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# Government Patenting and Technology Transfer

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## National Agricultural Library Cataloging Record:

*Government patenting and technology transfer.*  
(Economic research report (United States. Dept. of Agriculture. Economic Research Service) ; no. 15)

1. Patents and government-developed inventions--United States—Case studies.
2. Patent licenses—United States.
3. Intellectual property—United States. 4. Technology transfer—United States.
5. United States. Agricultural Research Service. I. Heisey, Paul W. II. United States. Dept. of Agriculture. Economic Research Service. S541

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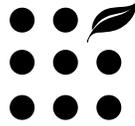
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United States  
Department  
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Economic  
Research  
Report  
Number 15

February 2006



A Report from the Economic Research Service

[www.ers.usda.gov](http://www.ers.usda.gov)

# Government Patenting and Technology Transfer

**Paul W. Heisey, John L. King, Kelly Day  
Rubenstein, and Robbin Shoemaker**

## Abstract

Intellectual property rights such as patents protect new inventions from imitation and competition. Patents' major objective is to provide incentives for invention, sacrificing short-term market efficiency for long-term economic gains. Although patents are primarily granted to private firms, policy changes over the last 25 years have resulted in greater use of patenting by the public sector. This study examines government patenting behavior by analyzing case studies of patenting and licensing by the Agricultural Research Service (ARS) of the U.S. Department of Agriculture. ARS uses patenting and licensing as a means of technology transfer in cases in which a technology requires additional development by a private sector partner to yield a marketable product. Licensing revenue is not a major motivation for ARS patenting. More widespread use of patenting and licensing by ARS has not reduced the use of traditional instruments of technology transfer such as scientific publication. Once the decision has been made to patent and license a technology, the structure of the licensing agreement affects technology transfer outcomes. As commercial partners gain experience with the technology and learn more about the market, mutually advantageous revisions to license terms can maintain the incentives through which private companies distribute the benefits of public research.

**Keywords:** Patents, licenses, intellectual property rights, technology transfer, Agricultural Research Service, agricultural research and development

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## Acknowledgments

The authors thank Barry Bozeman of the Georgia Institute of Technology, Josh Lerner of Harvard Business School, John Nail of the Advanced Technology Program, National Institute of Standards and Technology; and an anonymous internal reviewer for their careful reviews and valuable comments. June Blalock, Patent Licensing Specialist at the Office of Technology Transfer, Agricultural Research Service, USDA, provided guidance and insight to this project from its conception to its completion. We are very grateful for her assistance as well as her careful review of this report, all of which was crucial to its completion. In addition, we are grateful to the ARS Patent Advisors and representatives of licensee firms who patiently answered our questions about their experiences with the patenting and licensing processes. We also would like to thank Jeremy Foltz of the University of Wisconsin and Art Small of Columbia University for their helpful direction at the inception of the project, and Keith Wiebe and Kitty Smith of ERS for their useful observations on a later report draft. We are grateful to Karl Schneider, Reference Librarian of the National Agricultural Library, for excellent assistance with recovering and interpreting data on scientific publications. While we benefited from the assistance of all of these individuals, we alone are responsible for any remaining errors of commission or omission. Finally, special thanks are extended to Priscilla Smith for editorial support and to Juanita Tibbs for design work.

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## Summary

Intellectual property rights—patents, copyrights, and trade secrets, for example—protect new creations from imitation and competition. Patents provide an incentive for invention by granting a proprietary right to generate income from the invention—temporarily limiting the number of suppliers in a market. In granting patents, short-term market efficiency is sacrificed for long-term economic gains. Society in return gets new products and services, as well as voluntary disclosure of the technology needed to create them, which is made public upon grant of the patents. Major legislative and other developments in U.S. intellectual property rights (IPR) policy over the past 25 years have resulted directly or indirectly in greater use of patents by the public, as well as the private sector. These measures have generated considerable analysis of IPR policy.

The private sector depends on clearly defined and enforceable property rights for markets to function. Patents exist to restrict the use, sale, and manufacture of inventions and thereby to stimulate private sector investment in research and development. The Federal Government also holds numerous patents on inventions and discoveries from successful public research.

### What Is the Issue?

Why does the government need to patent at all? Patent rights are a means not only of capturing revenue but also of providing a mechanism through which publicly owned laboratories and other government research facilities can widely distribute a technology they have developed. Patent rights on Federal research are typically licensed to corporate partners, providing incentives for further development into commercial products—from prototype to near-market readiness. Awarding patents to government entities also can raise awareness of public research results; patents can also be employed defensively to promote wider use of a research tool if it seems likely that another entity might patent a similar technology in order to restrict access.

If a primary public policy objective behind government patents is to widely distribute the benefits, how well is that objective being achieved? Little analysis has been done on patenting as a means of technology transfer from Federal laboratories. This report examines government patenting behavior by focusing on patenting and licensing by USDA's Agricultural Research Service (ARS) as a means of technology transfer.

### What Did the Study Find?

Patenting and licensing can be consistent with the objective of widespread distribution of the benefits of ARS research. A technology that reaches society through private sector development of ARS research provides more net social benefits than a technology that is not developed at all because no private firm commercializes it—provided technology transfer activities do not withdraw too many resources from ARS's most important missions. This conclusion is likely applicable to other Federal research agencies as well.

ARS has been patenting and licensing innovations primarily as a means of technology transfer, not as a means of generating revenue to finance research. ARS licensing revenue only partially funds the operations of its Office of Technology Transfer (OTT), and only makes up 0.3 percent of the ARS total budget. An important factor in the ARS patent-application process is the likelihood of finding an acceptable partner for commercialization of the technology.

Increased patenting and licensing by ARS has not reduced the number of traditional instruments of technology transfer, such as scientific publications. From 1990 through 2003, as ARS patenting and licensing—and other newer means of technology transfer—increased, scientific publication counts for ARS remained relatively stable.

The ARS Office of Technology Transfer is often compared with university OTTs. Although both are nonprofit institutions, they have different objectives. Protocols for technology transfer through licensing are more restrictive for the Federal Government than for universities. The Federal Government follows specific guidelines to ensure transparency and fairness in its licensing arrangements. All other things equal, first preference for federally licensed technologies is given to smaller firms (typically fewer than 500 employees).

Determining the success of licensing terms and practices is very difficult—the success of a license depends on market size, market characteristics, and technology characteristics, and is subject to both “technology risk” and “appropriation risk.” “Technology risk” refers to the probability that a technology can be improved and developed into a feasible commercial product or process that is an improvement over available alternatives. “Appropriation risk” is the likelihood that a company will be able to earn profits from the new technology and not have them captured almost entirely by competitors. Potential market and technology parameters (e.g., size and characteristics) are often not known in detail when licenses are negotiated.

ARS does retain some flexibility in renegotiating license terms. The relevant market size and characteristics may become clearer over time. Similarly, different characteristics of a particular technology may turn out to have greater market potential than initially envisioned. *Ex post* flexibility can correct *ex ante* mistakes in predicting technology success or failure.

Also, licensing to more than one firm is more likely to be successful if the market is segmented geographically or by stages in a production process than if all firms are competing for the same market niche. Co-exclusive licensing when licensees are direct competitors for the same market niche can reduce collaborative efforts with ARS inventors in product development.

Federal research agencies differ in size of research budget, markets for possible commercial applications of their research, and management structure. Further research would be needed to determine how this report’s specific findings might apply to practices in other agencies.

## How Was the Study Conducted?

The study relied on two principal areas of analysis. The first was four case studies of technologies developed, patented, and licensed by ARS. The case studies were selected through consultation with the ARS Office of Technology Transfer (OTT). The authors interviewed scientists responsible for the inventions, ARS patent advisors who helped to determine patentability, and representatives of the eventual licensees. Secondly, the study drew on information from an earlier Economic Research Service (ERS) study that examined licenses of ARS technologies by research area and by characteristics of the technologies' social benefits.

The authors compared data on technology transfer, including data on patenting and licensing by ARS, with data from other institutions such as private firms, U.S. universities, and other Federal laboratories. This was accomplished through a review of the literature on the use of patenting and licensing by these different types of institutions, and analysis of data from the U.S. Patent and Trademark Office, the Department of Commerce, and ERS's Agricultural Biotechnology Intellectual Property database, available at: <http://www.ers.usda.gov/Data/AgBiotechIP>.

## Introduction

The Federal Government holds numerous patents on inventions and discoveries from successful public research. But patents exist to restrict the use, sale, and manufacture of inventions. If a primary objective of the public sector is to distribute the benefits of public research as widely as possible, why does the government patent at all?

The key principle behind patenting is that granting a proprietary right to generate income from inventive activity is expected to spur inventions. At the same time, disclosing the invention adds to the stock of knowledge, thereby enabling further discovery. Inventiveness and technical change are the engines of economic growth—so it is generally presumed to be in the public interest to grant intellectual property rights (IPR). The private sector depends on clearly defined and enforceable property rights for markets to function and, therefore, enforceable IPR might stimulate private sector investment in research and development. But this does not explain why the public sector would need to patent its technologies.

One explanation for public sector use of patents is that patent rights are not only a means of capturing revenue, but also a mechanism through which public laboratories and other government research facilities can transfer technology they have developed into widespread use. Patent rights on Federal research are typically licensed to corporate partners, providing incentives for subsequent development of commercial products. The Bayh-Dole and Stevenson-Wydler Acts of 1980 were intended to increase the rate at which new technologies are commercialized and to facilitate inventor involvement in technology development.<sup>1</sup>

Patent awards raise awareness about public research results. Greater awareness of recent results can spur further private sector development. Government patenting allows Federal research facilities to take credit for their work. Another rationale for government patenting is defensive in nature—the increasingly widespread use of patents could obstruct the government from pursuing public research objectives. Overlapping patent rights—for example, when a large number of owners hold rights in previous discoveries that could be used as building blocks in future research—might motivate patenting of Federal research when such overlapping rights threaten commercial use of the research, or when they hamper widespread use of federally developed research tools.

The debate over the appropriate role of patenting for public sector research dates back to the 1920s and 1930s, when increasing links between university and industry research stimulated discussion of patent policy by university administrators and the American Association for the Advancement of Science. Some issues raised in those early decades anticipated the debates over the Bayh-Dole Act 45 years later (Mowery and Sampat, 2001). Debates about the Federal Government’s right to patent the results of federally funded research date back to the 1880s, but assumed greater importance at the beginning of World War II (Jaffe and Lerner, 2001; Cohen and Noll, 1996).

<sup>1</sup>The Bayh-Dole Act allowed universities, nonprofit institutions, and small businesses to patent research discoveries partially financed with Federal funds. The Stevenson-Wydler Act allowed Federal laboratories to issue exclusive licenses for patents of their inventions. For a fuller discussion, see the chapter titled “Technology Transfer by Federal Agencies.”

The Bayh-Dole and Stevenson-Wydler Acts were part of a series of broad IPR policy changes over the past 25 years. This legislation extended privileges for patenting and licensing by inventors in universities and government laboratories whose inventions were developed partly or wholly with Federal funding. The other major changes were:

- (1) The creation of the Court of Appeals for the Federal Circuit (CAFC) in 1982 to provide a single national court for the judicial review of patent decisions
- (2) The extension of the applicability of patent rights to new technological areas, particularly gene technology, software, or business methods<sup>2</sup>
- (3) Attempts to extend and harmonize intellectual property protection internationally through trade agreements (Jaffe, 2000).

These policy changes have stimulated a great deal of economic analysis of IPR policy (Jaffe, Lerner, and Stern, 2001; 2002; 2003; 2004; 2005; Cohen and Merrill, 2003). To date, this research has focused particularly on patenting by private firms and universities. With a few exceptions, little analysis has been done regarding patenting as a means of technology transfer from Federal laboratories (Jaffe and Lerner, 2001). The same instrument—e.g., patenting and licensing—may often be used with different, although partially overlapping, ends in mind, as firms and universities have different objective functions. Jaffe and Lerner’s research suggests that the objective functions of Federal laboratories are likely to differ further from those of both private firms and universities. Our report provides a detailed examination of issues raised by government patenting behavior, with empirical examples drawn from patenting and licensing by the Agricultural Research Service (ARS) of the U.S. Department of Agriculture (USDA). Our analysis, like Jaffe and Lerner’s, suggests that ARS uses patents and licenses in different ways than firms or universities do.

<sup>2</sup>These extensions were signaled both by judicial decision—for example, the Supreme Court ruling in *Diamond vs. Chakrabarty* extending patentability to genetically modified microorganisms in the case of gene technology—and modifications in the U.S. Patent and Trademark Office’s examination procedures.

## The Public Policy Background and the Economic Case for Intellectual Property

To answer the question of why ARS patents and what it does with the patents it holds, we focused particularly on case studies of technologies patented and licensed by the agency. The case study methodology provides detailed information from interviews with the actors in the process—the inventors, the patent and technology transfer specialists, and the licensees. Case studies can lead researchers to conclusions that are obvious to practitioners but not evident from data (Helper, 2000). Case study information does not allow statistical tests, however, so it needs to be complemented by other empirical information to support the conclusions drawn. In this report, “other empirical information” includes:

- (1) A history of U.S. patent institutions and their hypothesized functions
- (2) Brief discussions of data on Federal Government activity in scientific research and technology transfer
- (2) Equivalent data for ARS as the agency principally responsible for agricultural research within the Federal Government
- (4) The alternative technology transfer mechanisms used by ARS

The aggregate data demonstrate the change in the Federal Government’s patenting and licensing strategy since the 1980s. For many years, the Federal Government often took title to the patentable research it funded. Licenses, if any, were nonexclusive, and many Federal patents were considered to have little commercial value. Following the policy changes of the 1980s, patenting and licensing increasingly became instruments of Federal technology transfer policy. This study of ARS looks in detail at the operation of an office of technology transfer (OTT) in a particular Federal agency, and clarifies the ways in which such an OTT accomplishes technology transfer through patenting and licensing.

### Constitutional Law and Incentives for Science

Intellectual property law in the U.S. arises from the U.S. Constitution. Article I, section 8, of the U.S. Constitution states:

*Congress shall have power ... [t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.*

Over time, Congress used this power to pass laws for the encouragement of inventive and creative efforts. The Patent Act of 1790 was the first such law. Patent law provides the economic incentive to undertake such efforts because of the temporary exclusive rights of owners to generate income from these inventions. Thomas Jefferson, first head of the Patent Office, believed that inventive activity was the engine of growth. At the same time, the idea of owning new knowledge and inventions conflicted with the idea that new knowledge should be freely available to encourage further inventiveness

and economic growth. For Jefferson, the role of the patent office was to encourage and disseminate inventions, not conceal or contain them. Because of these beliefs he formulated a policy for patents that encouraged invention but maintained restrictions on what could be patented. That policy is essentially the basis for our patent law today.

## **An Overview of Intellectual Property**

Intellectual property rights (IPR), such as patents, copyrights, and trade secrets, protect new creations from imitation and competition. The major policy objective of IPR is to restrict temporarily the number of suppliers in a market in order to provide incentives for innovation by allowing innovators to reap commercial success from their creations. In return, society gets new products and services, as well as voluntary disclosure of the technology needed to create them. Intellectual property rights usually last for a limited period; when intellectual property rights expire and an invention is no longer protected, anyone is free to compete against the original inventor. In general, granting IPR aims to sacrifice short-term market efficiency for long-term economic gains (King, 2001).

An important role of IPR is to create a market for innovation. Institutions or individuals with important intellectual property assets do not necessarily possess the complementary assets, commercial skills, or market presence necessary to bring their products to market. IPR provide inventors a negotiating tool with which to license or sell an invention to other firms better positioned to commercialize it.

