMATION
[Q36]### WANTED TO KEEP SECRET

been a major concern, a minor concern or not really a concern?
GO TO Q. #133 ====> < 1 > Major concern
GO TO Q. #133 ====> < 2 > Minor concern
GO TO Q. #133 ====> < 3 > Not really a concern

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GO TO Q. #133 ====> < 4 > (VOL) Not sure
GO TO Q. #133 ====> < 5 > (VOL) Refused

*** QUESTION #133 ***
-Dlb- Has concern that...

GOVERNMENT SCIENTISTS MAY GO TO WORK FOR A COMPETING COMPANY, LEADING TO DISCLOSURE TO A COMPETITOR OF INFORMATION [Q36]### WANTED TO KEEP SECRET

been a major concern, a minor concern or not really a concern?
GO TO Q. #134 ====> < 1 > Major concern
GO TO Q. #134 ====> < 2 > Minor concern
GO TO Q. #134 ====> < 3 > Not really a concern
GO TO Q. #134 ====> < 4 > (VOL) Not sure
GO TO Q. #134 ====> < 5 > (VOL) Refused

*** QUESTION #134 ***
-Dlc- Has concern that...

THE REASONABLE PRICING CLAUSE REQUIRED IN THE CRADA CONTRACT MAY RESTRICT PROFITABILITY OF ANTICIPATED PRODUCTS FROM THE CRADA

been a major concern, a minor concern or not really a concern?
GO TO Q. #135 ====> < 1 > Major concern
GO TO Q. #135 ====> < 2 > Minor concern
GO TO Q. #135 ====> < 3 > Not really a concern
GO TO Q. #135 ====> < 4 > (VOL) Not sure
GO TO Q. #135 ====> < 5 > (VOL) Refused

*** QUESTION #135 ***
-Did- Has concern that...

THE REASONABLE PRICING CLAUSE REQUIRED IN THE CRADA CONTRACT MAY REDUCE PROFITABILITY OF UNANTICIPATED PRODUCTS FROM THE CRADA

been a major concern, a minor concern or not really a concern?
GO TO Q. #136 ====> < 1 > Major concern
GO TO Q. #136 "===> < 2 > Minor concern
GO TO Q. #136 "===> < 3 > Not really a concern
GO TO Q. #136 ====> < 4 > (VOL) Not sure
GO TO Q. #136 ====> < 5 > (VOL) Refused

*** QUESTION #136 ***
-Die- Has concern that...

THE CRADA DOES NOT GUARANTEE AN EXCLUSIVE LICENSE FOR UNANTICIPATED PRODUCTS THAT MIGHT BE DEVELOPED FROM THE CRADA

been a major concern, a minor concern or not really a concern?
GO TO Q. #137 ====> < 1 > Major concern
GO TO Q. #137 ====> < 2 > Minor concern
GO TO Q. #137 ====> < 3 > Not really a concern
GO TO Q. #137 ====> < 4 > (VOL) Not sure
GO TO Q. #137 ====> < 5 > (VOL) Refused

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*** QUESTION #137 ***
-Dlf- Has concern that...

THE GOVERNMENT MAY NOT HONOR TERMS OF THE CRADA ABOUT EXCLUSIVITY OF
LICENSING PRODUCTS
.
been a major concern, a minor concern or not really a concern?
  GO TO Q. #138 ====>  < 1 > Major concern
  GO TO Q. #138 ====>  < 2 > Minor concern
  GO TO Q. #138 ====>  < 3 > Not really a concern
  GO TO Q. #138 ====>  < 4 > (VOL) Not sure
  GO TO Q. #138 ====>  < 5 > (VOL) Refused

*** QUESTION #138 ***
   << CONDITIONAL ASSOC IATED WITH THIS QUESTION >>
    IF Q#132 NE CODE(S) 1                          CONDITIONAL # 54
   AND Q#133 NE CODE(S) 1                          CONDITIONAL # 5[redacted]
   AND Q#134 NE CODE(S) 1                          CONDITIONAL # 5[redacted]
   AND Q#135 NE CODE(S) 1                          CONDITIONAL # 5[redacted]
   AND Q#136 NE CODE(S) 1                          CONDITIONAL # 5[redacted]
   AND Q#137 NE CODE(S)                            CONDITIONAL # 5[redacted]
   THEN GO TO Q.#139 ELSE GO TO Q.#138
!IF NO MAJOR CONCERNS  IN Dla-f SKIP TO D3 ELSE D2
-D2- Have any of these concerns actually caused [Q36]###
to choose not to pursue or not to continue a [Q117]### CRADA?
  GO TO Q. #139 ====> < 1 > Yes, chose not to pursue
  GO TO Q. #139 ====> < 2 > Yes, chose not to continue
  GO TO Q. #139 ====> < 3 > Yes, both
  GO TO Q. #139 ====> < 4 > No
  GO TO Q. #139 ====> < 5 > (VOL) Not sure
  GO TO Q. #139 ====> < 6 > (VOL) Refused

