United States General Accounting Office

GAO

Report to Congressional Committees

July 2003

TECHNOLOGY TRANSFER

Agencies' Rights to Federally Sponsored Biomedical Inventions

GAO-03-536

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Highlights

Highlights of GAO-03-536, a report to Congressional Committees

Why GAO Did This Study

The Bayh-Dole Act gives federal contractors, grantees, and cooperative agreement funding recipients the option to retain ownership rights to inventions they create as part of a federally sponsored research project and profit from commercializing them. The act also protects the government's interests, in part by requiring that federal agencies and their authorized funding recipients retain a license to practice the invention for government purposes. GAO examined (1) who is eligible to use and benefit from the government's license to federally funded biomedical inventions, (2) the extent to which the federal government has licenses to those biomedical inventions it procures or uses most commonly, and (3) the extent to which federal agencies and authorized federal funding recipients have actually used or benefited from these licenses. GAO focused its work on the Department of Veterans Affairs (VA), the Department of Defense (DOD), and the National Institutes of Health (NIH).

NIH commented that the report implies that the government's right to use its license is more limited than it actually is. GAO recognizes that the right of federal agencies and their funding recipients to use a federally funded invention is unrestricted. However, GAO believes that these license rights can be used only to meet needs that are reasonably related to the requirements of federal programs.

www.gao.gov/cgi-bin/getrpt?GAO-03-536.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Robin Nazzaro at (202) 512-3841 or nazzaror@gao.gov.

What GAO Found

Federal agencies and their authorized funding recipients are eligible to use the government's licenses to federally funded inventions for the benefit of the government. Government researchers can use the technology without paying a royalty, and federal agencies can authorize their funding recipients to use the government's licenses for specific contracts, grant awards, or cooperative agreements meeting a federal government need. The government is not entitled to automatic price discounts simply because it purchases products that incorporate inventions in which it happens to hold a license. Furthermore, the government's rights attach only to the inventions created by federally funded research and do not necessarily extend to later inventions based on them. Thus, the government may have no rights in a next-generation invention that builds on federally funded technology if the new invention were not itself created by federally sponsored research.

Few of the biomedical products that federal agencies most commonly buy appear to incorporate federally funded inventions. In 2001 the government had licensing rights in only 6 brand name drugs associated with the top 100 pharmaceuticals that VA procured and in 4 brand name drugs associated with the top 100 pharmaceuticals that DOD dispensed. GAO was unable to determine the extent to which the government had rights to other types of biomedical products because there are no databases showing the underlying patents for most of these products and such products may incorporate numerous components that might not be covered by identifiable patents.

The federal government uses its licenses to biomedical inventions primarily for research; however, researchers generally do not document such usage. These licenses are valuable because researchers can use the inventions without concerns about possible challenges for unauthorized use. Neither VA nor DOD has used the government's licenses to procure biomedical products because they cannot readily determine whether products use federally funded technologies and they believe they already receive favorable pricing through the Federal Supply Schedule and national contracts. Furthermore, neither VA nor DOD has used the government's license to manufacture a biomedical product for its use.

Rights to Federally Sponsored Inventions

- Federal agencies and their authorized funding recipients can use the government's license to federally funded inventions without paying a royalty.
- Federal agencies can authorize their contractors to make products that incorporate federally funded inventions for government use without risking patent infringement.
- The government's license does not entitle federal agencies to automatic price discounts just because a product incorporates a federally funded invention.

Contents

Abbreviations

AIDS	acquired immunodeficiency syndrome
DOD	Department of Defense
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
NIH	National Institutes of Health
USPTO	U.S. Patent and Trademark Office
VA	Department of Veterans Affairs

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United States General Accounting Office
Washington, DC 20548

July 1, 2003

Congressional Committees

Since 1980, the Bayh-Dole Act and subsequent executive actions generally have given federal contractors, grantees, and cooperative agreement funding recipients the option to retain ownership rights to, and profit from, commercializing the inventions they create as part of federally sponsored research projects. In return for these rights, they are required to file for patent protection, pursue commercialization of the inventions, give preferences to small businesses in licensing, ensure that any products resulting from the inventions are substantially manufactured in the United States, and comply with certain reporting requirements. The Bayh-Dole Act also provides federal agencies and their authorized funding recipients with a "nonexclusive, nontransferable, irrevocable, paid-up license" to practice these federally funded inventions for government purposes.

We assessed (1) who is eligible to use and benefit from the government's licenses to biomedical inventions created under federally sponsored research, (2) the extent to which the federal government has licenses to those biomedical inventions it procures or uses most commonly, and (3) the extent to which those eligible have actually used or benefited from these licenses. We focused our work on the Department of Veterans Affairs (VA) and the Department of Defense (DOD)—which are responsible for the bulk of the government's biomedical procurements—and the National Institutes of Health (NIH), within the Department of Health and Human Services (HHS), which funds most biomedical research.