However, IPR also have drawbacks. They insulate IPR owners from competition, creating market inefficiencies. Protected markets permit higher prices that may maximize profits but may also restrict the widespread use of new inventions. IPR owners might also feel less incentive to innovate because they risk cannibalizing their own markets (Reinganum, 1983). Strong IPR also might hinder innovation if granted for a research tool or fundamental technology necessary for future improvements. While IPR can be licensed to other parties, owners of these kinds of IPR might refuse to grant licenses for strategic reasons. The problem could compound in areas of rapid and complex research in which many licenses might be necessary for further improvements, because the owner of any one of them could hold up further research (Heller and Eisenberg, 1998; Shapiro, 2001).

The net social gains from intellectual property (IP), particularly the patent system, sometimes are assumed to be positive. That is, the benefits to society from greater innovation are thought to outweigh the costs of market power or research holdup. This has certainly been the reasoning behind the major changes in IP policy in recent years. However, the empirical evidence to support this contention is limited and nuanced. Patents are only one of a number of factors that motivate invention, and their influence may be stronger in some industries, such as pharmaceuticals and chemicals, than in others. This might be caused in part by the combination of relatively high research intensity in these industries with the fact that new drugs or chemicals typically are composed of a relatively small number of patentable components (Scherer et al., 1959; Taylor and Silberston, 1973; Mansfield

1986; Levin et al., 1987; Cohen et al., 2000). Differences in the operation of IP systems do result in subtle economic differences. For example, the Japanese system is designed in part to promote greater intra-industry knowledge spillovers than the U.S. system is (Cohen et al., 2002). It has become particularly difficult to measure the economic impacts of the U.S. patent system in recent years because of the large policy changes in that system that started in the 1980s and are still ongoing (Jaffe 2000).

Empirical studies of the economic impact of patent protection fall into one or more of several subcategories:

- (1) the impact of patents on innovation
- (2) the impact of patents on the disclosure of inventions
- (3) the impact of patents on technology transfer (Gallini, 2002)

Empirical research also has been initiated in response to criticisms of stronger patent protection, in particular problems associated with new subject matter, changes in the standard for nonobviousness,<sup>3</sup> and the rise in patent litigation costs (Gallini, 2002; see also Mazzoleni and Nelson, 1998).

The greatest empirical interest has concerned the question of the impact of patents on innovation, but strong patent protection also may promote vertical specialization and reduce transactions costs in negotiating contracts during the process of technology transfer (see a review in Gallini, 2002, especially pp. 141-144). Reduction of transactions costs has been considered particularly important in technology transfer from universities to industry (Jensen and Thursby, 2001; Hellmann, 2005).

Our study is particularly concerned with the impact of patents on the development and commercialization of inventions already produced by public sector institutions, in particular by the Agricultural Research Service (ARS) of the U.S. Department of Agriculture. Our focus is on the economic interaction between the IPR and technology transfer, and on how this interaction affects public research outcomes.<sup>4</sup>

## Approaches to the Empirical Study of Technology Transfer

One analytical approach to technology transfer is from the “market failure” perspective. In this approach, competitive markets allow buyers and sellers to communicate through price signals, leading to an efficient level of production. At times, however, markets fail to produce an efficient amount of a good for several reasons.

One of these reasons is the existence of “externalities.” Externalities occur when production or consumption of a good affects a party external to the transaction. A “positive externality” occurs when a transaction benefits a party external to the transaction. For instance, a homeowner who purchases flowerbeds and landscaping services to beautify the exterior of her house also benefits the next-door neighbors, who might enjoy the beauty of the flowers and an increase in neighborhood property values. The neighbors receive a benefit from the purchases, although they are not directly involved

<sup>3</sup>U.S. utility patents—the main patent category, as contrasted with other types such as plant patents—must meet standards of usefulness, novelty, and nonobviousness. “Nonobviousness” means the patented technology must not be obvious to an individual “skilled in the art.”

<sup>4</sup>Technology-transfer specialists may define “technology transfer” as “conversion of intellectual assets into goods and services functional for end users.” Some social-science research emphasizes the types of actors involved in domestic technology transfer, for example the transfer of technology from the public to the private sector, between private-sector institutions, or between public-sector institutions. In other studies, the term “technology transfer” refers to the transfer of technology among countries, in particular from industrialized to less-developed nations. Different definitions of technology transfer can overlap. In this study we focus both on the conversion of intellectual assets and on the roles of the public and private sectors.

in the transactions that create the benefit. The same example generates a “negative externality” if the transaction imposes costs on the neighbors: pollen from the flowers might cause an allergic reaction, necessitating medical expenses.

Lack of competition is another potential source of market failure. A limited number of sellers or buyers in a market may distort prices and keep the volume of transactions below the efficient level, resulting in prices that are too high and quantities exchanged that are too low compared with prices and quantities in a competitive market. Antitrust law exists to prevent this market failure. For example, the United States District Court of the District of Columbia held in 1998 that Microsoft Corporation “could charge a price for [the Windows operating system] substantially above that which could be charged in a competitive market.”<sup>5</sup> Additional competitors lower prices and increase the total social benefit of the market (albeit at the expense of the monopolist).

<sup>5</sup>(C.A.98-1232)

Markets might also fail to produce an efficient amount of a good when it is “nonexcludable” or “nonrival” (or both). Nonexcludability and nonrivalry are the two basic concepts used to define public goods. A nonexcludable good can be consumed by anyone for free. In the earlier gardening example, the homeowner cannot easily prevent people from enjoying the beauty of the flowers. (The homeowner could erect a fence and charge admission to the garden, so this particular good might be partially excludable.) Suppliers of nonexcludable goods can have difficulty forcing consumers to pay, and therefore nonexcludable goods are sometimes undersupplied. A nonrival good is one that many people can consume without diminishing the consumption of others, such as radio broadcasts and fireworks displays. Precisely because nonrival goods can be enjoyed so broadly, markets can undersupply them, which is socially inefficient.

The existence of market failures is often a basis for public intervention. Intervention might take the form of a tax policy to discourage negative externalities, a subsidy policy to encourage positive externalities, or antitrust policy to increase competition.

Public investments in research and development (R&D) are another response to market failure. Public R&D generates new information, in the form of scientific knowledge. Information is sometimes considered a pure public good. It is nonrivalrous, in that information can be understood and used by everyone simultaneously. It is also difficult to exclude, because many ways exist to convey information inexpensively. Because it displays both of these characteristics, information created by publicly provided R&D is often considered a public good.

Public research also can address problems of market failure more directly. Federal laboratories can research new technologies to reduce pollution byproducts of manufacturing. The research is itself a public good, in the sense that it generates information that is nonexcludable and nonrival. In addition, the subject of the research is aimed at correcting a market failure arising from the negative externalities of pollution.

Although universities, the Federal Government, and private firms all may conduct research with some public-good aspects, universities often are regarded as the primary source of public-good research. For much of their history, U.S. universities emphasized engineering and applied technology development more than they did basic research (Rosenberg and Nelson, 1994). Following World War II, U.S. universities became one of the world's most important sources of public-good research, a role consistent with the market-failure paradigm (Bozeman, 2000).<sup>6</sup> These two roles—provision of information with public good externalities, and research in areas where market failure is an issue—represent the public response to market failure in this approach to technology transfer.

There are analytical approaches other than “market failure” to the study of technology transfer. The “mission technology” paradigm “assumes that the government should perform R&D in service of well-specified missions in which there is a national interest not easily served by private R&D” (Bozeman 2000). The pre-eminent example of mission-related technology development in the U.S. is defense- and national security-related R&D. Civil engineering or sponsorship of the National Armory—which helped in the development of manufacturing techniques using interchangeable parts and mass production—are among the earliest examples of research in support of the military mission. Agricultural research and extension was another relatively early example of mission-related research, with some activities such as seed importation and classification carried out by the Agriculture Division of the Patent Office even before the establishment of the U.S. Department of Agriculture in 1862 (Dupree, 1986; Hounshell, 1984; Huffman and Evenson, 1993).<sup>7</sup>

Finally, the “cooperative technology policy” paradigm stresses cooperation among industry, government, and universities, and cooperation among rival firms in the development of precompetitive technologies (Larsen and Wigand, 1987; Wigand and Frankwick, 1989; Link and Tasse, 1987). In this paradigm, government can serve both as a research performer and as a research broker, developing policies that affect industrial innovation. This paradigm is based on the belief that government technology planning and coordination can enhance innovation and productivity. The cooperative technology policy paradigm is one of the major factors behind the many policy changes, including changes in IP policy, which began in the 1980s. However, this paradigm is sometimes in conflict with the market failure paradigm that characterizes many economists' thinking on IP and technology transfer policy (Bozeman, 2000).<sup>8</sup>

## The Economic Case for Intellectual Property in Federal Technology Transfer

The objective of a Federal office of technology transfer (OTT) is to serve the public interest by maximizing the value of Federal research.<sup>9</sup> In many cases, the public interest is best served by the publication and wide dissemination of Federal research, placing it in the public domain where anyone can put it to use. However, when Federal research creates a product or technology with potential commercial applications, laws provide scope for further development by private sector firms. In this way, the government can

<sup>6</sup>In many instances, students of research policy distinguish between basic and applied research. However “basic research” is not always identical with “public goods research,” nor is “applied research” always identical with “private goods research.” “Some applied research serves to develop public goods, and some basic research results can be held as private goods depending on how they are disseminated” (Just and Huffman, 2004). This is part of the context for our remarks on the development of pollution control technology, for example.

<sup>7</sup>Other currently important government mission research areas are medicine and public health, energy production and conservation, and space (Bozeman, 2000).

<sup>8</sup>In the “market failure” paradigm, the government's role is seen as residual; in the “cooperative technology policy” paradigm, the government plays a considerably more active role in coordinating research across sectors.

<sup>9</sup>The Stevenson-Wydler Act mandated “that all major Federal laboratories establish an Office of Research and Technology Applications to undertake technology transfer activities” (Jaffe and Lerner, 2001).

pursue Federal research priorities and provide incentives for the development of resulting technologies, and at the same time harness the economic efficiency of market competition.

Generally speaking, technology developed with the support of Federal research is not immediately ready for commercialization. A technology developed to the point of patentability might require further investments in research and development before it can be marketable. A scientist may patent a plant trait with beneficial agronomic properties, but it is unlikely that the invention can succeed commercially unless it can be incorporated into a crop variety with a competitive yield. Likewise, a patented mechanical process or invention might work well at a small scale, but it might need additional development to realize its benefits at a larger scale. Additional research might be necessary to improve a technology and learn more about its properties, or additional development effort might be necessary to integrate the technology into a feasible production process. Commercialization is the final step, incurring marketing and advertising costs along with production costs.

When additional investments in research and development are necessary to commercialize a patented technology, firms may be willing to pay money up front to develop a technology that is expected to be profitable in the future. The licensing fee they pay to a Federal OTT is usually only a small fraction of all the investments they make before a technology breaks even: R&D expenses, capital costs, marketing, and advertising are among them. Companies that invest are risking their capital and effort, and they must expect a suitable return on their investment to be willing to license a technology. Patents play an important part in increasing the perceived profitability of a technology, since patents limit competition in the early stages of business development.

Technology licensees face two distinct types of risk—"technology risk" and "appropriation risk." Technology risk is the chance that a technology can be improved and developed into a feasible commercial product or process. The technology must not merely work; it must be an improvement over available alternatives for the additional expense of development to be worth the investment.

Appropriation risk is the likelihood that a company is able to reap profits successfully from its investments in the new technology. After a released technology is found to be profitable, competitive forces put pressure on profits. Competitors might lower prices, or existing companies and new entrants might try to imitate the new technology. In time, competitors can try to "invent around" the technology to achieve the same result in a different way. Other inventors might create further improvements to the technology and capture market share and profits that way. In the long run, new inventions, technologies, and changing production practices and customer choices limit the possible profits even when a technology is patented. If a commercial partner is not found, because the Federal Government is not likely to bring the invention into commercial production, it is improbable that the technology will have widespread impact.

The Stevenson-Wydler Act reduces appropriation risk for potential licensees by providing scope for patent protection of federally funded research. This reduction in risk encourages the additional investments necessary for technology commercialization, and increases the likelihood that Federal research can be transformed into commercial applications. Without patent protection, appropriation risk is typically very high, especially if competitors are able to learn from the additional investments made by the first developer. Patent protection may help to solve the potential problem of “me too” developers. If no one wants to develop the technology first because most of the profits from the invention are earned by subsequent developers, even the first steps toward eventual commercialization of the technology may be stymied.

The government has other means to transfer technology; one is by publishing research.<sup>10</sup> When an OTT believes that the best way to maximize the value of Federal research is to issue licenses, it must balance the incentives offered to licensees.<sup>11</sup> Too much incentive can enrich licensees at the expense of customers and consumers; too little incentive increases appropriation risk and can result in the abandonment of development efforts and the failure to commercialize the technology.

A carefully chosen licensing strategy might increase the probability that an invention will be developed into a commercial product or process. What can the Federal Government do to increase incentives for potential technology partners to take out a license? Additional research support can mitigate technology risk. Federal researchers, along with the OTT, can offer more integrated licensing and research support, perhaps conducting additional testing and extensions of the original research. The original inventor is the most skilled practitioner of the research, and, following mutual agreement, can support product developers with further testing or research. An OTT also may reduce the terms of a technology license, lowering licensing fees.

Sometimes an OTT might opt to attenuate licensee incentives. Since reducing technology risk benefits licensees, the OTT might be able to negotiate more demanding terms in license agreements, for example through higher licensing fees. An OTT might also choose to diversify the technology risk across more than one licensee by choosing nonexclusive licenses, co-exclusive licenses, or licenses exclusive by territory or field of use. Although the definition of these terms often remains loose, nonexclusive licenses<sup>12</sup> are freely granted to as many parties as wish to negotiate them. Co-exclusive licenses may be offered in overlapping fields or territories, but only to a limited number of entities. Licenses exclusive by territory or field of use are issued to different entities in nonoverlapping territories or fields<sup>13</sup> (see box, “Varying Degrees of License Exclusivity”).

Technology development and commercialization can fail for a variety of reasons—lack of financial capital, poorly suited human capital such as a scientific research staff with limited knowledge of the particular area of technology, bad luck, etc.—so a greater number of technology partners might increase the chances that one of them can successfully commercialize the technology. Offsetting this reduction in risk is the greater appropriation risk for licensees when licensing is open to multiple firms. Less exclusive licensing need not exacerbate appropriability risk: a sufficiently profitable market may be able to

<sup>10</sup>These means, and reasons for choosing among them, will be discussed further in this report.

<sup>11</sup>In patent law, a license is a written authority granted by the owner of a patent to another legal person, empowering the latter to make or use the patented product or process under certain restrictions.

<sup>12</sup>Nonexclusive licenses are occasionally referred to as “open licenses.”

<sup>13</sup>These licenses are occasionally referred to as “multiple exclusive licenses.”

## Varying Degrees of License Exclusivity

A patent's value stems from its ability to limit competition and thereby increase profits due to the scarcity value of the patented invention. The value of a patent license is therefore related to the extent to which it excludes competitors. Exclusivity is not an absolute, however, but rather exists on a scale. When the Federal Government obtains a patent on its research, it determines the degree of exclusivity in part by how it licenses the patent. Factors such as appropriability risk and market contestability also are relevant to the scarcity value of a technology.

Patent license exclusivity		
Exclusivity	Type of license	
 <p>Least exclusive</p>	<b>Publication</b>	Research is published into the public domain; invention becomes unpatentable and free for anyone to use.
	<b>Nonexclusive licensing</b>	The Federal Government obtains patent rights, but licenses the patent to any interested party.
	<b>Co-exclusive licensing</b>	The Federal Government obtains patent rights, but offers a limited number of licenses that may be in overlapping fields or territories.
	<b>Licensing exclusive by territory or field of use</b>	The Federal Government obtains patent rights, but offers a set (usually small) limited number of licenses in nonoverlapping territories or fields.
	<b>Sole exclusive licensing</b>	The Federal Government obtains patent rights, but offers only one license. As in all other cases, the Federal Government retains its own ability to use the invention.
	<b>No licensing</b>	Some technologies are not available for license on any terms. Examples include military weapons and nuclear power technology.
Most exclusive		

Source: ERS analysis.

support numerous licenses. Licensing the same technology to different industries or to different industry segments may create additional markets for a technology and increase its value to society.