*** QUEsT1oN #139 ***
-D3-"In general which of the following BEST characterizes the
ATTITUDES of [Q36]###'s having a
[Q117]### CRADA?    (READ LIST)
  GO TO Q. #140 ====> < 1 > HE BENEFITS GREATLY OUTWEIGH THE RISKS AND
                            EXPENSES
  GO TO Q. #140 ====> < 2 > THE BENEFITS SOMEWHAT OUTWEIGH THE RISKS AND
                            EXPENSES
  GO TO Q. #140 ====> < 3 > THE BENEFITS ARE ABOUT EQUAL TO THE RISKS AND
                            EXPENSES
  GO TO Q. #140 ====> < 4 > THE RISKS AND EXPENSES SOMEWHAT EXCEED THE
                            BENEFITS
  GO TO Q. #140 ====> < 5 > THE RISKS AND EXPENSES GREATLY EXCEED THE
                            BENEFITS
  GO TO Q. #140 ====> < 6 > (VOL) None of these
  GO TO Q. #140 ====> < 7 > (VOL) Not sure
  GO TO Q. #140 ====> < 8 > (VOL) Refused

*** QUESTION #140 ***
!SECTION E: RETURNS ON INVESTMENT IN CRADA
Earlier we asked about the terms of your [Q117]### CRADA(s);
now we want to ask you about actual results.
```

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(ENTER TWICE TO CONTINUE)
====> < 1 > Text screen
-- TEX$ SCREEN --

*** QUESTION #141 ***
-El- How important have the intellectual contributions of government scientists been to [Q36] ###'s CRADA project?
Would you say. ..(READ LIST
GO TO Q. #142 ====> < 1 > VERY IMPORTANT
GO TO Q. #142 ====> < 2 > SOMEWHAT IMPORTANT
GO TO Q. #142 ====> < 3 > NOT TOO IMPORTANT
GO TO Q. #142 ====> < 4 > NOT AT ALL IMPORTANT
GO TO Q. #142 ====> < 5 > (VOL) Not sure
GO TO Q. #142 ====> < 6 > (VOL) Refused

*** QUESTION #142 ***
-E2- Did the government actually provide biological samples, biomaterials other materials or equipment as part of [Q36]###'S CRADA(s)?
GO TO Q. #143 ====> < 1 > Yes
GO TO Q. #144 ====> < 2 > No
GO TO Q. #144 ====> < 3 > (VOL) Not sure
GO TO Q. #144 ====> < 4 > (VOL) Refused

*** QUESTION #143 ***
-E3- How important was the use of these materials or equipment to [Q36]###? Would YOU say. ..(READ LIST
====> < 1 > VERY IMPORTANT
GO TO Q: #144 ====> < 2 > SOMEWHAT IMPORTANT
GO TO Q. #144 ====> < 3 > NOT TOO IMPORTANT
GO TO Q. #144 ====> < 4 > NOT AT ALL IMPORTANT
GO TO Q. #144 ====> < 5 > (VOL) Not sure
GO TO Q. #144 ====> < 6 > (VOL) Refused

*** QUESTION #144 ***
-E4- As part of [Q36] ###'s [Ql17]### CRADA(s), did the government make available for use biological samples, biomaterials, other materials or equipment that would be unavailable or prohibitively expensive to the company outside the CRADA(S)?
GO TO Q. #145 ====> < 1 > Yes
GO TO Q. #145 ====> < 2 > No
GO TO Q. #145 ====> < 3 > (VOL) Not sure
GO TO Q. #145 ====> < 4 > (VOL) Refused

*** QUESTION #145 ***
-E5- Did Government scientists contribute original research ideas to 36 ### that would not have been available without the CRADA(s)?
#146 ====> < 1 > Yes
GO TO Q: #146 ====> < 2 > No
GO TO Q. #146 ====> < 3 > (VOL) Not sure
GO TO Q. #146 ====> < 4 > (VOL) Refused

*** QUESTION #146 ***

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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-E6- Did government scientists provide technical know-how to [Q36]### that would not have been available without the CRADA(s)?
#147 ====> < 1 > Yes
GO TO Q: #147 ====> < 2 > No
GO TO Q. #147 ====> < 3 > (VOL) Not sure
GO TO Q. #147 ====> < 4 > (VOL) Refused

*** QUESTION #147 ***
-E7- Throughout the [Q117]### CRADA(s) did [Q36]###'s scientists form working relationships with government scientists that have continued or you expect to continue beyond the terms of the CRADA(s)?
GO TO Q. #148 ====> < 1 > Yes
GO TO Q. #149 ====> < 2 > No
GO TO Q. #149 ====> < 3 > (VOL) Not sure
GO TO Q. #149 ====> < 4 > (VOL) Refused

*** QUESTION #148 ***
-E7a- Are these simply informal working relationships, or is the intent possibly to seek another CRADA or an extension of t e current one(s)?
GO TO Q. #149 ====> < 1 > Informal
GO TO Q. #149 ====> < 2 > Seek further CRADA
GO TO Q. #149 ====> < 3 > (VOL) Not sure
GO TO Q. #149 ====> < 4 > (VOL) Refused

*** QUESTION #149 ***
-E8- Did your CRADA(s) result in an orphan drug or do you anticipate that it will?
GO TO Q. #150 ====> < 1 > Yes, has resulted
GO TO Q. #150 ====> < 2 > Yes, anticipated
GO TO Q. #150 ====> < 3 > Yes, both
GO TO Q. #150 ====> < 4 > No
GO TO Q. #150 ====> < 5 > (VOL) Not sure
GO TO Q. #150 ====> < 6 > (VOL) Refused

*** QUESTION #150 ***
-E16- If [Q36]### had the option to do it over again, would they repeat the CRADA(s) for all, most, some, a few or none of them?
GO TO Q. #151 ====> < 1 > All
GO TO Q. #151 ====> < 2 > Most
GO TO Q. #151 ====> < 3 > Some
GO TO Q. #151 ====> < 4 > Few
GO TO Q. #151 ====> < 5 > None
GO TO Q. #151 ====> < 6 > (VOL) Not sure
GO TO Q. #151 ====> < 7 > (VOL) Refused

*** QUESTION #151 ***
!SECTION F: ADMINISTRATIVE PROCESS OF FORMING CRADAs
-Fla- How did [Q36]### first become aware of [Q117]### CRADAs? (READ LIST - MULTIPLE RECORD
GO TO Q. #153 ====> < 1 > JOURNAL OR NEWSLETTER ARTICLE
GO TO Q: #153 ====> < 2 > ADVERTISEMENT IN JOURNAL OR NEWSLETTER
GO TO Q. #153 ====> < 3 > PROFESSIONAL MEETING OR TRADE SHOW

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)