To determine who is eligible to use and benefit from the government's licenses to biomedical inventions, we reviewed the Bayh-Dole Act, other statutes, federal agencies' implementing regulations, applicable case law, and the positions taken by federal agencies in interpreting these laws. To assess the extent to which the government has licenses to the underlying inventions for the biomedical products it uses, we primarily analyzed the patents behind the top 100 pharmaceuticals that VA procured and DOD dispensed during 2001. For our analysis, we used databases maintained by the Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office (USPTO) as well as VA, DOD, and NIH. Finally, to assess the extent to which eligible parties have used or benefited from the government's licenses, we determined (1) whether VA and DOD

contracting personnel used them in procuring pharmaceuticals and medical devices and (2) whether VA, DOD, and NIH research personnel used them in conducting research. We conducted our review from April 2002 through April 2003 in accordance with generally accepted government auditing standards. Additional details on our scope and methodology are included in appendix I.

Results in Brief

Federal agencies and their authorized funding recipients are eligible to use the government's licenses to federally funded inventions for the benefit of the government. Specifically, government researchers can use the technology without having to pay a royalty, and a federal agency can have a contractor produce the item for its use without obtaining a separate license. Third parties—contractors, grantees, and cooperative agreement funding recipients—can use the government's licenses when granted this authority for a specific contract, grant award, or cooperative agreement meeting a federal government need. The government is not entitled to automatic price discounts simply because it purchases products that incorporate inventions in which it happens to holds a license. In addition, the government's rights attach only to the inventions created by federally funded research and do not necessarily extend to later inventions based on them. Thus, the government may have no rights in a next-generation invention that builds on federally funded technology if the new invention were not itself created by federally sponsored research.

Few of the biomedical products that the federal government most commonly buys appear to incorporate federally funded inventions. We found, for example, that federally funded inventions were used to make only 6 brand name drugs associated with the top 100 pharmaceuticals that VA procured for use by veterans and 4 brand name drugs associated with the top 100 pharmaceuticals that DOD dispensed in 2001. We could not determine the extent to which the federal government holds rights to other types of biomedical products, such as hospital beds and wheelchairs, because (1) there are no databases showing the underlying patents for most of these products and (2) the products may incorporate numerous components that might not be covered by identifiable patents. However, we found no federal government rights to the selected medical devices we examined; and VA and DOD officials told us that the government would rarely have patent rights in such products.

The federal government uses its licenses to biomedical inventions primarily for performing research; however, the extent of such usage cannot be determined because researchers generally do not keep records,

according to VA, DOD, and NIH officials. Citing a generally accepted practice among government and university scientists, government researchers have typically used the patented technologies of others without obtaining permission or a license. However, patent law does not appear to provide for such use without obtaining permission or a license from the patent owner. Agency officials said that when their scientists' use of federally funded inventions is challenged, they inform the patent holders of the government's license. Neither VA nor DOD has used the government's licenses to procure biomedical products because they cannot readily determine if products incorporate federally funded technologies and they believe they already receive favorable pricing through the Federal Supply Schedule and national contracts. Furthermore, neither VA nor DOD has used the government's license to hire a contractor to manufacture a biomedical product for its use.

In commenting on a draft of this report, NIH stated that because we tie the exercise of the government's license rights to the needs of the federal government, we give the impression that the government's license rights are more limited than they actually are. While we agree with NIH that federal agencies and their funding recipients have unrestricted rights to use a federally funded invention for federal government purposes, it is important to recognize that they can use these rights only to meet needs that are reasonably related to the requirements of federal programs.

Background

Prior to 1980, federal agencies generally retained title to any inventions resulting from federally funded research—whether the research was conducted by contractors and grantees or by federal scientists in their own laboratories—although specific policies varied among the agencies. Increasingly, this situation was a source of dissatisfaction because of a general belief that technology resulting from federally funded research was not being transferred to U.S. businesses for developing new or improved commercial products. For example, there were concerns that biomedical and other technological advances resulting from federally funded research at universities were not leading to new products because the universities had little incentive to seek uses for inventions to which the government held title. Additionally, the complexity of the rules and regulations and the lack of a uniform policy for these inventions often frustrated those who did seek to use the research.