Flexible licensing approaches also can reduce risk. For example, high upfront licensing fees or high royalty rates might appear sustainable at early stages of commercialization (see the chapter “Technology Transfer by Federal Agencies”). If the technology reveals itself to be more difficult to develop or the market is less profitable than originally thought, the OTT can revise the terms of a license to maintain technology partner involvement.

# Technology Transfer by Federal Agencies

## Federal Guidelines for Technology Transfer

Between 1980 and 2003, the U.S. Federal research budget grew from \$66.7 billion to \$119.6 billion in real terms and represented nearly 30 percent of all R&D investments—public and private (table 1). More than half of the total was allocated to defense-related research. Of nondefense R&D spending, human health research represented 20 percent in 1980—growing to nearly 50 percent by 2003. NASA and the Department of Energy represent the next largest shares of nondefense R&D spending. Federal agricultural research spending grew from \$1.4 billion (4.1 percent of nondefense R&D) to \$2.37 billion (4.3 percent of nondefense R&D) in 2003.

What do these investments in research accomplish? Most of the research investments by the Federal Government are to support specific mission areas, e.g., military objectives, advances in basic health-related issues, and space exploration. Often there are scientific discoveries made in the process of carrying out the mission-oriented research that if made available to the private sector, with additional developmental research, may result in commercially viable products. Computed axial tomography (CAT) and magnetic resonance imaging (MRI) medical scanning technology, freeze-dried foods, and cordless power tools are examples of products derived from investments in the space program that benefited American consumers once the technology became commercially viable. These products are often

Table 1

### Federal research and development (R&D) expenditures by agency, selected years, 1980-2003<sup>1</sup>

Agency	FY 1980	FY 1985	FY 1990	FY 1995	FY 2000	FY 2003
	<i>\$ millions</i>					
Department of Defense	28,317	49,251	49,983	41,124	42,853	60,074
National Aeronautics and Space Administration	10,589	5,485	9,386	11,004	10,182	10,822
Department of Energy	11,651	9,208	9,223	7,464	7,460	8,565
Department of Health and Human Services	7,687	8,474	11,262	13,399	19,498	28,059
National Institutes of Health <sup>2</sup>	6,958	8,109	10,701	12,520	18,482	26,744
National Science Foundation	1,842	2,186	2,282	2,787	3,143	3,978
Department of Agriculture	1,444	1,543	1,615	1,730	1,904	2,373
Department of the Interior	828	599	701	777	663	652
Department of Transportation	802	676	467	775	651	709
Environmental Protection Agency	691	471	560	645	598	575
Department of Commerce	723	603	597	1,301	1,259	1,213
Department of Homeland Security	0	0	0	0	0	747
Department of Veterans Affairs	275	330	288	306	692	828
Other	1,888	854	1,336	1,227	931	1,078
<b>Total R&amp;D</b>	<b>66,735</b>	<b>79,678</b>	<b>87,700</b>	<b>82,539</b>	<b>89,834</b>	<b>119,672</b>
Defense R&D	31,162	53,465	54,086	44,014	46,286	64,544
Nondefense R&D	35,573	26,213	33,614	38,525	43,548	55,127

Note: Constant dollar conversions based on OMB's gross domestic product deflators from the FY 2005 budget.

<sup>1</sup>Years are fiscal years (FY), from October 1-September 30.

<sup>2</sup>The National Institutes of Health are part of the Department of Health and Human Services; the HHS numbers include the NIH ones.

Source: American Association for the Advancement of Science Reports I through XXIX, based on Office of Management and Budget (OMB) and agency R&D budget data, including conduct of R&D and R&D facilities.

referred to as “spinoffs” from the space or other programs. Recognizing the potential benefits to business, industry, and consumers from federally funded scientific and technical advances, the government has developed considerable legislation over time to facilitate transfer of discoveries from the public to the private sector.

Federal involvement in technology transfer stems from several concerns. The government needs specific goods and services for its various missions, and those goods and services often cannot be purchased directly in the marketplace. Contracting, cooperation, and licensing arrangements between Federal labs and private industry facilitate the development of products the government needs. A key example is military equipment produced by private contractors. Cooperation between Federal labs and private firms also provides government researchers with access to state-of-the-art technical developments. But the chief reason for Federal involvement in technology transfer is to promote technological development and change that can spur economic growth. Technological change has been credited with responsibility for one-quarter of the economic growth in the U.S. economy during the last half of the last century and has been a major source of long-term economic growth and welfare (Jorgenson and Stiroh, 2000).

There are three hypothesized goals of Federal technology transfer policy:

- (1) To bring the benefits of public R&D to potential users. One of the motivating factors behind technology transfer policy was concern that too many publicly developed technologies were useful, but unused. The Bayh-Dole Act “constituted a congressional endorsement of the argument that failure to establish patent protection over the results of federally funded university research would limit the commercial exploitation of these results” (Mowery et al., 2001).
- (2) To draw on private sector resources when possible, as the public sector shifts resources to areas in which it has a comparative advantage. In U.S. agriculture, for example, the public agricultural research system has been characterized by a decentralized State-led structure, which fosters geographically specific applied research (Schultz, 1971; Huffman and Evenson, 1993). Public and private entities cooperated closely, with the public sector playing a strong applied research role. However, influential reports published by the National Academy of Sciences (1972) and by the Rockefeller Foundation (1982) argued that agricultural research had become overly focused on applied research, and had moved too far from the cutting edge of biological research. Since that time, many public agricultural research institutions have sought to pass more applied work to the private sector, and focus instead on basic research and applied research with strong public-good characteristics. Technology transfer has offered public research institutions an opportunity for private firms to assume certain forms of applied research and development.
- (3) To allow public institutions to influence the development of new technologies. Like other industries, agricultural production offers benefits to society, but it may also impose certain externalities. Technology transfer offers public institutions an opportunity to promote the development of technologies that increase agriculture’s benefits to society or mitigate the costs of agricultural production (Fuglie et al., 1996).

## Key Legislation

Prior to the 1980s only about 5 percent of federally owned patents were being licensed and used by the private sector. While many patented technologies held by the public sector are specific to Federal mission needs and may have no commercial potential, it was nonetheless felt that there were unexploited discoveries within the public sector that could benefit the private sector and, as a result, the general public. Also, most Federal agencies would take title to discoveries made with Federal funds—regardless of who made the discovery—and then would only license the patents with nonexclusive licenses. Without ownership of the technology, or at least a partially exclusive license, private firms had little incentive to develop and commercialize the technologies. To remedy these concerns, two key pieces of legislation were enacted with the explicit purpose of getting Federal research from the lab into the market: The Patent and Trademark Act (P.L. 96-517), referred to as the Bayh-Dole Act, and the Stevenson-Wydler Technology Innovation Act (P.L. 96-480). The purpose of the Bayh-Dole Act was to create a uniform national policy (out of the 26 different agency policies) to minimize bureaucratic inconsistency and encourage private industry to invest in the commercial development of federally produced research. The legislation would allow universities, nonprofit institutions, and small businesses to obtain patents arising from research that was funded with Federal funds. This law allowed these entities to derive royalties from their patents, which then would support further research and enhance the return on their investment. The Stevenson-Wydler Act was similarly designed to encourage the use of federally funded research through technology transfer. Transfer is achieved by transferring legal rights (licensing), assigning patent title to private contractors, or through personal interactions. Both Acts also encouraged the licensing of technologies to small businesses.

The Federal Technology Transfer Act of 1986 (P.L. 99-502), which amended the Stevenson-Wydler Act, permitted the use of cooperative research and development agreements (CRADAs). A CRADA is a legal document that defines a collaborative venture between a government lab and another entity, e.g., a university or private firm.<sup>14</sup> The Bayh-Dole Act permits nongovernment cooperators in a CRADA to receive title to an invention. The Federal Technology Transfer Act also increased employee incentives by including technology transfer in performance evaluations (see box, “U.S. Legislation Governing Patenting and Transfer of Federally Funded R&D”).

<sup>14</sup>Throughout this report, the term CRADA is used to refer to the specific legal mechanism described in the Stevenson-Wydler Act, and not to more general cooperative research efforts.

## U.S. Legislation Governing Patenting and Transfer of Federally Funded R&D

Since 1980, Congress has enacted a series of laws to promote technology transfer and to provide technology transfer mechanisms and incentives. These laws and related executive orders encourage the dissemination of new knowledge and foster the development of commercial technologies. Sharing between federal laboratories and private industry can include not only technologies, but personnel, facilities, methods, expertise, and technical information in general.

**The Stevenson-Wydler Technology Innovation Act (1980)** required Federal laboratories to facilitate the transfer of federally owned and originated technology to State and local governments and the private sector. The act required offices of technology transfer in Federal agencies and established budgeting and reporting requirements.

**The Bayh-Dole University and Small Business Patent Act (1980)** permitted government grantees and contractors to retain title to federally funded inventions and encouraged universities to license inventions to industry. The act is designed to foster interactions between academia and the business community.

**The Small Business Innovation Development Act (1982)** established the Small Business Innovation Research (SBIR) program within the major Federal R&D agencies to increase government funding of research that has commercialization potential within small high-technology companies.

**The National Cooperative Research Act (1984)** encouraged U.S. firms to collaborate on generic, precompetitive research by establishing a rule of reason for evaluating the antitrust implications of research joint ventures. The act was amended in 1993 by the National Cooperative Research and Production Act (NCRPA), which let companies collaborate on production activities as well as research activities.

**The Federal Technology Transfer Act (1986)** amended the Stevenson-Wydler Technology Innovation Act to authorize cooperative research and development agreements (CRADAs) between Federal laboratories and other entities, including state agencies.

**The Omnibus Trade and Competitiveness Act (1988)** established the Competitiveness Policy Council to develop recommendations for national strategies and specific policies to enhance industrial competitiveness. The act created the Advanced Technology Program and the Manufacturing Technology Centers within the National Institute for Standards and Technology to help U.S. companies become more competitive.

**The National Competitiveness Technology Transfer Act (1989)** amended the Stevenson-Wydler Act to allow government-owned, contractor-operated laboratories to enter into CRADAs.

**The National Cooperative Research and Production Act (1993)** relaxed restrictions on cooperative production activities, enabling research joint venture participants to work together in the application of technologies they jointly acquire.

**The Technology Transfer Commercialization Act (2000)** amended the Stevenson-Wydler Act and the Bayh-Dole Act to improve the ability of government agencies to monitor and license federally owned inventions.

Source: Science and Engineering Indicators 2004, National Science Foundation.

## Federal Agency Use of Intellectual Property

The changes in technology transfer policies for federally funded, as well as federally performed research, outlined in the previous section, were one of four major changes in U.S. intellectual property policy that began in the 1980s.<sup>15</sup> The economic effects of these policy changes have been complex and not always well understood, although it is clear that both private and public sector institutions have responded to shifts in policy (Jaffe, 2000). Public data on patents are available from the U.S. Patent and Trademark Office (PTO), and more detailed information on invention disclosures, patenting, and licensing is available from the U.S. Department of Commerce. Available data suggest that although the level of patenting by Federal agencies has remained essentially unchanged for the past 25 years or more, the incidence of technology transfer from the Federal Government to the private sector has increased markedly with the passage of the Bayh-Dole, Stevenson-Wydler, and other technology transfer amendments.<sup>16</sup>

From 1976 through 2003, the number of patents issued each year to all Federal agencies and laboratories remained essentially unchanged (fig. 1). The total number of patents granted in all sectors grew about 140 percent over this period. The most striking change was for U.S. universities, for which issued patents increased 1,164 percent over this period. During this entire period, it should be noted that U.S. private sector patents consistently averaged 95 percent of the total issued to all U.S.-based institutions (fig. 1; USPTO). Patenting by the U.S. Department of Agriculture shrank from over 6 percent of the Federal total to about 3 percent by the mid-1980s, but has risen back to 5 or 6 percent today (figs. 2 and 3).

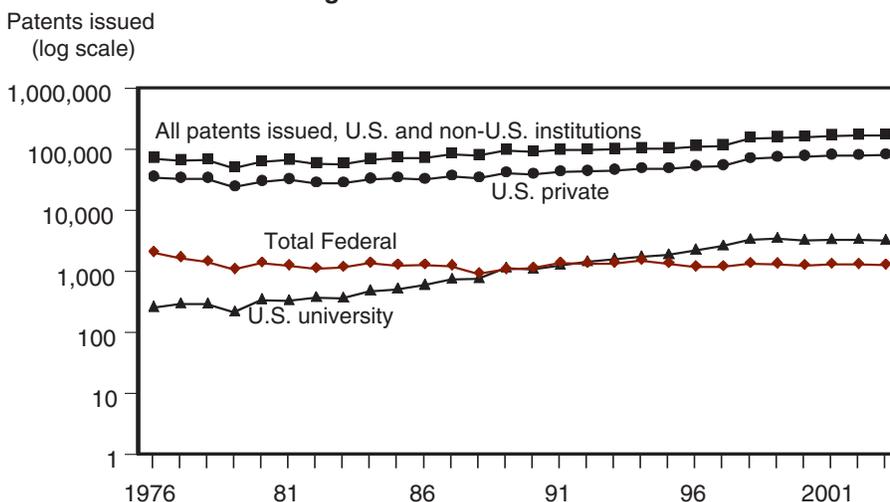
Issued patents are only one measure of the disclosure of research information by Federal entities. In recent years, Department of Commerce technology transfer data show positive trends for many indicators for the 10 largest government research agencies (unfortunately, in this source, issued patents were only recorded from 1997 and active licenses from 1999.)<sup>17</sup> For

<sup>15</sup>The others were the creation of the Court of Appeals for the Federal Circuit (CAFC) specifically to review patent decisions; the extension of patent rights to new technological areas; and agreements under the General Agreement on Tariffs and Trade (GATT) to harmonize IP policy worldwide.

<sup>16</sup>Market structure in the relevant industries likely to license technologies may differ from Federal agency to Federal agency. For example, the pharmaceutical industry, a likely recipient of National Institutes of Health (NIH) research, consists of large firms but is less consolidated than the agricultural biotechnology sector. Although USDA licenses relatively little to the narrowly defined agricultural biotechnology industry, agricultural markets are sometimes niche markets, served by relatively few firms, even if the firms are not large.

<sup>17</sup>In contrast to the patent data in the preceding paragraph, which were derived directly from the U.S. PTO, these data come specifically from technology transfer reporting by the Department of Commerce.

Figure 1  
**Patents issued to U.S. assignees**

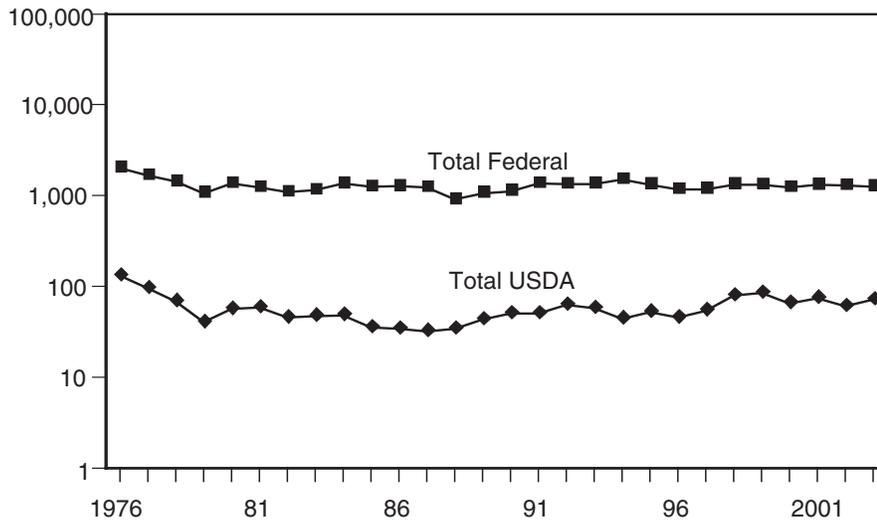


Source: ERS calculations based on U.S. Patent and Trademark Office (USPTO) data.