```
  GO TO Q. #153 ====> < 4 > PERSONAL CONTACTS
  GO TO Q. #153 ====> < 5 > GOVERNMENT PROMOTIONAL MATERIAL
  GO TO Q. #153 ====> < 6 > OTHER
  GO TO Q. #153 ====> < 7 > % (VOL) Not sure
  GO TO Q. #153 ====> < 8 > % (VOL) Refused
-- MULTI-PUNCH --

*** QUESTION #152 ***
*-Fla- Other way found out about [Ql17]### CRADAs
  GO TO Q. #153 ====> < 1 > Associated other open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION #153 ***
-Fib- Were discussions for Q36 ###'s first
[Ql17]### CRADA begun. ..(READ LIST - SINGLE RECORD)

  1 > PRIMARILY BY INDIVIDUALS FROM [Q36]###
. 2 > PRIMARILY BY INDIVIDUALS FROM THE GOVERNMENT
. 3 > EQUALLY BY BOTH PARTIES
  GO TO Q. #154 ====> <  1 > *primarily by individuals from your (parent)
                           company
  GO TO Q. #154 ====> < 2 > *Primarily  b individuals from the government
  GO TO Q. #154 ====> < 3 > *Equally by both parties
  GO TO Q. #154 ====> < 4 > (VOL) Not sure
  GO TO Q. #154 ====> < 5 > (VOL) Refused

*** QUESTION #154 ***
-F1c- Which Party started contacts for the majority of
 [Q36]###'s
 [Q117]### CRADAs?     (READ LIST)

  1 > [Q36]###
. 2 > GOVERNMENT
. 3 > EQUAL CONTRIBUTION
  GO TO Q. #155 ====> < 1 > *Your (parent) company
  GO TO Q. #155 ====> < 2 > *Government
  GO TO Q. #155 ====> < 3 > *Equal contribution
  GO TO Q. #155 ====> < 4 > (VOL) Not sure
  GO TO Q. #155 ====> < 5 > (VOL) Refused

*** QUESTION #155 ***
-Fld- Within [Q36]###, who usually initiates
 or is the most enthusiastic advocate for) the CRADA process?
 READ LIST - SINGLE RECORD)
' GO TO Q. #156 ====>  < 1 > THE RESEARCH SCIENTISTS
  GO TO Q. #156 ====>  < 2 > THE MARKETING REPRESENTATIVES
  GO TO Q. #156 ====>  < 3 > THE VICE PRESIDENT FOR RESEARCH
  GO TO Q. #156 ====>  < 4 > THE GOVERNMENT LIAISON
  GO TO Q. #156 ====>  < 5 > THE VICE PRESIDENT FOR FINANCE
  GO TO Q. #156 ====>  < 6 > SOMEONE ELSE
  GO TO Q. #156 ====>  < 7 >  (VOL) Not sure
  GO TO Q. #156 ====>  < 8 >  (VOL) Refused