In 1980, the Congress enacted two laws that have fostered the transfer of federal technology to U.S. businesses.[1] The Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480, Oct. 21, 1980) promoted the transfer of technology from federal laboratories to the private sector. The Bayh-Dole Act (P.L. 96-517, Dec. 12, 1980) gave universities, nonprofit organizations, and small businesses the option to retain title to inventions developed with federal funding. It also authorized federal agencies to grant exclusive licenses to patents on federally owned inventions that were made at federal laboratories or that federal agencies patented after a federal funding recipient opted not to retain title.

To protect the public's interest in commercializing federally funded technology, the Bayh-Dole Act required, among other things, that a contractor or grantee that retains title to a federally funded invention (1) file for patent protection and attempt commercialization and (2) comply with certain reporting requirements.[2] The act also specified that the government would retain "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."[3]

The Bayh-Dole Act did not give large businesses the right to retain title to their federally funded inventions. Subsequently, in February 1983, President Reagan issued a memorandum on patent policy to executive agency heads stating that, to the extent permitted by law, the government's policy is to extend the policy enunciated in the Bayh-Dole Act to all federally funded inventions arising under research and development contracts, grants, and cooperative agreements. In April 1987, President Reagan issued Executive Order 12591, which, among other things, requires executive agencies to promote the commercialization of federally funded inventions in accordance with the 1983 memorandum.

[1]Technology transfer is a process through which research results, including inventions, computer software, and technical information, are provided to potential users in a manner that encourages and accelerates their evaluation and use.

[2]See 35 U.S.C. § 202(c)(1)-(3). In addition, 35 U.S.C. § 203 protects the public interest by authorizing a federal agency to "march in" and reassert control over a federally funded invention if, for example, a patent owner fails to take steps to commercialize the invention. If the government invokes its march-in rights, which is believed never to have happened, it could license a third party to commercialize the invention.

[3]35 U.S.C. § 202(c)(4).

Our 1999 report noted that federal agencies were not always aware of the government's licenses and could not tell us the circumstances under which these licenses had been employed.[4] Nevertheless, agency officials said that the government's license to practice federally funded inventions is important because agency scientists could use these inventions without being concerned that such use would be challenged.

The Government's License Has Limited Applicability

Federal agencies and their authorized funding recipients have the right to benefit from the use of a federally funded invention without risk of infringing the patents. Government scientists can use these inventions in their research without having to pay royalties. Federal contractors, grantees, and cooperative agreement funding recipients may use the government's license if they are authorized to do so. For example, federal agencies can contract with a third party to manufacture products containing such inventions. However, the government's license to use a federally funded invention does not automatically entitle the government to price discounts when purchasing products that happen to incorporate the invention. The government's license also does not necessarily extend to later inventions related to or based on the federally funded invention.

The Government's License Protects Its Right to Practice the Invention

The Bayh-Dole Act gives the government the right to "practice"—or use—a federally funded invention without being liable for patent infringement. There are two primary ways in which the government can use its right to practice an invention in which it has retained a license. First, the government can contract with a third party to make a product that incorporates the invention for or on behalf of the government without either the government or the contractor being liable for patent infringement. It is our understanding that this right has never been invoked for biomedical products. Second, the government can use the invention itself without obtaining a license from or paying a royalty to the patent owner. As discussed later in this report, federal research officials say that this is a common occurrence in the research arena, making the license to use federally funded inventions a valuable asset to the government.

[4]See U.S. General Accounting Office, *Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision*, GAO/RCED-99-242 (Washington, D.C.: Aug. 12, 1999).

The Government's License Is Available to Federal Agencies and Authorized Funding Recipients

The government's right to practice an invention is limited to federal agencies and their funding recipients specifically authorized to use the invention for federal government purposes. The Bayh-Dole Act provides that the license is "nontransferable," which means that the government may not sell or otherwise authorize another to practice an invention in its stead. This concept is not unique to the Bayh-Dole Act. Such language appears frequently in patent practice, where nonexclusive licensing agreements are typically construed as restricting assignment of the license without the licensor's consent. In the Bayh-Dole Act, the term "nontransferable" is followed immediately by qualifying text—language that allows the government to authorize others to practice the invention for or on its behalf but which restricts the purposes for which it may do so.

Federal agencies typically have authorized contractors to use the government's license to develop and produce mission-critical hardware, such as a weapon system. This use of the government's license satisfies a legitimate federal governmental need in support of a congressionally authorized program.