Figure 2

### USDA and Federal patenting

Patents issued  
(log scale)

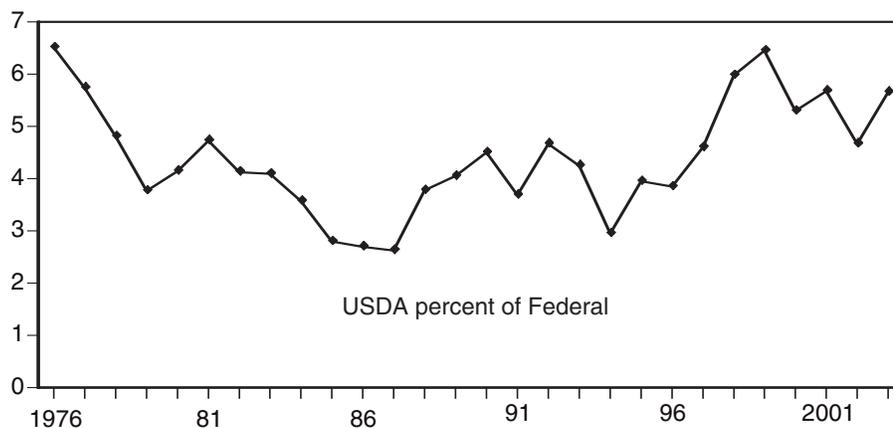


Source: ERS calculations based on USPTO data.

Figure 3

### USDA patenting as a percentage of all Federal patenting

Percent



Source: ERS calculations based on USPTO data.

these agencies, the number of inventions disclosed grew from 2,662 in 1987 to 3,909 in 2001 (table 2).<sup>18</sup> Patent applications grew from 848 in 1987 to 2,172 in 2001. More than half of all inventive activity as measured by invention disclosures arises from the Departments of Energy and Defense. USDA invention disclosures have been more modest, with 83 in 1987, 260 in 1997, and 118 in 2001. The licensing of patents by Federal agencies also grew considerably over this period. The number of new licenses issued by all agencies grew from 128 in 1987 to 578 in 2001. The number of active licenses was 3,142 in 2001.<sup>19</sup> The number of new licenses from the USDA each year was around 20 to 30 over this period. The total number of active USDA licenses was 255 in 2001. The use of CRADAs by all agencies also

<sup>18</sup>An invention disclosure contains information about new inventions and discoveries that help intellectual property managers determine if a patent application is necessary.

<sup>19</sup>License terms, including the length of the license, are subject to negotiation. Furthermore, licenses are sometimes abandoned (see below). A theoretical limit for the license of a patented technology is the patent term of 20 years.

grew over this period, from 34 active CRADAs for the 10 major agencies in 1987 to 3,603 in 2001. The number of active USDA CRADAs grew from 9 to well over 200 during the same period.

These indicators suggest that although changes in IP policy have not led to a rapid upsurge of patenting by the Federal Government, in contrast to the trends for the private sector and particularly universities, the incidence of technology transfer from the Federal Government to the private sector has increased with the passage of the Bayh-Dole, Stevenson-Wydler, and other technology transfer amendments. As we have noted, the purpose of these laws is to transfer technology—not to raise funds for the Federal Government through licensing. Licensing income for the whole Federal Government was \$5.8 million in 1987 and grew to \$69.5 million in 2000—the last year for which we have data on Federal licensing revenue. The total Federal R&D budget in 2000 was \$89.8 billion, which overshadowed the income from licenses. USDA license income grew from \$133,000 in 1987 to \$2.5 million in 2000, only about 0.3 percent of the total ARS R&D budget of \$885 million. In both cases, license income is not a complete measure of the benefits of public sector investments in science and technology; it is merely a reflection of the amount of technology being transferred through licensing agreements.<sup>20</sup> Licensing patents to firms is often desirable for agencies because the contracts bind the firms to developing and utilizing the technology, thus diffusing it into the marketplace. License fees also serve as a way to screen out firms with insufficient ability or interest to develop the licensed technology. License fees impose costs that a successful firm can expect to recoup in product sales, while discouraging unsuccessful firms from going forward. If the technology is successfully commercialized, the firm's resulting profits and the consumer benefits from the technology are the major direct economic benefits from the original research. This aspect of licensing is an important incentive that furthers the technology transfer mission, outweighing the importance of the total licensing revenues collected relative to the Federal R&D budget.

<sup>20</sup>The benefits to investment in R&D are difficult to measure and have been the subject of considerable research, (see Mansfield, 1977, 1991, or Alston et al., 1995 for excellent expositions on this research). Nonetheless, estimates of the rate of return to public agricultural research have had a wide range, with medians of around 50 percent to 60 percent. Even after adjusting for potential biases, the U.S. rate of return has likely been around 35 percent, indicating large public benefits (Fuglie et al., 1996; see also Alston et al., 2000 and Evenson, 2001 for worldwide estimates).

Table 2

**Federal technology transfer indicators, by selected U.S. agencies, FY 1987-2001<sup>1</sup>**

Agency	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
<i>Numbers</i>															
Invention disclosures and patenting															
All 10 agencies	2,662	3,047	3,168	3,772	4,213	3,901	3,538	3,753	4,001	4,153	3,842	3,503	3,646	3,564	3,909
Inventions disclosed	848	1,131	1,466	1,727	1,940	1,867	1,838	1,724	1,803	1,723	1,850	1,894	2,089	2,083	2,172
Patent applications filed	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1,265	1,466	1,448	1,391	1,608
Patents issued															
USDA	83	144	127	158	127	83	110	111	133	129	260	208	162	109	118
Inventions disclosed	44	50	71	76	110	70	68	40	80	91	56	64	84	78	83
Patent applications filed	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	45	75	74	64	64
Patents issued															
Invention licenses															
All 10 agencies	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2,736	3,009	3,142
Active invention licenses	128	129	150	164	206	239	260	337	408	462	487	492	596	511	578
New invention licenses															
USDA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	218	225	255
Active invention licenses	30	24	23	33	29	31	28	9	21	26	22	23	29	24	32
New invention licenses															
<i>Thousands of current dollars</i>															
Income from licenses of patented inventions															
All 10 agencies	5,875	6,346	7,304	9,413	18,163	14,070	18,570	26,641	27,922	36,969	50,234	57,563	60,174	69,498	NA
USDA	133	120	420	559	836	1,044	1,483	1,450	1,635	2,091	2,300	2,400	2,377	2,555	NA
<i>Numbers</i>															
Cooperative research and development research agreements (CRADAs) <sup>2</sup>															
All 10 agencies	34	98	271	460	731	1,078	1,628	2,471	3,121	3,530	3,078	3,038	3,227	3,133	3,603
Total active CRADAs	9	51	98	128	177	172	172	208	229	244	273	288	298	257	219
USDA															

NA = Data not requested or not available.

<sup>1</sup>The 10 agencies are the Department of Commerce, the Department of Defense, the Department of Energy, the Department of the Interior, the Department of Transportation, the Environmental Protection Agency, the Department of Health and Human Services, the National Aeronautics and Space Administration, the Department of Agriculture, and the Department of Veterans Affairs.<sup>2</sup>Data for CRADAs are for agreements established under the authority of 15 U.S.C. Sec. 3710a. Nontraditional CRADAs are agreements for special purposes, such as material transfer or technical assistance. Before 1999, NASA performed all of its technology transfer activities under the authority of the 1958 Space Act.Source: U.S. Department of Commerce, Office of the Secretary, *Summary Report on Federal Laboratory Technology Transfer: 2002 Report to the President and the Congress Under the Technology Transfer and Commercialization Act* (Washington, DC, 2002); and *Science & Engineering Indicators—2004*, Appendix table 4-38.

## Technology Transfer at the Agricultural Research Service (ARS)

The U.S. Department of Agriculture has a long history of close collaboration with private agricultural industries, in part because public agricultural research has in the past been more applied in nature than other types of public research (Fuglie et al., 1996). Still, new mechanisms for public-private collaboration in research have had a significant impact at the agency. ARS has increased technology transfer to the private sector considerably in the last decade (table 3). All three goals of Federal technology transfer policy—bringing the benefits of public R&D to potential users, finding innovative ways to fulfill the agency mission in an era of relatively scarce resources, and influencing the direction of technology development—may have played a role in this expansion of technology transfer.<sup>21</sup>

### Alternatives and Complements in ARS Technology Transfer Policy

#### Patents and Licensing

Patents are both an old and a new means of technology transfer. The Federal laboratories have long had the option of patenting innovations, but before 1980 only nonexclusive licenses could be granted. Passage of the Stevenson-Wydler Act in 1980 allowed Federal laboratories to issue exclusive licenses to patents

<sup>21</sup>Actual implementation of Federal technology transfer policy may differ from agency to agency. For example, ARS has a relatively small research budget and a single coordinated technology transfer program. The National Institutes of Health (NIH) have a large research budget, but also a coordinated technology transfer program. Department of Energy labs, on the other hand, are often run by different contractors, and these labs differ in, for example, the extent to which employees are encouraged to pursue commercially relevant activities.

Table 3

#### USDA technology transfer activities

Year	Patents awarded <i>Number</i>	Patent license royalties <i>Million dollars</i>	Active CRADAs <sup>1</sup> <i>Number</i>	Value of CRADAs <sup>2</sup> <i>Million dollars</i>
1987	34	0.09	9	1.6
1988	28	0.10	48	8.7
1989	47	0.42	86	15.6
1990	42	0.57	145	18.9
1991	57	0.83	181	17.1
1992	56	1.0	172	15.0
1993	57	1.5	172	50.5
1994	40	1.4	208	32.9
1995	38	1.6	229	33.2
1996	53	2.1	244	98.9
1997	35	2.3	273	155.5
1998	57	2.4	271	120.2
1999	74	2.4	298	136.7
2000	64	2.6	257	125.1
2001	64	2.62	219	117.9
2002	53	2.57	225	114.7
2003	64	2.29	229	84.8
2004			205	89.0

<sup>1</sup>Number of Cooperative Research and Development Agreements (CRADAs) with the private sector.  
<sup>2</sup>Value of CRADAs includes the total value of USDA and private-sector resources committed to active CRADAs over their lifetime.

Sources: Agricultural Research Service, USDA; Cooperative State Research, Education, and Extension Service, USDA.

on their inventions. In ARS, the decision to apply for a patent is taken by a Patent Review Committee, working in conjunction with the inventor and a patent advisor (see box, “The Patent Review Committee”).

ARS structures its total licensing fees such that they partially cover the technology transfer program costs. Licensing fees are not used to fund research.<sup>22</sup> The individual inventor(s) receives a percentage of the fee, usually 25 percent, and the remainder goes toward defraying the costs of patenting and licensing.<sup>23</sup>

While patenting and licensing are the focus of this report, there are other mechanisms for transferring technologies developed within the Federal Government. The multiple means used by ARS to transfer technologies are not mutually exclusive. For example, for a given technology, several aspects may be reported in scientific publications; another aspect may be the subject of a patent application; and a licensed patent may be further developed through a Cooperative Research and Development Agreement, or CRADA (described in the next section).

### ***Publications and Networking Among Scientists***

The traditional means of scientific exchange, publications, are ARS’s primary means of conveying the results of its research. Scientists publish results of their research both within ARS and through external organizations, such as refereed journals or books and book chapters produced by academic and commercial publishers. Internal publications may be specialized, but also include less technical newsletters and reports for nonspecialists.

Researchers, whether Federal, academic, or private, attend many of the same professional conferences. Through such conferences and through the literature associated with particular fields of study, private sector scientists are informed about the activities of their public sector counterparts (and vice versa). This familiarity often leads to informal relationships that contribute to technology transfer. We observed these relationships in several of our case studies.<sup>24</sup>

### ***TEKTRAN***

ARS informs potential cooperators of research advances through announcements at workshops and conferences, advertisements in the *Federal Register*, electronic postings, and an Internet database Technology Transfer Automated Retrieval System (TEKTRAN). Maintained by ARS, the database reports research findings that have been peer-reviewed and cleared by ARS management. TEKTRAN summaries are synopses of published or soon-to-be-published articles describing recent research (though some summaries are excluded to protect potential patents before publication). Thus, the summaries can help potential technology transferees identify new innovations.

The ARS Office of Technology Transfer also posts available technologies (whether protected by patent, the subject of a patent application, or other) on its website.

<sup>22</sup>Table 2 shows that in FY 2000, the mean annual revenue per license for ARS was just over \$11,000. For all 10 Federal agencies reported in that table, the mean annual revenue per license was around \$23,000. In the same fiscal year, universities and other academic institutions reported a mean annual revenue per license of about \$60,000 (AUTM, 2002). As table 4 will show, many ARS licenses do not generate revenue in a given year, and the distribution of license revenue is skewed, with mean annual revenue higher than median annual revenue. This kind of skewed license revenue distribution is typical of other Federal agencies and academic institutions as well. Revenue data for licensing from private sector technology owners are usually not publicly available.

<sup>23</sup>ARS inventors also receive the first \$2,000 in licensing revenue.

<sup>24</sup>In the economics of science, informal networking is one basis for the assumption that knowledge spillovers have a geographic component.

## **The Patent Review Committee: How ARS Decides To Patent An Invention**

At ARS, the patent process begins when an invention report is submitted by an ARS scientist. Each scientist has an assigned patent adviser, who is available for consultations regarding issues of patentability. Invention reports are submitted through the scientist's line managers, who approve the invention for patent filing, subject to the recommendation of a Patent Review Committee. Each committee consists of ARS scientists and representatives of the Office of Technology Transfer, who participate in the discussions as nonvoting members.

For each invention report submitted, a Patent Review Committee considers the following questions in deciding whether to recommend patent protection:

- (1) Is there current commercial interest in the invention or a high probability of commercialization in the future?
- (2) Is the magnitude of the market relative to the costs of commercialization large enough to warrant a patent?
- (3) Would a patent likely play a significant role in transferring the technology to the user?
- (4) Would a patent be enforceable; i.e., is the invention drawn to, or does it employ, a unique and readily identifiable material or device which could be bought or sold?
- (5) Is the invention of sufficient scope to justify patenting?

The committee can recommend to “approve,” “defer,” or “suspend” an invention report. “Approve” means that a patent application should be filed. “Defer” means that the invention report is sent back to the scientist for some specific additional information. Often, the committee recommends seeking potential commercial partners in order to be able to respond to the first question above. “Suspend” means that patent protection will not be sought, and information about the invention will be distributed through some other means, such as scientific publication.

After an invention report is approved, a patent application is prepared and submitted to the U.S. Patent and Trademark Office, and licensees are sought. Prior to granting an exclusive license, a notice must be published in the Federal Register, with a comment period during which objections may be raised. If more than one U.S. business would like to obtain a license, co-exclusive licenses, or multiple licenses in different fields or territories, may be granted. There is a preference for small businesses if they are as qualified to receive the license as a larger company is.

Source: Office of Technology Transfer, Agricultural Research Service, USDA.

## **Cooperative Agreements**

Cooperative Research and Development Agreements (CRADAs) are a tool for formally linking government and industry researchers. This program, authorized under the Federal Technology Transfer Act of 1986, allows Federal laboratories and businesses to form commercial partnerships that help move new technologies into the marketplace. ARS scientists and companies work together to develop a research plan that is consistent with the agency's mission. Under a CRADA, ARS scientists collaborate with outside institutions (e.g., private firms) to help commercialize technologies.