*** QUESTION #156 ***
```

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-Fle- How effective are the U.S. government's efforts to raise
[Q36]###'s awareness of CRADAs with
Federal laboratories? Would you say . . . READ LIST)
GO TO Q. #158 ====> < 1 > VERY EFFECTIVE
GO TO Q. #158 ====> < 2 > SOMEWHAT EFFECTIVE
GO TO Q. #157 ====> < 3 > SOMEWHAT INEFFECTIVE
GO TO Q. #157 ====> < 4 > VERY INEFFECTIVE
GO TO Q. #158 ====> < 5 > (VOL) Not sure
GO TO Q. #158 ====> < 6 > **(VOL)** Refused

*** QUESTION #157 ***
-Flf- How could the process be improved?

(ENTER RESPONSES ON SAF NEXT TO Flf, THEN,
.ENTER TWICE TO CONTINUE)
GO TO Q. #158 ====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION #158 ***
-F2- Would you characterize the government's involvement in writing
the CRADA application(s) as: (READ LIST)
.
1 > VERY HELPFUL TO [ 36 ###
. 2 > SOMEWHAT HELPFUL TO [Q36] ###
3 > NEITHER HELPFUL NOR OBSTRUCTIVE
4 > SOMEWHAT OBSTRUCTIVE
. 5 > VERY OBSTRUCTIVE
GO TO Q. #159 ====> < 1 > *Very helpful to your (parent) company
GO TO Q. #159 ====> < 2 > *Somewhat helpful to your (parent) company
GO TO O. #159 ====> < 3 > *Neither helpful nor obstructive
GO TO Q. #159 ====> < 4 > *Somewhat obstructive
GO TO Q. #159 ====> < 5 > *Very obstructive
GO TO Q. #159 ====> < 6 > (VOL) Not sure
GO TO Q. #159 ====> < 7 > (VOL) Refused

*** QUESTION #159 ***
-F3- Did the government require that you use a model form for any
CRADA application(s)?
====> < 1 > Yes
GO TO Q: #161 ====> < 2 > No
GO TO Q. #161 ====> < 3 > (VOL) Not sure
GO TO Q. #161 ====> < 4 > (VOL) Refused

*** QUESTION #160 ***
-F3a- Would you characterize the model form as: (READ LIST)
GO TO Q. #161 ====> < 1 > VERY HELPFUL
GO TO Q. #161 ====> < 2 > SOMEWHAT HELPFUL
GO TO Q. #161 ====> < 3 > NEITHER HELPFUL NOR OBSTRUCTIVE
GO TO Q. #161 ====> < 4 > SOMEWHAT OBSTRUCTIVE
GO TO Q. #161 ====> < 5 > VERY OBSTRUCTIVE
GO TO Q. #161 ====> < 6 > (VOL) Not sure
GO TO Q. #161 ====> < 7 > (VOL) Refused

*** QUESTION #161 ***
-F4- In any CRADA application(s), did [Q36]###

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seek exclusive licensing of patents that might result from your CRADA?
GO TO Q. #162 ====> < 1 > Yes
GO TO Q. #163 ====> < 2 > No
GO TO Q. #163 ====> < 3 > (VOL) Not sure
GO TO Q. #163 ====> < 4 > (VOL) Refused

*** QUESTION #162 ***
-F4a- Was the scope of such licenses an issue in the negotiations?
GO TO Q. #163 ====> < 1 > Yes
GO TO Q. #163 ====> < 2 > No
GO TO Q. #163 ====> < 3 > (VOL) Not sure
GO TO Q. #163 ====> < 4 > (VOL) Refused

*** QUESTION #163 ***
-F5- In any of its [Q117] ### CRADA application(s), did
[Q36] ### seek exclusive licensing of government
held patents that are material to the CRADA but are not based on
the CRADA?
GO TO Q. #164 ====> < 1 > Yes
GO TO Q. #164 ====> < 2 > No
GO TO Q. #164 ====> < 3 > (VOL) Not sure
GO TO Q. #164 ====> < 4 > (VOL) Refused

*** QUESTION #164 ***
-F5a- Was the scope of such licenses a major issue, a minor issue or
not really an issue at all in the negotiations?
GO TO Q. #165 ====> < 1 > Major Issue
GO TO Q. #165 ====> < 2 > Minor issue
GO TO Q. #165 ====> < 3 > Not really an issue
GO TO Q. #165 ====> < 4 > (VOL) Not sure
GO TO Q. #165 ====> < 5 > (VOL) Refused

*** QUESTION #165 ***
!IF YES TO Blc AND NO TO Blb SKIP TO F6 ELSE F5b
-F5b- Did you receive the exclusive licensing of government held
patents?
GO TO Q. #166 ====> < 1 > Yes
GO TO Q. #166 ====> < 2 > No
GO TO Q. #166 ====> < 3 > (VOL) Not sure
GO TO Q. #166 ====> < 4 > (VOL) Refused

*** QUESTION #166 ***
-F6- Was there a government administrator who was clearly responsible
for coordinating the CRADA application process or for negotiating the
terms of the CRADA?
GO TO Q. #168 ====> < 1 > Yes
GO TO Q. #167 ====> < 2 > No
GO TO Q. #168 ====> < 3 > (VOL) Not sure
GO TO Q. #168 ====> < 4 > (VOL) Refused

*** QUESTION #167 ***
-F6a- Would it have been helpful to have the process coordinated by
an administrator?
GO TO Q. #168 ====> < 1 > Yes
GO TO Q. #169 ====> < 2 > No

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  GO TO Q. #169 ====> < 3 > (VOL) Not sure
  GO TO Q. #169 ====> < 4 > (VOL) Refused

*** QUESTION #168 ***
-F6b- Would you characterize the contribution of this administrator
to the application process as:   READ LIST)
          ====> <  1 > VERY HELPFUL
  GO TO Q. #169 ====> <  2 > SOMEWHAT HELPFUL
  GO TO Q. #169 ====> <  3 > NEITHER HELPFUL NOR OBSTRUCTIVE
  GO TO Q. #169 ====> <  4 > SOMEWHAT OBSTRUCTIVE
  GO TO Q. #169 ====> <  5 > VERY OBSTRUCTIVE
  GO TO Q. #169 ====> <  6 > (VOL) Not sure
  GO TO Q. #169 ====> <  7 > (VOL) Refused

*** QUESTION #169 ***
-F7- To your knowledge, was your CRADA application(s) reviewed by a
government committee?
  GO TO Q. #170 ====> < 1 > Yes
  GO TO Q. #174 ====> < 2 > No
  GO TO Q. #174 ====> < 3 > (VOL) Not sure
  GO TO Q. #174 ====> < 4 > (VOL) Refused

*** QUESTION #170 ***
Were any of the following true of [Q36]###'s
experience with the [Q117]### CRADA review committee?

(ENTER TWICE To continue)
  GO TO Q. #171 ====> < 1 > Text screen
  -- TEXT SCREEN --

*** QUESTION #171 ***
-F8a- The (first/next) is...

THE COMMITTEE'S REVIEW TOOK LONGER THAN WAS REASONABLE FOR THE
COMPLEXITY OF THE AGREEMENT UNDER REVIEW

(Was this true of [Q36]###'s experience
with the [Q117]## CRADA review committee?)
  GO TO Q. #172 ====> < 1 > Yes
  GO TO Q. #172 ====> < 2 > No
  GO TO Q. #172 ====> < 3 > (VOL) Not sure
  GO TO Q. #172 ====> < 4 > (VOL) Refused

*** QUESTION #172 ***
-F8b- The (first/next) is...

THE COMMITTEE POINTED OUT AMBIGUITIES OR PROBLEMS IN THE DRAFT
AGREEMENT THAT WERE OR MIGHT HAVE BEEN IMPORTANT TO RESOLVE

(Was this true of [Q36] ###'s experience
with the [Q117]### CRADA review committee?)
  GO TO Q. ###  ====> < 1 > Yes
  GO TO Q. #173 ====> < 2 > No
  GO TO Q. #173 ====> < 3 > (VOL) Not sure
  GO TO Q. #173 ====> < 4 > (VOL) Refused
```

