Technology Transfer and NIH and DOE

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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).

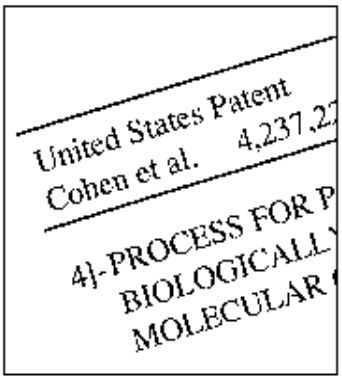
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TABLE 2-1: NIH and DOE Funding for the Human Genome Project

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).

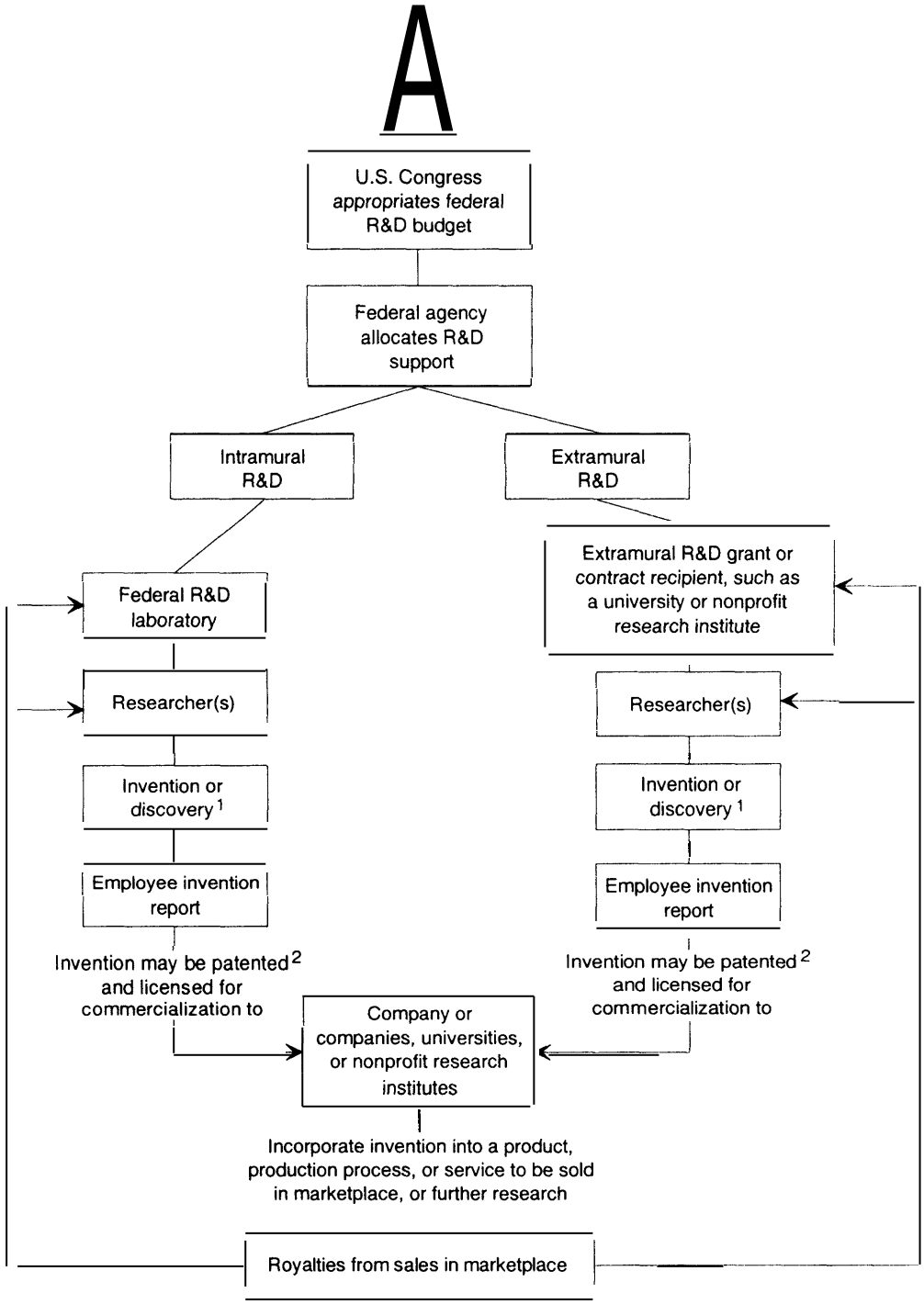
Technology transfer at federal facilities such as NIH and DOE is important, but since the majority of federally funded life sciences and biomedical research is conducted at universities and nonprofit research institutions, the impact of academic-based technology transfer is much greater. In fact, the 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.