With CRADAs, both sides may contribute inhouse research resources such as personnel, equipment, and laboratory privileges. The non-Federal collaborator may provide the Federal laboratory with research funds; however, Federal laboratories do not provide financial resources to non-Federal partners (Congressional Research Service, 1991). Patents resulting from a CRADA may be jointly owned. In cases where the Federal laboratory retains title, the non-Federal partner has first right to negotiate an exclusive license. Some data also may not be publicly disclosed for a certain amount of time.

CRADAs are generally initiated by ARS scientists (W. Phelps, personal communication, 1997). According to USDA technology transfer officials, the guidelines for these arrangements are that the research must be consistent with the agency's mission, that there be no conflicts of interest, and that fairness be shown to potential cooperators (D.J. Blalock, personal communication, 1997).

## **Other Means of Protecting and Transferring Technologies**

ARS also has used Plant Variety Protection Certificates (PVPCs) to protect its innovations. PVPCs allow for the use of the variety in breeding programs without permission of the holder and permit farmers and growers to save seeds for their own use; thus, they are less likely to be licensed.<sup>25</sup> Most of the plant variety protection certificates are held with State agricultural experiment stations.

ARS scientists use material transfer agreements (MTAs) when they want to provide material to someone outside of ARS but also want to maintain control over the material. This agreement states specifically what the material is and what it can be used for, restricts giving it to a third party without permission, and prohibits commercial use of the material. All MTAs are reviewed by an ARS technology transfer coordinator.

In some cases, ARS must share certain confidential information with a company to determine if there is sufficient mutual interest to proceed with a CRADA and/or a patent license. A confidentiality agreement is used to prevent public disclosure of potentially patentable innovations.

## **Trends in ARS Patenting**

The "Technology Transfer by Federal Agencies" chapter demonstrated that as the number of U.S. utility patents increased rapidly over the past 25 to 30

<sup>25</sup>The intellectual property regime for cultivars of commercial crops includes plant patents for asexually reproduced crops, dating to 1930, PVPCs, dating to 1970, and utility patents, first formally recognized in 1985. See Fuglie et al. (1996). Although ARS holds utility patents across a wide range of agricultural technologies, it has only occasionally used IP protection of any kind for cultivars.

years, the number of patents issued to Federal Government and affiliated research agencies held relatively steady.<sup>26</sup> This implied a decline in the already small percentage of total patents issued to Federal labs. Over the same period, the number of patents issued to ARS fluctuated, although from 1985 onward there has been a fairly strong upward trend in these patents. Nonetheless, the rate of increase in the number of patents issued to ARS (4.4 percent annually from 1985 through 2003) was not as great as the rate of increase in total patents issued (5.1 percent annually over the same period).

There seems to be little evidence that over time technology transfer via patenting and licensing has come at the expense of publishing as the traditional means for disseminating research results from ARS. Figure 4 compares ARS patent counts from 1990–2003 with publication counts over the same period. Patent counts, which are much lower in absolute terms, are normalized by 100 scientist years, and publication counts by scientist years.<sup>27, 28</sup> This is done to give trends a common denominator for easy comparison. Publication counts, taken from the Institute for Scientific Information’s Current Contents database, identified all publications for which at least one author had “ARS” or “Agricultural Research Service” as an affiliation. Around 1998, ARS patent counts rose somewhat, while publication counts dipped slightly for several years before rising slightly again. However, even with this increase in patenting, ARS was granted roughly 60 to 80 patents a year, at the same time that scientists with ARS affiliations were partially or fully responsible for roughly 4,000 or more publications annually.<sup>29</sup> Normalization by scientist years suggests that output/input ratios have not decreased over time for publications even as patenting has increased. Normalization by ARS budgets, not shown here, also supports this conclusion. Recent empirical studies of the relationships between patenting and publishing in the life sciences (Azoulay et al., 2005; Murray and Stern, 2005) suggest that patenting and publishing can be complementary. The ARS data are consistent with these findings.

### ***Patenting at USDA versus Other Public Agricultural Institutions***

Within the U.S. public sector agricultural research system, the land grant universities could be considered to be the State level counterpart to ARS. Comparing changes in the numbers of patents issued to both sets of institutions gives a sense of the relative importance different institutions give to patenting. The available data indicate that in recent years ARS patenting has increased only modestly when compared with university patenting, whether or not the universities are land grants. This is completely consistent with the modest changes in all Federal patenting compared with university patenting (see chapter titled “Technology Transfer by Federal Agencies”). It is difficult to disentangle patents applicable to agriculture from general biological patents, but the available data suggest that university biological patenting that may have agricultural applications also grew much more rapidly than ARS patenting.

It is important to note that many patents issued to land grant universities fall outside the area of agriculture. Large research universities such as the University of California-Berkeley or the University of Wisconsin have many other subject areas in their patentable research portfolios. It is also important to note that it is usually not possible to determine whether a patent has potential agricultural applications without looking at the individual patent. For example,

<sup>26</sup>In the USPTO database patents resulting in part from ARS research are assigned to “the United States of America as represented by the Secretary of Agriculture.” In some cases, such patents could have other assignees as well, for example, universities that also participated in the research.

<sup>27</sup>Patent and publication counts could also be normalized by ARS’s real budget. There is also a question of lags—what is the average length of time between initial research investment and output in the form of publications, a patent, or both? In fact, for both scientist years and budgetary measures, incorporation of a 5-year lag suggested greater increases in per scientist year output, over the period reported here, for both publications and patents.

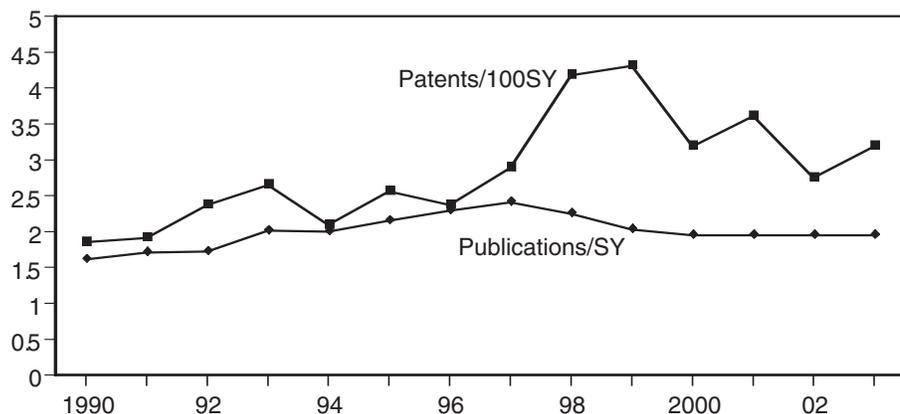
<sup>28</sup>A scientist year is the work done by a person who has responsibility for designing, planning, administering, and conducting research in 1 year (i.e., 2,080 hours).

<sup>29</sup>We examined publication counts using the AGRICOLA database of the National Agricultural Library. Changes in catalogues over time have hampered the creation of a consistent, long-term time series of ARS publication counts in this database. Using the search terms “Agricultural Research Service” or “ARS” in several different ways showed no particular secular trend in publication counts in this database, either.

Figure 4

**ARS patents and publications, normalized by scientist years**

Normalized counts



Source: ERS calculations based on USPTO, Institute for Scientific Information (ISI) Current Contents, and USDA Current Research Information System (CRIS) data.

USPTO classifications 435 (molecular biology and microbiology) and 800 (multicellular living organisms) are two important codes that may have potential medical applications, agricultural applications, or both.<sup>30</sup>

In any case, the rate of increase in patenting by land grant universities over the period since 1976 is striking. Although the number of patents issued to the land grant universities appears to have leveled off somewhat in recent years, from 1985 to 2003 this figure rose at an average annual rate of 11.2 percent, compared with the average annual rate of 4.4 percent for USDA patents (fig. 5). Furthermore, patenting in biologically related categories grew faster than in many other areas. The USPTO (2002) has published a breakdown of patents issued to all universities, and to individual research universities in the top 100, by patent class and by date of application (as opposed to date of issue). Before 1980, less than 5 percent of all patent applications by top research universities were in classes 435 and 800. By the mid- to late 1990s, over 20 percent were in these classes. We looked at annual growth rates in university patent applications for easily identifiable biological classes—primarily 435 and 800 but also including several more traditional agricultural categories. Over the 1980s and early 1990s, these growth rates were very high (13 percent to 20 percent or more) whether universities were land grants with significant medical research expenditures, land grants with little to no medical research, non-land grants with significant medical research, or non-land grants with little to no medical research. This suggests that university biological patenting with potential agricultural applicability grew rapidly whether or not it was primarily medical in intent.

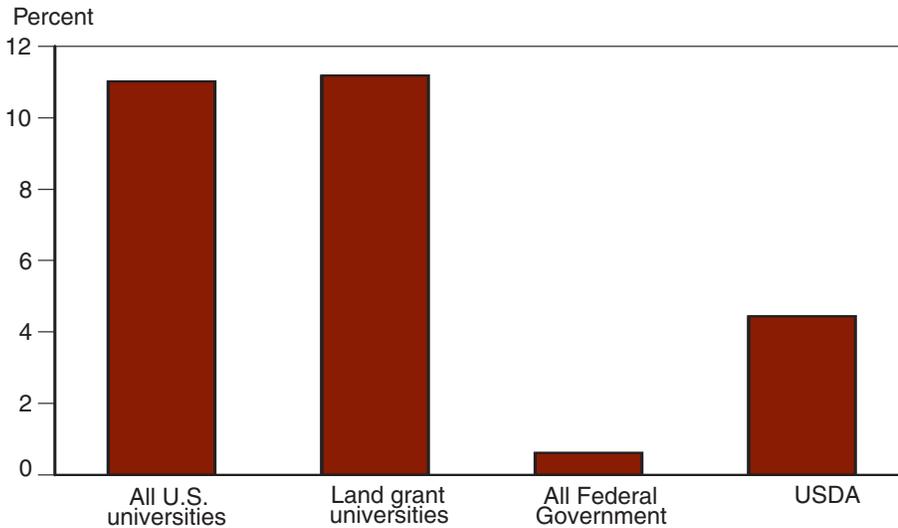
**Patenting of Agricultural Biotechnologies**

The Economic Research Service (ERS) and other research partners have recently completed the first phase of an online database of agricultural biotechnology intellectual property (ABIP). One major component is a database of U.S. agricultural biotechnology utility patents issued from 1976–2000. Agricultural biotechnology was broadly defined to refer to

<sup>30</sup>In some cases biological research findings that might be patented under these classifications originally may have been directed at medical applications, but might have potential agricultural uses as well.

Figure 5

**Percentage growth rate in utility patents awarded, 1985-2003**



Source: ERS calculations based on USPTO data.

general biological processes in agriculture and food. The selection procedure was designed to include patents not only for genetically engineered agricultural plants or animals, or the processes used to produce such genetically engineered species, but also for research processes such as tissue culture, research tools with potential applications to agriculture, crop varieties produced via biotechnologies other than genetic engineering, and other biological processes (such as fermentation) used in the food and nutrition industries. The database also features a rule-based classification scheme that allows alternative, narrower definitions of agricultural biotechnology, for example, genetic transformation technologies (King and Heisey, 2003; 2004).

Agricultural biotechnology patenting has grown at a faster rate than the rate of utility patenting in general. Figure 6 shows, in logarithmic scale, changes over time in agricultural biotechnology patents issued to various U.S. based institutions: U.S. private companies, U.S. universities (land grant and non-land grant), and U.S. Government.<sup>31</sup> Most of the U.S. Government agricultural biotechnology patents were issued to ARS. For comparative purposes, the time series for all patents, “biotech” and “non-biotech,” issued to ARS is also shown.

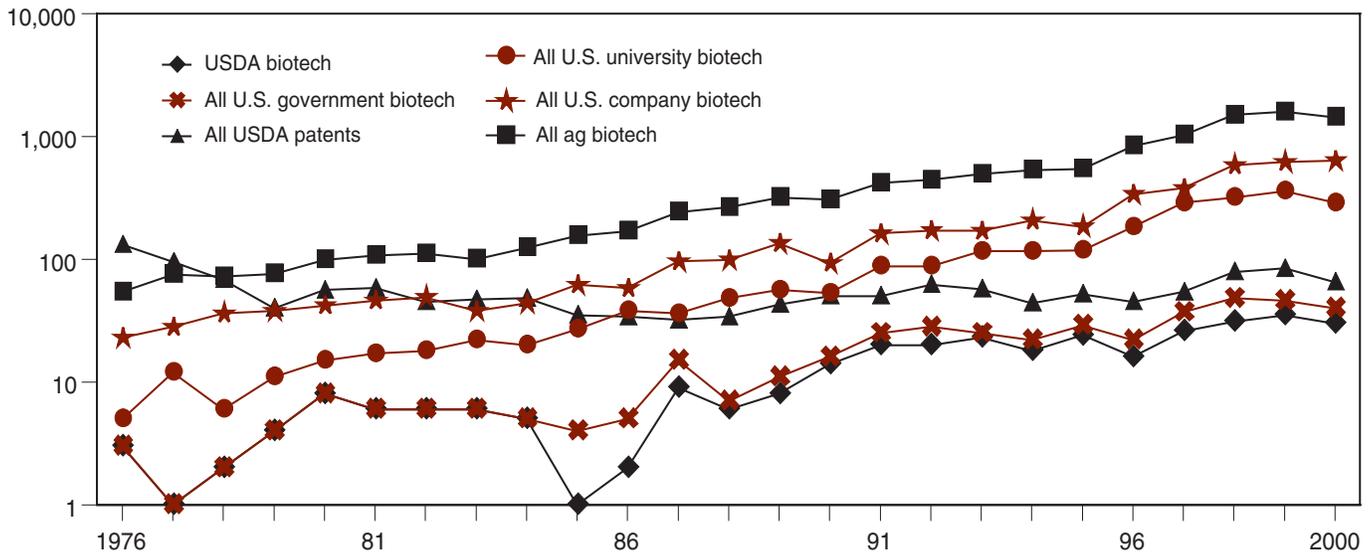
It is clear from figure 6 that (especially since the mid-1980s), agricultural biotechnology patenting has grown rapidly in all U.S.-based sectors. Over certain periods, it appears to have grown even faster for universities than for private sector firms. Agricultural biotechnology patenting by ARS has grown somewhat more slowly than it has for the other two U.S. sectors. However, biotechnology patenting by ARS has grown much more rapidly than ARS patenting in general. Thus, since the mid- to the late 1980s it has occupied an increasing share of ARS’s patent portfolio.

<sup>31</sup>The database also includes U.S. utility patents issued to non-U.S. institutions, but these are omitted as separate categories to maintain clarity.

Figure 6

**USDA and other U.S. agricultural biotechnology patents**

Log scale



Source: USDA ERS Agricultural Biotechnology Intellectual Property Database and ERS calculations based on USPTO data.

The area of agricultural biotechnology that has received the most public attention, genetic transformation of plants, comprises a relatively limited proportion of ARS patents. Figure 7 compares patenting in genetic transformation and plant technologies with total agricultural biotech patents as defined in the ABIP database.<sup>32</sup> Patents that fall under both the “genetic transformation” and “plant technology” headings simultaneously are more likely to be those relating to the commonly used, narrow definition of biotechnology. The figure demonstrates that only in the last 3 years of the database did ARS receive more than a single patent falling under both classifications. Instead, ARS patented more frequently in areas such as biological control of pests or animal protection technologies such as vaccines than in the agricultural biotechnology subfield of genetic transformation.

**Licensing of ARS-Patented Technology**

Trends in patenting provide one measure of the intellectual property produced by an institution. The licensing of these patents is another measure that shows how this intellectual property is being used. Table 4 indicates the current state of technology transfer for patented and licensed USDA technologies. Of the currently active patent licenses, about one-fifth are generating earned royalty income. The median earned royalty income is small (\$3,102) in FY 2003. Apart from the amounts set aside for inventors, ARS applies financial returns to the operation of its OTT, not to financing research (Day Rubenstein, 2003).