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*** QUESTION #173 ***
-F8c- The (first/next) is...

IN LATER ROUNDS OF REVIEW, THE COMMITTEE TOOK ISSUE WITH ELEMENTS
OF THE AGREEMENT THAT THEY OVERLOOKED IN EARLIER ROUNDS

(Was this true of [Q36] ###'s experience
with the [Q117]## CRADA review committee?)
  GO TO Q. #174 ====> < 1 > Yes
  GO TO Q. #174 ====> < 2 > No
  GO TO Q. #174 ====>  < 3 > (VOL) Not sure
  GO TO Q. #174 ====> < 4 > (VOL) Refused

*** QUESTION #174 ***
*GO TO Nonprofit QUESTIONS
  GO TO Q. #183 ====> < 1 > Ski to F9a
  GO TO Q. #183 ====> < 2 > *hold

*** QUESTION #175 ***
!SEC$TION G: CRADAs FROM THE POINT OF VIEW OF COMPANIES THAT HAVE
!NOT APPLIED FOR CRADAs
-G1- Had you ever heard of CRADAs?
  GO TO Q. #176 ====> < 1 > Yes
  GO TO Q. #183 ====> < 2 > No
  GO TO Q. #183 ====>  < 3 > (VOL) Not sure
  GO TO Q. #183 ====>  < 4 > (VOL) Refused

*** QUESTION #176 ***
-G2- Would [Q36]### ever consider developing one?
          IT     ====> < 1 > Yes
  GO TO O: #178 ====> < 2 > No
  GO TO '. #178 ====> < 3 > Other
 -- ABOVE  ANSWER ASSOCIATED WITH OPEN END QuEsTIoN #177 --
  GO TO Q. #178 ====> < 4 > (VOL) Not sure
  GO TO Q. #178 ====>  < 5 > (VOL) Refused