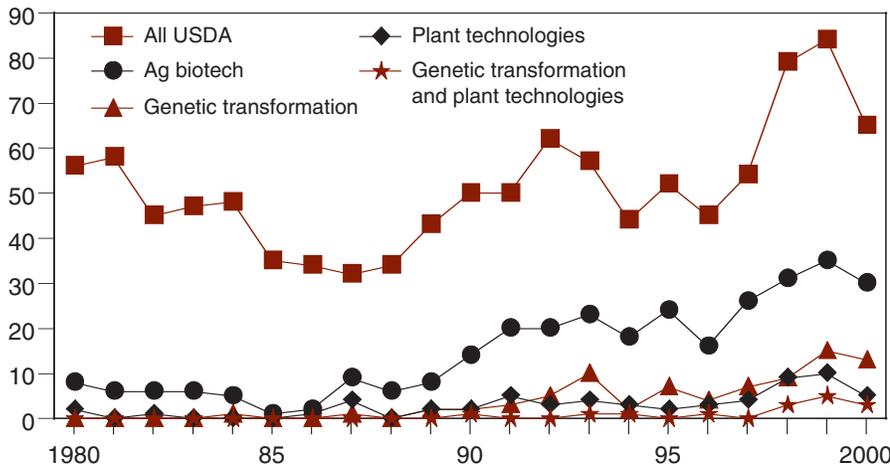
Day Rubenstein recently completed a comprehensive examination of 224 active licenses granted by USDA’s Agricultural Research Service through June 2000. These licenses were categorized on the basis of research problem areas

<sup>32</sup>The time period 1980-2000 was chosen in preference to 1976-2000 to make trends more clear; the total patents issued to the USDA fell steeply from 1976-79.

Figure 7

**USDA biotech and other USDA patents**

Patents issued



Source: USDA ERS Agricultural Biotechnology Intellectual Property Database and ERS calculations based on USPTO data.

Table 4

**Selected USDA technology transfer data for FY 2003**

Item	Amount
Active CRADAs <sup>1</sup>	229
U.S. patent applications filed	60
U.S. patents issued	64
Active patent licenses	270
Licenses generating earned royalty income	56
Total license revenues	\$2.3 million
Median earned royalty income	\$3,102

<sup>1</sup>CRADA: Cooperative Research and Development Agreement.

Source: D.J. Blalock, 2004.

as designated by the Current Research Information Systems (CRIS). Here we consider some of the characteristics of these licensed technologies.

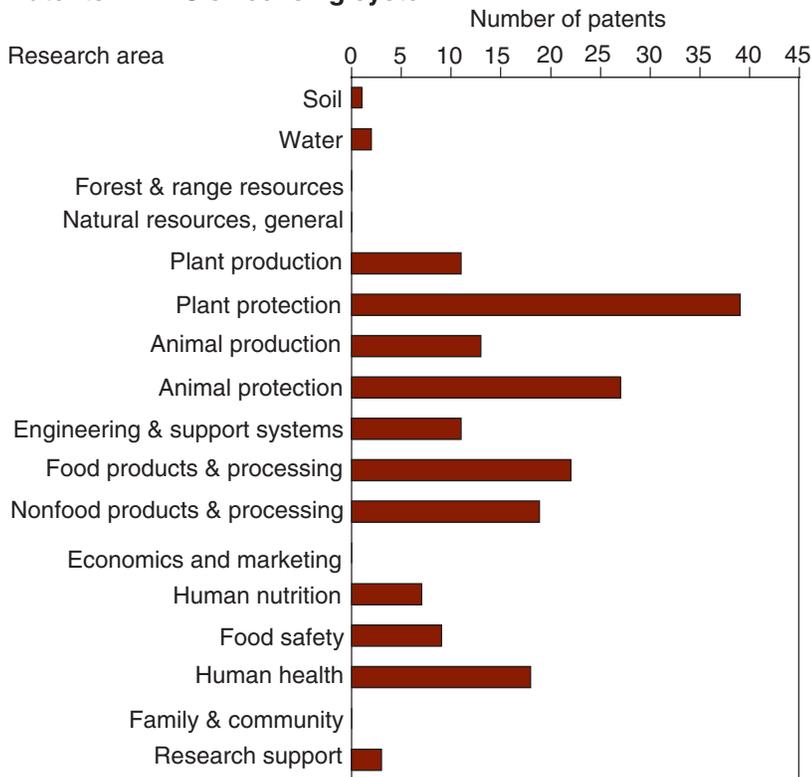
On the basis of patent counts (i.e., not taking into account the effects of multiple licenses issued for certain patents), the most frequent areas for licensing were plant protection, animal protection, food products and processing, nonfood products and processing, and human health (fig. 8). Somewhat fewer patents were licensed in the traditional research areas of plant and animal production. Food safety and human nutrition are areas with strong public-good components. There were relatively few technologies patented in the environmental research area, which also includes strong public-good components.

Day Rubenstein also examined licensed technologies for the social (as opposed to purely private) benefits they might offer. As she points out, exclusively licensed technology is, almost by definition, unlikely to offer pure public good. Nonetheless, each licensed technology was examined to determine whether it offered one of four social benefits: food safety, human nutrition, human health, and environmental or natural resource protection.<sup>33</sup>

<sup>33</sup>The author's judgment was the basis for this examination. Criteria were explicitly stated, consistently applied, and therefore replicable.

Figure 8

**Patents in ARS's licensing system<sup>1</sup>**



<sup>1</sup>Patents may be captured in more than one category.

Source: Day Rubenstein, 2003.

In a sense, this exercise attempted to answer the question of whether the patenting and licensing mechanism can still be used to transfer technologies that have some public-good components that may not necessarily be captured by the private sector partner.

The number of licensed technologies in each research area with some of these social benefits depended on two things: the total number of technologies in that research area and the percentage of licensed technologies associated with one or more of the four social benefits. Over half the technologies licensed offered one of the four social benefits, though findings varied by research area. Plant protection technologies—primarily those in the sub-areas of biological pest control or resistant varieties—had the greatest number of licenses that offered particular social benefits. Almost 70 percent of the licenses for nonfood products and processing technologies (an area typically associated with higher private benefits) provided one or more social benefits. Therefore, evidence from the study indicates that the use of patenting and licensing is not limited to technologies whose benefits are associated solely with private research interests.

## Case Studies of ARS Technology Transfer Using Patents

This chapter provides descriptions of the technology transfer process for four specific patented technologies, summarized in table 5. It allows the observation of idiosyncratic aspects of patented technologies and special circumstances of licensee firms, as well as other details of technology transfer that might not appear at a more abstract, statistical level of analysis. Observation of these case studies is primarily based on interviews with technology transfer practitioners, including research scientists, licensing professionals, and technology partners at licensed firms. The cases provide detailed observations of research and licensing behavior as it is practiced in reality.

The selection of cases is an important element of case study analysis. For instance, the choice of cases involving the transfer of patented technology limits the scope of the study to technologies for which ARS primarily pursued patent protection rather than other channels of technology transfer. In general, selecting too narrow a range of cases can lead researchers to overlook issues that do not happen to be prominent in the cases at hand. Likewise, issues that happen to be important for the selected cases might be otherwise uncommon.

We limited the case studies to ARS technologies protected by patents because of the significance of this method of technology transfer. As discussed in previous chapters, the use of patents and licensing is a relatively new and increasingly important means of technology transfer not just for ARS but also for other Federal research agencies. Furthermore, the case studies described in this chapter also show that other technology transfer methods such as CRADAs and open publication often accompany patent-assisted technology transfer. To avoid other pitfalls from case selection, this report drew its case studies from research in very different fields of science. Also, the case study technologies resulted in a variety of licensing outcomes that range from a successfully commercialized product that is still generating licensing royalty revenue for ARS, to licenses that are still at various phases of development, to still other licenses that have been abandoned.

With these precautions in place, the case studies in this chapter are representative of major licensing practices at ARS. They serve as a basis for observing a wide range of patenting and licensing policies as they are currently implemented, and do so at a level of detail that complements the statistical analyses presented in the “Technology Transfer by Federal Agencies” and “Technology Transfer at the Agricultural Research Service” chapters.

### Case 1: Enhancement of Nitrogen Fixation with *Bradyrhizobium japonicum* Mutants

In the late 1970s, ARS researchers began working with bacteria from the genus *Bradyrhizobium* that were eventually the subject of a U.S. patent. Researchers isolated a particular strain of *Bradyrhizobia* that was effective in inducing nodulation in leguminous plants. Nodulation is a symbiotic process in which a leguminous seedling (such as soy) secretes the amino

Table 5

**Patents used in case studies**

Patent number and issue date	Inventor	Title	Abstract
5,021,076 June 4, 1991	Kuykendall et al.	Enhancement of nitrogen fixation with <i>Bradyrhizobium japonicum</i> mutants	<p>“A prototrophic revertant of a <i>Bradyrhizobium japonicum</i> tryptophan auxotroph was isolated and found to fix more nitrogen symbiotically than wild-type bacteria. The increase in nitrogen fixation is due to an increase in nodule mass because of an increase in nodule number. The physiological basis for this improved symbiosis appears to be an alteration of the tryptophan biosynthetic pathway.”</p>
5,591,434 January 7, 1997	Jenkins et al.	DNA sequence encoding surface protein of <i>Cryptosporidium parvum</i>	<p>“Recombinant proteins have been developed for the immunization of animals against cryptosporidiosis. The proteins are effective for the immunization of a variety of animals against <i>Cryptosporidium parvum</i>, particularly for the production of hyperimmune colostrum that may be used to confer passive immunity against the parasite. Isolated DNA sequences which encode these proteins have also been developed. The DNA sequences may be inserted into recombinant DNA molecules such as cloning vectors or expression vectors for the transformation of cells and the production of the proteins.”</p> <p>Also see United States Patent 6,277,973 B1, Cloning and expression of a DNA sequence encoding a 41 kDa <i>Cryptosporidium parvum</i> oocyst wall protein.</p>
5,689,054 November 18, 1997	Raboy	Low-phytic-acid mutants and selection thereof	<p>“Single-gene, nonlethal mutations responsible for low-phytic-acid-containing seeds are selectable by means of a method for assaying seeds which are otherwise phenotypically, or nearly phenotypically, normal. Maize mutants having from 20 percent to 95 percent reductions in kernel phytic acid phosphorus compared to the wild-type, without any noticeable reduction in total phosphorus, were isolated by this method. Mutants obtained in accordance with the invention are useful for developing commercial, low phytic acid seed, plant lines.”</p> <p>Also see United States Patent 6,111,168, Low-phytic-acid mutants and selection thereof.</p>
5,705,030 January 6, 1998	Gassner, III et al.	Fiber and fiber products produced from feathers	<p>“A wide variety of end products may be manufactured from fibers or fiber pulp derived from feathers. Examples of such end products are paper and paper-like products, non-woven and woven fibers, insulation, filters, extrusions, and composite sheets and plates.”</p> <p>Also see United States Patent 6,027,608, Conversion of avian feather-waste stream to useful products. (Not assigned to the U.S. Department of Agriculture.)</p>

Source: U.S. Patent and Trademark Office.

acid tryptophan, which encourages the growth of *Bradyrhizobia*. These *Bradyrhizobia* infect the seedling, after which they secrete an enzyme that increases seedling nitrogen fixation. Nitrogen fixation helps plants make more efficient use of fertilizer, which can improve yields or reduce fertilizer input requirements.

The patent application for the *Bradyrhizobium* strain was filed in 1989, and the patent was granted in 1991. At the time the patent was issued, ARS did not have a technology partner to market the discovery, but research at ARS indicated that coating soy seeds with the bacteria through a process called inoculation generated higher yields in some tests. ARS negotiated material transfer agreements with both major suppliers in the relatively small U.S. inoculant market so that they could perform further testing and development. Although one inoculant supplier declined to license the technology, the other firm agreed to a licensing agreement with ARS in 1994. Sales of an inoculant product using the *Bradyrhizobium* strain began shortly thereafter, generating licensing royalty payments to ARS. This license has been recognized with several awards for successful implementation of technology transfer commercialization.

### **Case 2: DNA Sequence Encoding Surface Protein of *Cryptosporidium parvum***

Cryptosporidiosis is a diarrheal disease caused by a microscopic parasite, *Cryptosporidium parvum*. This parasite can live in the intestine of humans and animals and is passed in the stool of an infected person or animal. It had been a particularly difficult disease to prevent or treat because infected animals were unresponsive to vaccines and no medications were available to treat infections. Kansas State University researchers discovered a protein antibody that could be used in the diagnosis of cryptosporidiosis, and ARS researchers joined the research effort to clone the gene associated with this antibody and produce recombinant proteins suitable for vaccinations. Kansas State was relatively new to the patenting process, and as a result assigned patent rights to ARS. ARS filed a patent application in 1994 and was awarded a patent in 1997.

Initial private sector interest in the technology came from the human pharmaceutical market. In particular, acquired immunodeficiency syndrome (AIDS) patients with compromised immune systems were at higher risk for cryptosporidiosis. A CRADA with a pharmaceutical company led to an exclusive license for the antibody. As new human immunodeficiency virus (HIV) drugs became available, one of their beneficial side effects was to reduce the risk of cryptosporidiosis in these patients. With the accompanying decrease in the potential market for the antibody, the pharmaceutical company terminated its technology license.

Licensing interest shifted to development of a veterinary vaccine, particularly for cryptosporidiosis in bovines. Correspondence with two companies with substantial animal health product lines began by 1999, and they negotiated terms for co-exclusive licenses. As required by the Federal Technology Transfer Act of 1996, ARS published a notice in the *Federal Register* of its intent to issue the licenses. Before the licenses could issue, another company with an animal health product line objected. To accommodate this

third company, ARS agreed to issue another co-exclusive license. ARS agreed to limit the number of co-exclusive licenses to these three firms. To date, at least one of these firms is continuing efforts to develop and commercialize a vaccine using the licensed technology.

### **Case 3: Low-Phytic-Acid Mutants and Selection Thereof**

Research into the metabolic pathways of phytic acid was first motivated by nutritional needs of both humans and animals, but environmental considerations also became a consideration for this research. High-phytic-acid concentrations in animal feed prevent monogastric animals like swine and poultry from absorbing phosphorus, an important nutrient. Dietary supplements such of phytase enzymes can increase phosphorus availability to the animals, but at an additional expense. Another effect of unabsorbed phosphorus is that it can pass into animal waste, eventually leading to phosphorus contamination of land surfaces and surface and ground water.

Low-phytic-acid mutants in maize—a major source of animal feed in the U.S.—were isolated by an ARS researcher in the early 1990s. A potential application of this discovery was for animal feed that did not require supplements, improving animal health and reducing phosphorus runoff in the environment. ARS contacted 12 companies to gauge interest in technology licenses. Of those companies, six expressed interest, and eventually a CRADA was signed with a large seed/genetic research company in 1993, before the first patent application was filed in 1994. The patent was granted in 1997. A license was negotiated with the original CRADA partner, but two other seed/genetic research companies requested and successfully negotiated co-exclusive licenses. Two of the three seed companies were large companies that have since been acquired by multinational chemical/life sciences firms. The other genetic research company was a small company spun off from a large seed multinational in 1994 but bought by a large multinational chemical/life sciences firm in 2000.

Three aspects of the low-phytic-acid breeding technology have posed problems for commercial development:

- (1) Cultivated varieties with the low phytic acid trait also appear to carry a yield penalty. Neither the potential cost savings from a reduction in phytase dietary supplements nor the increase in animal health from greater phosphorus uptake are sufficient to make up for the higher cost of producing the low phytic acid maize varieties.
- (2) Changes in ownership among the licensees may have brought corresponding changes in the R&D strategies of the licensee firms.
- (3) Views on the importance of mitigating environmental release of phosphorus may have changed since the initial research project.

This remains an active license, although no commercial products are immediately forthcoming.

### **Case 4: Fiber and Fiber Products Produced from Feathers**

In the course of research into chemical and physical properties of materials, ARS scientists discovered that keratin from chicken feathers can be made

into fibers that behave similarly to plant fibers made from cellulose. Chicken feathers make up a large waste stream for modern poultry production facilities, so an alternative use for this material could possibly have environmental as well as economic benefits. In addition, the market for fiber products from cellulose-base sources is very large: examples include diapers, industrial and automotive filters, fabrics, insulation, and structural components. This large market improves the chances of finding a market segment for which feather fibers offer a cost or performance advantage.

There are currently three possible means of disposing of poultry feathers:

- (1) Burning, which poses environmental concerns and is difficult and costly because the feathers emerge wet from chicken-processing facilities
- (2) Burying, which is uneconomical because of their low density
- (3) Grinding into feather meal, a low-cost, low-quality animal feed

A patent application for a technique of cleaning and drying feathers and mechanically separating keratin fibers was filed in 1995 and a patent issued in 1998. Initially a large poultry producer collaborated with ARS in a 3-year CRADA, and had the option to license the technology exclusively. After a few extensions from ARS, this producer declined to exercise its licensing rights.

ARS followed this unsuccessful attempt at technology transfer by licensing the technology co-exclusively to three firms: a different large poultry producer, which also needed to manage its feather waste stream; a rendering plant, which had the same need; and a firm that was already using the quill component of feathers as a production input for a line of nutritional and cosmetic products. Although one firm has abandoned its license, at least one other firm is actively pursuing new commercial applications of the technology.

## Policy Lessons from Technology Transfer Case Studies

Case studies provide an opportunity to observe actions and behaviors. The case studies described in the “Case Studies of ARS Technology Transfer Using Patents” chapter illustrate many of the economic tradeoffs underlying the decisions of technology transfer officers and their licensing partners. These observations permit an economic analysis, which can then be compared with the stated rationales of practitioners from interviews. For instance, some situations call for ARS’s OTT to balance policy objectives against the demands of potential licensees, as it does when deciding how many licenses to grant. Open licensing of a technology might be the least restrictive approach to licensing, but potential technology partners sometimes demand an exclusive license to compensate for technology and appropriation risks associated with the project.

Although the case studies provide a wealth of information, interpreting their specific circumstances to arrive at more general conclusions about technology transfer policy poses some problems. One issue is the confidentiality of licensing agreements between the USDA and its technology partners. Licenses contain sensitive business information that might create problems for the licensees if it were divulged: for example, the degree to which any particular licensee is pursuing development of a technology, whether a particular license is generating royalty income for USDA, and if so, the amount of that royalty income.<sup>34</sup> Furthermore, interviews with technology transfer participants were conducted under a pledge of confidentiality to ensure candid observations for the case studies. Preserving the confidentiality of case study information sometimes requires details from the case studies to be omitted from the conclusions presented in this chapter. Where possible, this chapter attempts to support conclusions by presenting them alongside specific facts from relevant case studies.

The technology transfer process frequently involves several decisions made simultaneously under tight legal and commercial deadlines. In other cases, the path toward commercialization is indirect and idiosyncratic. This chapter organizes conclusions of economic analysis of the case studies into a sequence that roughly follows a linear model of the technology transfer process, from research to license negotiation to commercialization.

### Technology Partners

The determination of the ARS Patent Review Committee to patent and license a technology is frequently made with a technology partner already in mind, although this is not always the case (e.g., *Bradyrhizobium*). OTT managers spend a significant amount of time performing the critical task of identifying a wide variety of potential licensing partners to find appropriate matches. Choosing from a broad set of licensing partners diversifies technology risk across different companies and industries and increases the likelihood of successful commercialization. The *Cryptosporidium* case is an example of a technology with potential application in multiple markets; pursuing licenses for both veterinary and human pharmaceutical applications provided more opportunities for successful commercialization.

<sup>34</sup>Knowledge of the terms of the license along with royalty payments also would reveal another confidential item, product sales.

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*ARS seeks out a wide variety of technology partners.*

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Technology transfer officers have an obvious choice of licensing partner when initial research is conducted under a CRADA. Most of the case study technologies were developed at some point with a CRADA partner.<sup>35</sup> Under the Federal Technology Transfer Act of 1996, CRADA partners have the right of first refusal for an exclusive technology license before a license can be granted to another party.

When technology is developed without a CRADA partner, or after a CRADA partner declines the option to license exclusively, ARS is free to search for other licensing partners. One strategy is to pursue licenses in a niche market. By definition, niche market technologies are served by a small number of firms, in which case the technology itself suggests technology partners. Another strategy is for Federal researchers to explore interest in the relevant field of science for the invention through contacts at research conferences and professional meetings. Both of these strategies for finding technology partners were employed in the eventual licensing of the *Bradyrhizobium* patent.

Industry structure can be an additional guide to possible technology partners. Firms upstream and downstream in the supply chain from a technology partner candidate are also potential licensees. Depending on interactions between suppliers and customers, licensees at different positions in the supply chain might have different incentives for cooperation and technological development.

The feather fiber patent is an example of how this strategy for finding licensing partners can work. ARS reached a licensing agreement with an obvious source of soiled feathers, a large processor of poultry for human consumption. Another license was offered to a firm downstream in the poultry-processing supply chain that processed poultry offal as pet food. A third license was offered to another downstream firm already using feather protein to manufacture nutritional supplements.

## License Exclusivity

A critical licensing decision for an OTT is the number of licenses it should grant. The agency can grant one license, multiple licenses, or even publish the discovery so that it is freely available to all (see box, “Varying Degrees of License Exclusivity” p. 10). Potential licensees expressed a preference for exclusive licenses to remove one source of appropriation risk: competition from other licensees. Economic theory predicts higher prices and profits when there is only one supplier, explaining this preference. In some cases, expanding the number of co-exclusive licenses may have had the effect of reducing incentives for further product development.

However, under the right market conditions and licensing strategies, multiple co-exclusive license agreements did not pose a barrier to successful technology transfer in some case studies. The advantages of multiple licenses for diversifying technology risk are discussed in the previous section. Another goal of technology transfer is to maximize the use of a technology. In general, suppliers in competitive markets offer lower prices and thus encourage more widespread introduction of the technology adop-

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<sup>35</sup>Although many ARS technologies are now developed with a CRADA, the proportion of licenses to CRADA partners is somewhat smaller because not all of them exercise their licensing option; see the chapter titled “Technology Transfer at the Agricultural Research Service (ARS).”

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*Multiple licenses address appropriation risk, while exclusive licenses focus on technology risk.*

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tion. Co-exclusive licenses and other less exclusive licensing agreements increase competitive pressure compared with sole exclusive licenses.

Although it is not possible to generalize the net result of multiple licenses on technology transfer directly from the case studies, it is interesting to consider what might have happened to commercialization of the *Bradyrhizobium* inoculant if both major inoculant suppliers had licensed the patent instead of just one. Would the prospect of competition have undermined investments in development? Or would the competition have driven both competitors to distribute the technology at a lower price to more customers? Another question is whether ARS can adopt licensing policies and practices that influence the outcome, a possibility discussed in subsequent sections of this chapter.

Licensee business plans, market size, profitability, and the availability of substitutes for the invention are some of the relevant factors that determine the degree of exclusivity that potential licensees will accept. For instance, one business plan might involve selling a product or service based on the invention at a small profit margin, but to a large number of customers. In a potentially profitable market where one licensee would have trouble satisfying demand for the product, it appears that additional supply from competitors under co-exclusive licenses did not slow down licensee development efforts. Likewise, where noninfringing substitutes already limit the markup over production costs that a licensee can charge, competition from these substitutes may be more relevant than competition from other licensees that price at a similar markup. An example of a noninfringing substitute from the feather-fiber license is feather meal. The potential use of soiled feathers as feather meal places a lower bound for the profitability of cleaned feathers for other industrial uses. However, if competition with other licensees erodes the already small profit margin, licensees may balk at taking out a license and technology transfer may not occur.

Another licensee business plan might involve selling a product or service based on the invention at a very high price, a strategy that is more likely to succeed when the quantity demanded is relatively unresponsive to price. Charging a high price already limits the number of willing buyers somewhat, but the absence of feasible alternatives might justify high profit margins in this market. This strategy might not be sustainable under co-exclusive licensing. If customers can obtain a close substitute from other licensees, this business plan might not be sufficiently profitable to justify interest in technology transfer. The risks posed by either licensee might cause both to avoid the technology. None of the technologies in the case studies appeared to adopt this strategy for commercialization.

## Licensee Characteristics

Although there are numerous ways that licensing can work, successful licensees share some common attributes. A certain degree of entrepreneurial energy was necessary for all of the eventual licensees to find out about ARS research and apply for technology licenses. Small startup firms organized around the development and commercialization of a new ARS technology were relatively focused on its development. However, larger and more established firms often proved to be equally aggressive in pursuing licenses and carrying out development.

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*Technology partners contribute different backgrounds and abilities.*

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Each of the licensees required access to financial capital necessary for upfront expenditures on technology development. Sources and cost of that capital were factors in the ability to obtain a license and pursue technology development. When patents, licenses, and other intangible assets represent a significant fraction of a firm's total value, valuation of those intangible assets can affect access to collateralized loans or the terms of additional equity investment. In these cases, licensees cited licenses of patent-protected ARS research as an important factor for raising capital for commercialization investments. Moreover, inability to raise sufficient capital was a constraining factor in several licenses, notwithstanding OTT efforts to screen out undercapitalized firms.

More established firms in our case studies were able to finance their own investments in technology development, through previous issuance of debt or equity or through earnings retained from other operations.<sup>36</sup> While funding from these internal sources might be less expensive, their availability depends on a firm's other resources and investment opportunities. For instance, access to inexpensive capital financing did not guarantee that the company had the managerial time, talent, or complementary assets to carry out a successful technology development program for licensed ARS technology. Other factors were certainly at play, including market demand, technology risk, and the profitability of existing operations or alternative projects.

### **Industry Experience**

Industry experience is another characteristic that can be important. Do licensees have the background and experience to succeed? Firms already familiar with an industry might be better suited to take advantage of a new technology, and might be able to develop technology as an ancillary operation rather than as a central business concept.

From the case studies, a challenge confronting some licensees of the low-phytic-acid maize patent was obtaining a competitive maize hybrid in which to incorporate the low-phytic-acid trait. Since the early embodiments of the technology also had a side effect of reducing yields, placement of the trait in an already high-yielding variety would be an advantage. A company with complementary assets in the form of an existing corn breeding program is likely to face less difficulty meeting this challenge than a company without relevant experience. Similarly, a potential advantage among feather fiber licensees was prior industry experience with efficient disposal of feathers and other poultry processing byproducts. A firm already managing a waste stream of chicken feathers might have greater incentive and aptitude for development of the feather fiber technology.

### **Company Size**

Small and large companies alike can benefit from successful technology transfer. Small businesses like the niche market licensee of the *Bradyrhizobium* patent can be effective competitors, satisfying market demand and successfully moving technology into profitable development. Moreover, license grants to small businesses satisfy the explicit intent of Federal technology transfer legislation. First preference for federally licensed technologies typically goes to businesses with fewer than 500 employees, provided they have equal or greater likelihood of bringing the invention to practical application within a reasonable time (35 USC 209).<sup>37</sup>

<sup>36</sup>Debt refers to a liability that must be repaid; interest is usually paid on debt. Equity refers to stock issued by a company.

<sup>37</sup>The Small Business Administration publishes the Small Business Size Regulations that defines "small businesses" for each industry, based on either number of employees or size of annual revenues.

## Licensing Terms

### ***Ex ante technology assessment***

A challenge to negotiations between licensees and OTT is that the exact size and characteristics of a market are typically not known in advance, or *ex ante*. Until a product is developed and made available for sale, the size and characteristics of a market can only be estimated. Unfortunately, terms of a licensing agreement must be negotiated before technology transfer can move forward or market size can be definitively known. Licensing negotiations must account for differing estimates about the value of the technology, with repercussion on the licensing terms. Negotiations can adjust terms of a license to reflect different views on market size, market characteristics, technology risk, and appropriation risk, but reasonable people can often differ in their assessment of these factors.

Negotiating license agreements in this environment is therefore a difficult but intrinsic challenge to technology transfer. Flexible licensing approaches, including renegotiation, may be necessary as more is learned about a technology and the market in which the technology is commercialized. Against this flexible approach, technology transfer officers must weigh the need for credible commitments from both sides.

Empirical studies of licensing behaviors show that royalties are used in a majority of licensing agreements, and that agreements often combine license execution fees, milestone payments, and royalties (Taylor and Silberstone, 1973; Rostoker 1984; Macho-Stadler et al., 1996; Basquet 1998; Thursby et al., 2001). The case studies show a similar diversity as to which licensing terms were employed. By tailoring the specificity of performance milestones, the incentives of licensing fees, the risk allocation of royalties, and the degree of competition implied by the number of licenses offered, an OTT can craft a licensing agreement that is appropriate for its technology and acceptable to its technology partners.

### ***Specific Performance Clauses***

Licensing terms seek to expedite technology development. One way to achieve this is to require specific goals to be met in a given time period. For example, some licenses required construction of a production facility within a predetermined date after license execution. Specific performance requirements are useful in comparing the measures that different licensees will undertake to develop and commercialize a licensed invention.

### ***Licensing Fees***

Licensing fees are a straightforward element of a technology transfer license, involving a transfer of a specific amount of money in exchange for a license to use the technology. License fees are typically payable upon execution of the license.

Another type of licensing fee, sometimes referred to as a “milestone payment,” is payable at some point after license execution. Milestone payments can be triggered by an agreed time interval (e.g., 5 years after license execution) or by completion of a specific performance requirement

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*Terms of a licensing agreement affect more than the bottom line.*

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(e.g., completion of a working prototype or production facility). Licensing fees paid upon license execution commit licensee resources to the project, screening out licensees that lack the ability, resources, or motivation to proceed immediately with technology development. In addition, a portion of licensing fees is distributed to ARS inventors, creating incentives both to research patentable technology and to assist in its development.

Jensen and Thursby (2001) found that licensing fees payable at subsequent intervals may prevent “technology shelving,” instead prompting licensees to perform the technology development and commercialization efforts necessary to generate an income flow sufficient to meet fee payments. This analysis is consistent with views expressed by case study participants.

### **Licensing Royalties**

Royalties are another way to generate licensing revenue. Royalties stipulate a fee based on sales of products or services based on the licensed invention. Royalty fees assessed as a per unit charge on the licensee have the undesirable effect of increasing the licensee’s unit cost of producing and selling the invention, which discourages its widespread use at the margin. Kamien and Tauman (1986) show that fee-only licensing is theoretically superior to royalty-only licensing for patent owners, consumers, and society as a whole, because lump sum fees provide a monetary incentive to inventors, yet lack the price-distorting effect of royalties.

License negotiators can attempt to structure royalties to get around this problem. For instance, royalties based on sale revenues rather than units sold offer an improvement in both licensee profit and consumer benefit for the same amount of royalty revenue (Bousquet et al., 1998). Royalties can also be phased in at specific amounts. For instance, a fixed royalty payable when total sales reach specific increments does not discourage additional sales except very close to the incremental border. Royalty rates can also vary with the amount of sales (so called “nonlinear” royalty rates), which helps to tailor a license agreement to the specific circumstances of the technology. Although ARS used some of these royalty devices, achieving the theoretically optimal licensing structure in general might require an auction process (Kamien, 2002), which is at odds with the actual process of Federal technology transfer.

Despite their drawbacks, royalties can serve several important functions. Licensees confirmed that royalty components of licensing revenue were less risky for licensees than fixed licensing-fee components: under a royalty agreement, licensees did not pay royalties unless the invention overcomes technology and appropriation risks and enters a productive phase of development (Bousquet et al., 1998). In this way, royalties can reduce risk and help overcome the *ex ante* problem discussed above, even if they are less efficient *ex post*.