*** QUESTION #177 ***
-G2- Other view on developing a CRADA
  GO TO Q. #178 ====>  < 1 > Associated other open end
-- MULTI-PUNCH --
-- ANSWER REQUIRED --

*** QUESTION #178 ***
-G2a- Has [Q36]### ever made contacts with government
scientists or officials to explore the possibility of a CRADA?
  GO TO Q. #179 ====> < 1 > Yes
  GO TO Q. #182 ====> < 2 >No
  GO TO Q. #182 ====> < 3 > (VOL) Not sure
  GO TO Q. #182 ====> < 4 > (VOL) Refused

*** QUESTION #179 ***
-G3- Is it proceeding?
  GO TO Q. #180 ====> < 1 > Yes
  GO TO Q. #181 ====> < 2 > No
```

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)



GO TO Q. #181 ====> < 3 > (VOL) Not sure
GO TO Q. #181 ====> < 4 > (VOL) Refused

*** QUESTION #180 ***
-G3a- How is it going?

(ENTER RESPONSES ON SAF NEXT TO G3a, THEN,
.ENTER TWICE TO CONTINUE)
GO TO Q. #182 ====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION #181 ***
-G3b- Why has it been stopped?

(ENTER RESPONSES ON SAF NEXT TO G3b, THEN,
.ENTER TWICE TO CONTINUE)
GO TO Q. #182 ====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION #182 ***
-G4- How likely is it that [Q36]### will apply
for life science CRADAs in the near future? (READ LIST)
GO TO Q. #183 ====> < 1 > VERY LIKELY,
GO TO Q. #183 ====> < 2 > SOMEWHAT LIKELY,
GO TO Q. #183 ====> < 3 > SOMEWHAT UNLIKELY OR
GO TO Q. #183 ====> < 4 > VERY UNLIKELY?
GO TO Q. #183 ====> < 5 > (VOL) Not sure
GO TO Q. #183 ====> < 6 > (VOL) Refused

*** QUESTION #183 ***
Now, a few last questions about your company's relations with
non-profit research institutions outside of the United States.

(ENTER TWICE TO CONTINUE)
====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION #184 ***
-F9a~ Does your company have rights to intellectual property
licensed (or otherwise obtained from foreign non-profit research
institutions?
GO TO Q. #185 ====> < 1 > Yes
GO TO Q. #186 ====> < 2 > No
GO TO Q. #186 ====> < 3 > (VOL) Not sure
GO TO Q. #186 ====> < 4 > (VOL) Refused

*** QUESTION #185 ***
-F9b- Could you describe that agreement?

(ENTER RESPONSES ON SAF NEXT TO F9b, THEN,
.ENTER TWICE TO CONTINUE)
====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION #186 ***

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

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-F10a- Does your company participate in collaborative research agreements with foreign non- refit research institutions, in which you obtain or share intellectual property rights?
GO TO Q. #187 ====> < 1 > Yes
GO TO Q. #188 ====> < 2 > No
GO TO Q. #188 ====> < 3 > (VOL) Not sure
GO TO Q. #188 ====> < 4 > (VOL) Refused

*** QUESTION #187 ***
-F10b- Could you describe that agreement?

{ENTER RESPONSES ON SAF NEXT TO F10b, THEN,
.ENTER TWICE TO CONTINUE)
====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION #188 ***
-F11a- Does your company have rights to intellectual property licensed from other U.S. institutions, who had previously obtained rights from foreign non-profit research institutions?
Go To Q. #189 ====> < 1 > Yes
GO TO Q. #190 ====> < 2 > No
GO TO Q. #190 ====> < 3 > (VOL) Not sure
GO TO Q. #190 ====> < 4 > (VOL) Refused

*** QUESTION #189 ***
-F11b- Could you describe that agreement?

(ENTER RESPONSES ON SAF NEXT TO F11b, THEN,
.ENTER TWICE TO CONTINUE)
====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION #190 ***
-F12- Finally, do you have any suggestions for improving National Institutes of Health and Department of Energy processes for technology transfer to industry?

(ENTER RESPONSES ON SAF NEXT TO F12, THEN,
.ENTER TWICE TO CONTINUE)
====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION #191 ***
That completes the survey. Thank you very much for your time and cooperation!

(INTERVIEWER; PREPARE TO ENTER OPEN ENDS FROM SAF INTO CATI)

(ENTER TWICE TO CONTINUE)
GO TO . #192 ====> < 1 > Text screen
-- TEXT SCREEN --

*** QUESTION #192 ***
<< CONDITIONAL ASSOCIATED WITH THIS QUESTION >>

## Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

```
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     IF Q#lll EQ CODE(S 1                          (CONDITIONAL #60)
    THEN GO TO Q.#192 ELSE GO TO Q.#193.
 ENTER RESPONSES FROM SAF B6b HERE:

 -B6b- How have they (NIH/DOE CRADAs) differed?
   GO TO Q. #193 ====> < 1 > Open end
 -- MULTI-PUNCH --
 -- ANSWER REQUIRED --

 *** QUESTION #193 ***
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q#156 EQ CODE(S) 3,4                      (CONDITIONAL #61)
    THEN GO TO Q.#193 ELSE GO TO Q.#194.
 ENTER RESPONSES FROM SAF F1f HERE:

 -Flf- How could the process be improved?
   GO TO Q. #194 ====> < 1 > Open end
 -- MULTI-PUNCH --
 -- ANSWER REQUIRED --

 *** QUESTION #194 ***
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q#179 EQ CODE(S) 1                        (CONDITIONAL # 62)
    THEN GO TO Q.#194 ELSE GO TO Q.#195.
 ENTER RESPONSES FROM SAF G3a HERE:

 -G3a- How is it going?
   GO TO Q. #195 ====> < 1 > Open end
 -- MULTI-PUNCH --
 -- ANSWER REQUIRED --

 *** QUESTION #195 ***
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q#179 EQ CODE(S) 2-4                      (CONDITIONAL # 63)
    THEN GO TO Q.#195 ELSE GO TO Q.#196.
 ENTER RESPONSES FROM SAF G3b HERE :

 -G3b- Why has it been stopped?
   GO TO  Q. #196 ====> <  1 > Open end
 -- MULTI-PUNCH --
 -- ANSWER REQUIRED --

 *** QUESTION #196 ***
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q#184 EQ CODE(S) 1                        (CONDITIONAL #64)
    THEN GO TO Q.#196 ELSE GO TO Q.#197.
 ENTER RESPONSES FROM SAF F9b HERE:

 -F9b- Could you describe that agreement?
   GO TO Q. #197 ====> < 1 > Open end
 -- MULTI-PUNCH --
 -- ANSWER REQUIRED --

 *** QUESTION #197 ***
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
```

Survey Instrument B-2—Instrument for OTA Survey of Biotechnology Companies (Cont'd.)

```
Questionnaire name: 6191B            12/15/93 - 11:41 AM          Page: 3 6


     IF Q#186 EQ CODE(S) 1                          (CONDITIONAL # 65)
    THEN GO TO Q.#197 ELSE GO TO Q.#198.
 ENTER RESPONSES FROM SAF F10b HERE:

 -F10b- Could you describe that agreement?
   GO TO Q. #198 ====> < 1 > Open end
 -- MULTI-PUNCH --
 -- ANSWER REQUIRED --

 *** QUESTION #198 ***
    << CONDITIONAL ASSOCIATED WITH THIS QUESTION >>
     IF Q#188 EQ CODE(S) 1                          (CONDITIONAL # 66)
    THEN GO TO Q.#198 ELSE GO TO Q.#199.
 ENTER RESPONSES FROM SAF F11b HERE:

 -Fllb- Could you describe that agreement?
   GO TO Q. #199 ====> < 1 > Open end
 -- MULTI-PUNCH --
 -- ANSWER REQUIRED --

 *** QUESTION #199 ***
 ENTER RESPONSES FROM SAF F12 HERE:

 -F12- Finally, do you have any suggestions for improving National
 Institutes of Health and Department of Energy processes for technology
 transfer to industry?
   GO TO Q. #200 ====> < 1 > Open end
 -- MULTI-PUNCH --
 -- ANSWER REQUIRED --

 *** QUESTION #200 ***
 INTERVIEWER: COMPLETE YOUR SAF WITH THE FOLLOWING INFORMATION:

 1 - PHONE NUMBER:

 2 - ELAPSED TIME: \
                       HIT TAB KEY
 3 - BATCH ID:

 4 - CATI RESP #:

 {ENTER YOUR INITIALS TO COMPLETE)
   GO TO Q. #201 ====>  < 1 > Open end single mention
 -- ANSWER REQUIRED --
```

SOURCE: Office of Technology Assessment, 1995, based on D. Blumenthal and N. Causino, "Sample of Biomedical and Biotechnology Firms for the U.S. Congress Office of Technology Assessment Survey About Firms' Involvement in Joint Projects with National Institutes of Health and the department of Energy of the Study of the Effects of the Federal Technology Transfer Act on the Commercial and Academic Activities of Federal Scientists,'' Massachusetts General Hosptial, Boston, MA,Apr. 21, 1993

# Appendix C Acronyms and Glossary

C

## ACRONYMS

| | |
|---|---|
| **ADAMHA** | Alcohol, Drug Abuse, and Mental Health Administration (now Substance Abuse and Mental Health Services Administration) |
| **AIDS** | acquired immunodeficiency syndrome |
| **ATP** | Advanced Technology Program |
| **CDC** | Centers for Disease Control and Prevention |
| **CRADA** | Cooperative Research and Development Agreement |
| **DBC** | dedicated biotechnology company |
| **DHHS** | U.S. Department of Health and Human Services |
| **DNA** | deoxyribonucleic acid |
| **DOC** | U.S. Department of Commerce |
| **DOE** | U.S. Department of Energy |
| **DOJ** | U.S. Department of Justice |
| **ERTA** | Economic Recovery Tax Act of 1981 |
| **FDA** | U.S. Food and Drug Administration |
| **FTC** | Federal Trade Commission |
| **FTTA** | Federal Technology Transfer Act |
| **FY** | fiscal year |
| **GOCO** | government-owned and contractor-operated |
| **GOGO** | government-owned and government-operated |
| **HIV** | human immunodeficiency virus |
| **NCHGR** | National Center for Human Genome Research (NIH) |
| **NCTTA** | National Competitiveness Technology Transfer Act |
| **NIH** | National Institutes of Health |
| **NIST** | National Institute of Standards and Technology |
| **OLS** | ordinary least squares |
| **ORTA** | Office of Research and Technology Applications |
| **OTA** | Office of Technology Assessment |
| **OTCA** | Omnibus Trade and Competitiveness Act |
| **OTT** | Office of Technology Transfer (NIH) |
| **PHS** | Public Health Service (DHHS) |
| **PTO** | U.S. Patent and Trademark Office (DOC) |
| **R&D** | research and development |
| **RFP** | request for proposal |
| **USDA** | U.S. Department of Agriculture |

## GLOSSARY

**Antitrust**
The area of the law dealing with protection of trade and commerce against unlawful restraints and monopolies or unfair business practices.

**Basic research**
Research performed to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts, without specific applications toward products or processes in mind.

**Biotechnology**
Any technique that uses living organisms or substances from those organisms to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses. These techniques include the use of novel DNA, cell fusion, and other bioprocesses.

**Cooperative Research and Development Agreement (CRADA)**
A formal agreement between a federal laboratory and a nonfederal party (individual, university, or private firm) in which the nonfederal party provides resources in exchange for exclusive rights to license patents that result from collaboration. Congress gave federal laboratories the authority to enter into CRADAs as part of the Federal Technology Transfer Act of 1986 (Public Law 99-502).

**Deoxyribonucleic acid (DNA)**
The molecule that encodes genetic information. DNA is a double-stranded helix held together by weak bonds between base pairs of nucleotides.

**DNA**
See *deoxyribonucleic acid*.

**Exclusive license**
The exclusive right granted by patent holder to license to use, manufacture, and sell patented article. Compare *nonexclusive license*.

**Extramural research**
Federally funded research conducted at universities or research institutions through federal grants or contracts.

**Fair access**
The fairness of a firm getting a boost over its competitors in the marketplace by entering a CRADA.

**Fiscal year**
For the U.S. government, the accounting period from October 1 through September 30.

**Gene therapy**
See *human gene therapy.*

**Genome**
All the genetic material in the chromosomes of a particular organism; its size is usually given in total number of base pairs.

**Genome projects**
Research and technology development efforts aimed at mapping and sequencing some or all of the genome of human beings and other organisms.

**Human gene therapy**
Treatment of disease by insertion of new genetic material or permanent modification of existing genes.

**Human Genome Project**
An estimated 15-year, $3 billion initiative to identify and map the genes comprising the human genome in order to increase knowledge and understanding of genetic disorders and gene-environment interactions and to improve diagnosis and treatment of genetic disease.

**Intellectual property**
The area of law encompassing patents, trademarks, copyrights, trade secrets, and plant variety protection.

**Intramural research**
Research conducted within an organization. In this report, research conducted by federal scientists in government facilities—e.g., the National Institutes of Health.

**Joint venture**
Form of association by separate business entities that falls short of a formal merger but unites certain agreed on resources of each entity for a limited purpose; in practice most joint ventures are partnerships.

**Licensing**
The sale of a license permitting use of patents, trademarks, or other technology to another firm.

**Life sciences**
A branch of science that deals with living organisms and life processes.

**Nonexclusive license**
Right granted by the patent holder to multiple parties to license an agent to use, manufacture, and sell a patented article. This right to use, manufacture, and sell the same item may be granted to multiple parties. Compare *exclusive license*.

**Patent**
A grant issued by the U.S. government through the U.S. Patent and Trademark Office that gives the patent owner the right to exclude all others from making, using, or selling a patented invention in the United States and its territories and possessions for the term of the patent (twenty years). A patent does not grant the inventor any affirmative right to use the invention. Laws of nature, physical phenomena, and abstract ideas cannot be patented. Patents have come to be viewed by many as vital for the protection of commercial and intellectual interests in the uses and products of various biotechnology techniques.

**Royalty**
Payment to the holder for the right to use property such as a patented invention, copyrighted material, or natural resources. Royalties are set in advance as a percentage of income arising from the commercialization of the owner's rights or property.

**Statute**
A particular law enacted and established by the legislative department of government.

**Technology transfer**
The process of converting scientific knowledge into useful products. This most often refers to the flow of information between public and private sectors or between countries.

**Title in contractor policy**
A policy by which small businesses and nonprofit organizations, including universities, can retain intellectual property rights to results from federally funded federal research.

# Appendix D Acknowledgments

D

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