The economics literature suggests other important functions of royalties, although they might not always apply to Federal technology transfer. If the licensor knows that the technology is likely to be very valuable, reducing upfront licensing fees in exchange for higher royalty payments signals a high value of an invention to the licensee (Gallini and Wright, 1990). Similarly,

licensees with an advantage in or knowledge about the downstream market can offer to pay higher royalty payments to separate themselves from other potential licensees (Beggs, 1992). Some of these signaling models are sensitive to assumptions about the number of licensees, the sequence in which license terms are negotiated, and other factors that might conflict with the actual process of technology transfer as governed by Federal guidelines.<sup>38</sup> It is not clear that participants in the case studies explicitly utilized any of these insights from theoretical models of signaling and screening with royalties.

Royalties are efficient licensing mechanisms in another class of models, in which the licensor competes in the downstream market against licensees. In these models, the licensor profits both from the royalty payments and from raising competitors' marginal costs by the amount of the royalty (Rockett 1990; Kamien and Tauman, 2001). The efficiency of royalties in these models depends on two assumptions, that the licensor competes against the licensees and that the licensor maximizes licensing revenues; neither assumption is likely to apply to Federal technology transfer. With respect to the latter assumption, licensing revenues from fees and royalties are one goal of Federal technology transfer among many, with priority also given to moving technology "off the shelf," addressing market failures, encouraging small businesses, and other goals.

## Technology Development Assistance

Most Federal research requires additional development effort to become a successful product. Although primarily engaged in "basic" research on fundamental science problems with widespread applicability, ARS researchers in our cases also described a role in their jobs for "applied" development geared toward a specific product. This view of ARS scientists in our case study comports with a study by Crow and Bozeman (1998), who found that researchers at Federal laboratories view technology transfer as an important part of their jobs.

It is reasonable to conclude that the same researchers who invent patented research are uniquely well-suited to further development of the technology. Toole and Czarnitzki (2005) explore the role of scientist involvement in commercialization in the Federal Small Business Innovation Research program, and conclude that scientist involvement is an important factor in technology transfer. The case studies in this report exhibit a wide range of perceived and actual behaviors. In at least one case, an ARS scientist performed additional tasks that helped commercialize the resulting invention. In another case, the ARS scientist took a less active role, but still made some suggestions to help guide further research. The case studies also included a situation in which at least one licensee felt that lack of technology development assistance by ARS was a barrier to commercialization that eventually halted technology transfer.

Incentives exist to encourage Federal researchers to provide development assistance to licensing partners. For instance, patents are treated as a publication in performance evaluations of Federal scientists. In keeping with the

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<sup>38</sup>Parties to a transaction may not have the same information. A signaling model is one in which an observed economic action separates individuals or firms into two or more groups and reveals information that was not observable directly before that action.

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*Sometimes product development requires more research.*

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basic premise of the Stevenson-Wydler Act, scientists also receive a portion of licensing revenues resulting from their research.

However, there are some barriers to additional product-development assistance by Federal laboratories:

- (1) Time spent in development is taken from the primary role of researchers, which is to conduct basic research on the next set of problems identified by USDA National Program leaders.
- (2) Incentives for the researcher to work on further product development might be limited. Although monetary awards for developers exist, career advancement is primarily measured by the scientific value of research (7 USC 7657). To a lesser extent, this problem exists at the prepatent, basic stage of research as well: although patents are counted as a scientific publication towards annual performance reviews, interviews with ARS inventors suggest that patents are more time-consuming to achieve than journal publications.
- (3) Development assistance can set up potential conflicts of interest, especially when a patent has multiple licensees. Assistance rendered to one licensee might harm the competitiveness of the other licensees. Consumer surveys indicate that the Federal Government has a strong reputation for providing science-based, impartial information (Gaskell et al., 1999). USDA interactions require continuing adherence to the mission and core values of research agencies, which could be compromised if the USDA were to be viewed as partial to a particular commercial concern.

## License Abandonment

For some technologies in our case studies, licensees chose to abandon their licenses. Contributing causes included inability of licensees to secure financing, unforeseen problems with the technology, or other unexpected hurdles that were not apparent at license execution. Some amount of license abandonment is probably inevitable considering the risky nature of technology transfer and commercialization. Subsequent licensing fees (“milestone payments”) may have provoked license termination decisions, because they impose a direct cost for continued lack of success. In some cases, early termination of a license probably represented a more efficient course of action than carrying on unsuccessfully.

License abandonment can be mutually advantageous for both ARS and its licensees. Certainly, it is advantageous for a licensee with an unworkable technology to move on to other endeavors. Abandonment probably reduces OTT administration costs of unsuccessful licenses. Furthermore, in the case of co-exclusive licenses, remaining licensees see their share of the market increase, which increases incentives for additional development. For difficult, expensive, or marginal technologies—the ones most likely to see license abandonment in the first place—licensee exit is a self-equilibrating mechanism to reward successful licensees.

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*Circumstances might require parties to end their agreement.*

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## Agency Mission and Licensing Strategy

Federal technology transfer legislation and USDA technology transfer policy are designed to accomplish many goals, as outlined in chapters 3 and 4. Licensing of USDA technology is only one of several approaches to the fast and widespread dissemination of scientific research.

Even when technology transfer through licensing of Federal technology is an appropriate policy, technology transfer goals must be balanced against broader Federal research goals. Rules aimed at making the technology transfer process fair and transparent illustrate this point. For example, the names of technology partners selected for licenses are required to be published in the Federal Register, at which point other firms can file appeals and seek to obtain licenses themselves (37 CFR 404.7). Although members of the Association of University Technology Managers (AUTM) have policies in place that encourage technology transfer in the public interest, they are largely free from the specific disclosure requirements found in the Code of Federal Regulations. As a result, their licensing behavior is frequently very different than that of Federal OTTs. Greater prevalence of exclusive licenses by universities suggests that Federal technology transfer policies sometimes constrain Federal OTT choices. Process rules are not always the preferred means for technology transfer: the transparency and fairness required of Federal licensing offices is balanced against the potential for an open process to slow down technology transfer in many cases, or to preempt favorable terms for the Federal Government.

Another example of balancing Federal research goals against technology transfer outcomes is the case of “orphan markets.” An orphan market is one in which new and improved products are technologically feasible, but small market demand or limited ability to pay discourages firms from undertaking the risk and expense of R&D. Federal research priorities take into account a wide variety of national research needs, not just potentially lucrative markets. Technology transfer through a licensing agreement with a technology partner might still provide insufficient incentive to encourage supply and adoption of technologies in orphan industries, even if a functional technology is available from a Federal laboratory.

Other Federal goals and policies can weigh heavily on technology transfer outcomes. An example is the development of low-phytic-acid maize developed by USDA/ARS. Low-phytic-acid maize provides a potential environmental benefit by decreasing the amount of phosphorus in agricultural runoff. Standard economic analysis of agricultural runoff suggests that when polluters are not required to internalize the costs of environmental damage, they will have insufficient incentive to adopt a technology that minimizes the environmental costs from runoff. A complementary policy requiring polluters to internalize the cost of phosphorous runoff might create the necessary demand to induce adoption of low-phytic-acid maize. Although designing and implementing complementary policies are far beyond the scope of OTT resources and mission, the existence or lack of complementary policies has an important effect on technology transfer decisions and outcomes.

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*Successful technology transfer finds a balance among several goals and priorities.*

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Despite the limitations of the technology transfer paradigm, a large number of inventions are a good fit with the aims and practices of technology transfer legislation. Furthermore, the OTT does not set the policies and rules under which it operates. Instead, it must pursue its mandate while conforming to those policies and rules.

## Conclusions

The large intellectual property policy changes of the last quarter century—the extension of patenting and licensing by inventors in universities and government laboratories, the creation of the Court of Appeals for the Federal Circuit, the extension of patenting to new technological areas, and the attempts to harmonize IP protection internationally—have resulted in complex changes in behavior by private firms, universities, and Federal laboratories. The number of utility patents granted by the U.S. PTO has grown rapidly, and all three kinds of institutions have increased their patenting.

(1) *In general, ARS patents and licenses innovations as a means of technology transfer and not as a means of generating revenue.*

The most notable indirect evidence that revenue generation is not a major motivation for ARS patenting is how licensing funds are used. ARS licensing revenue is used to fund the operations of its OTT, not as a major source of research funding. In 2000, licensing revenue was only about 0.3 percent of ARS's R&D budget.<sup>39</sup>

The differences between university patenting trends and those of ARS is further indirect evidence that patenting and licensing by ARS is primarily done as a means of technology transfer. Although private firms still receive the vast majority (around 95 percent) of utility patents, patenting by U.S. universities has increased very rapidly, partly in response to specific policy factors such as the passage of the Bayh-Dole Act of 1980. But university patenting began to increase rapidly before the passage of the Act, so it cannot have been the only factor.<sup>40</sup>

Invention disclosures, patent applications, patent grants, patent licensing, and the use of related technology transfer mechanisms such as CRADAS by Federal Government research agencies have also increased in recent years, but available data suggest that these trends began later and were more modest than equivalent trends for universities. This pattern of more rapid growth in patenting and licensing by universities is also seen more specifically when comparing land grant universities with ARS. It is also paralleled in trends for particular technologies, for example, agricultural biotechnology.

Other indirect evidence that ARS patents and licenses primarily to transfer technology can be found. The ARS patent-application process follows careful protocols, with specific questions asked at each step. An important question is the likelihood of finding an acceptable private sector partner for commercialization of the technology. These questions are in addition to discovering the likelihood that a patent can be granted.

(2) *The ARS Office of Technology Transfer (OTT) operates in a different environment than university OTTs.*

Protocols for technology transfer through licensing are more restrictive for the Federal Government than for universities. As one example, ARS must publish intent to offer an exclusive license in the *Federal Register*. This may create greater incentives for eventual licensing by more than one firm. More

<sup>39</sup>The use of licensing funds to support OTT is similar to the practices of other Federal labs.

<sup>40</sup>For discussions of the relative roles of the Bayh-Dole Act and other factors in stimulating university patenting, see Henderson, Jaffe, and Tratjenberg (1998); Jaffe (2000); and Mowery et al. (2001).

generally, the Federal Government follows specific guidelines in the Code of Federal Regulations to ensure transparency and fairness in its licensing arrangements.<sup>41</sup> All other things equal, first preference for federally licensed technologies is given to smaller firms (typically fewer than 500 employees).

*(3) Increased patenting and licensing by ARS has not been associated with a decline of traditional instruments of technology transfer such as scientific publications.*

From 1990 through 2003, as ARS patenting and licensing (and other newer means of technology transfer, CRADAs) have increased, scientific publication counts for ARS have remained relatively stable. In general, this conclusion holds when output counts are normalized either by scientist-years or by ARS budgets.

*(4) Ex ante determination of successful licensing terms and practices is very difficult. The success of a license depends on market size, market characteristics, and technology characteristics, and is subject to both “technology risk” and “appropriation risk.” Potential market and technology parameters are often not known in detail when licenses are negotiated, and reasonable people might disagree about them.*

Many patents are issued at a proof-of-concept stage, or some other preliminary stage of development. Technology risk refers to the probability that a technology can be improved and developed into a feasible commercial product or process that is an improvement over available alternatives. Appropriation risk is related to the likelihood that a company will be able to earn profits from the new technology and not have them captured almost entirely by competitors. Both the OTT and the technology partner must agree first, to license, and second, to specific license terms in the absence of complete information. Patenting and licensing are one means of addressing appropriation risk, but changing the exclusivity in licensing terms can change appropriation risk. Furthermore, market characteristics influence the effects of exclusivity on appropriation risk. These characteristics include the nature of the demand for products embodying the technology, the size of the market, the degree of competitiveness in the market, and the expected growth of the market.

Performance incentives such as milestone requirements or periodic licensing fees are aimed at reducing technology risk on the part of the licensee. Using patents as a factor in evaluation of ARS scientists and rewarding successful patenting monetarily are incentives for reducing technology risk from the side of ARS.

*(5) ARS does retain some flexibility in renegotiating license terms.*

Flexibility in license terms is necessary when unforeseen circumstances arise. In particular, the relevant market size and characteristics may become clearer over time. Similarly, different characteristics of a particular technology may turn out to have greater market potential than initially envisioned. *Ex post* flexibility can correct *ex ante* mistakes in predicting technology success or failure.

<sup>41</sup>For example, although license terms are confidential, the identity of licensees is not.

(6) *Licensing to more than one firm is more likely to be successful if the market is segmented geographically or by stages in a production process than if all firms are competing for the same market niche.*

This phenomenon was observable within the case studies. In particular, co-exclusive licensing in which licensees are direct competitors for the same market niche can reduce collaborative efforts with ARS inventors in product development. The potential for direct market competition in an uncertain environment can also reduce the incentives for product development. Exclusive licensing by territory or field of use, on the other hand, can lead to greater success in transferring technology. When licensing is used to segregate markets geographically or by stages of production, synergies can be created in the market, enhancing the use or spread of the technology.

Using the single policy instrument of patenting and licensing to attempt to achieve multiple Federal policy goals is not feasible. Both the “mission technology” paradigm—the government conducts research in support of missions in which there is a national interest—and the “market failure” paradigm—the government conducts research when private markets do not provide the socially optimal amount and kind of research—help to explain why USDA conducts research in the first place. Under both paradigms, it is plausible to assume that a great deal of USDA’s research has been socially valuable even when it has not resulted in a relatively near-market, patentable technology. Estimates of positive returns to public sector agricultural research (Federal and State) confirm this view.

Because much ARS research cannot be directly commercialized, it is unlikely that generation of substantial revenue from patents and licensing would be a major goal of that instrument. The evidence suggests that it has not been. Other potential uses of government patenting that we initially considered were promoting awareness of public research results, bringing credit to the Federal agency performing the work, or patenting defensively to maintain freedom to operate or to encourage widespread use of federally developed research tools. Awareness and credit may be two results of ARS patenting, but they are clearly side benefits, not major motivations for patenting. In any case, other ARS technology transfer instruments also provide these benefits. The third motivation mentioned here, defensive patenting, may be justifiable but there is little evidence that it plays a role in patenting by ARS. There is a public interest in maintaining access to ARS technologies, but discussions of patentability by Patent Review Committees focus much more on finding a commercial partner than on preventing a private firm from gaining access to ARS technology and blocking others from using it. It would arguably be more likely for ARS to choose scientific publication over patenting as a major strategy in the case of a research tool that is expected to be widely applicable.

By focusing on technology transfer in situations where patenting and licensing are necessary to ensure private firm interest, ARS has reduced some of the inherent contradictions in a multiple-goal environment. Some of the tools used by ARS—issuance of licenses that are exclusive by territory or field of use, *ex post* flexibility in adjusting licensing terms—clearly help to maintain a balance between meeting Federal policy goals and making sure technology that can be commercialized actually is commercialized.

ARS's use of a broad range of technology transfer mechanisms, not restricted solely to patents and licensing, also helps to preserve this balance. Additional steps might make the patent and licensing process smoother in situations in which these instruments are chosen—for example, reducing the requirements that lead to multiple licenses when markets are overlapping, or further increasing the flexibility in negotiating licensing terms.

In short, patenting and licensing can be consistent with the objective of widespread distribution of the benefits of ARS research. A technology that reaches society through private sector development of ARS research may provide more net social benefits than a technology that is not developed at all because no private firm commercializes it—provided technology transfer activities do not withdraw too many resources from ARS' most important missions. This conclusion is likely applicable to other Federal research agencies, especially when legal requirements for technology transfer are the same for these agencies. On the other hand, Federal research agencies differ in the size of research budget, in the markets for possible commercial applications of their research, and in management structure (particularly for research conducted by outside contractors). As a result, there may also be subtle differences in specific technology transfer practices at other agencies. Further research would be needed to understand how our findings might apply to practices in other agencies.

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