Such linkages to an agency's mission are less prevalent when grants or cooperative agreements are used, as is typically the case with NIH, which sponsors biomedical research to benefit the public health. This research serves the public good through biomedical advances from publishing scientific results and developing new technology that improve people's life. This good may represent a sufficient government need for NIH to authorize its grantees to use the government's license as a basis for using federally funded inventions in their research. However, according to a senior NIH attorney, NIH does not use this rationale to authorize grantees to exercise the government's licenses and has not included a clause in its grant agreements authorizing the use of federally funded inventions as part of the research. As a result, NIH's grantees might be sued for infringement and must negotiate any licensing agreements they believe they need to support their work. Furthermore, the government's license to use a federally funded invention generally does not apply to HHS's purchases of drugs and vaccines because (1) HHS has never contracted for the manufacture of a pharmaceutical made with federal funds for the government's use and (2) HHS's funding assistance for acquiring drugs or

vaccines for distribution is intended to assist the states' public health services, rather than to meet a federal agency's need.[5]

The Government Is Not Automatically Entitled to Price Discounts

The "paid-up license" that the Bayh-Dole Act specifically confers on the federal government[6] is often referred to as a "royalty-free license." The term "royalty-free" license (and even "paid-up license") has sometimes been misinterpreted in a way that effectively eliminates the conditions set forth in the statute. The license for which the federal government is "paid up" entitles it to practice an invention itself, or to have others practice the invention on the government's behalf. The statute does not give the federal government the far broader right to purchase, "off the shelf" and royalty free (i.e., at a discounted price), products that happen to incorporate a federally funded invention when they are not produced under the government's license.

The Government's License May Not Extend to Related Inventions

An invention rarely represents a completely new form of technology because the inventor almost always has used "prior art" in developing the ideas that led to an invention. Prior art is the intellectual basis—the knowledge base—upon which the novelty of an invention is established or the basis that determines whether the "invention" would have been obvious to one skilled in the art. In making an invention, an inventor typically would build on the prior art in the particular technology, and some of this prior art might have been developed by either government scientists or federal funding recipients. However, an intellectual property interest in prior art does not in and of itself give one an interest in someone else's subsequent invention.

Also, an invention often is part of a family of related inventions. One research project may spawn multiple inventions that, for example, are separate and distinct or are further developments of a basic invention for specific applications. Similarly, the idea on which the original invention is based may trigger new inventions.[7] The question of whether the government has an interest in later inventions also arises in instances

[5]For example, HHS provides funding for the states' pediatric vaccine program.

[6]See 35 U.S.C. § 202(c)(4).

[7]The patent application for the first invention is referred to as the "parent" if a second application is filed on the basis of the same disclosure and at least one person is named as the inventor on both applications.

involving the same technologies when the patents to these inventions are related in some fashion. Patents may be related because they protect inventions springing from the same essential technologies or scientists discover additional uses for an invention. For example, while a patent application is pending at USPTO, the applicant may decide to clarify the description of an invention because what initially was viewed as a single invention is found to be two or more inventions or because the USPTO patent examiner determines that patent application claims must be separated and independently supported.

Whether the government has the right to practice an invention because it retains a license to use it under the Bayh-Dole Act depends upon whether the invention was developed with federal funding and is, therefore, subject to the act. An invention is a "subject invention" if it is conceived or first actually reduced to practice "in the performance of work under a funding agreement" (contract, grant, or cooperative agreement) to which the act applies. Rights to the parent patent do not automatically generate rights vis-à-vis related subsequent patents. In this regard, the government is not entitled to any different protection than other entities that fund research.

There is one exception to the general rule that inclusion depends upon whether each invention was itself conceived or first actually reduced to practice in performing federally funded research. This exception holds that while the owner of a "dominant patent" can block the unlicensed use of that patent and related patents, the owner may not assert that patent either to deprive its licensee's right to a "subservient patent" or, similarly, block the government's license to use a subservient patent for a federally funded invention. Thus, if the owner of a dominant patent subsequently makes a new invention in the course of work under a federal contract or other federal assistance, the owner cannot assert the dominant patent to frustrate the government's exercise of its license to use the second invention.

The Government Appears to Hold Few Licenses to the Biomedical Products It Purchases

Although determining the extent to which the government has licenses in biomedical products is difficult, the number appears to be small. For pharmaceuticals, one of the largest sectors of the biomedical market, we found that the government had an interest—either because of its license under the Bayh-Dole Act or as the owner or "assignee" of the patent—in only 6 brand name drugs associated with the top 100 products, by dollar value, that VA procured in fiscal year 2001 and 4 brand name drugs associated with the top 100 products, by dollar value, that DOD dispensed from July 2001 to June 2002. (See apps. II and III.) All four of the DOD

drugs were among the six federally funded pharmaceuticals that VA purchased. As shown in table 1, VA and DOD spent about $120 million on these six drugs in fiscal year 2001.

Table 1: DOD's and VA's Expenditures on Drugs Incorporating Federally Sponsored Inventions, Fiscal Year 2001

Dollars in millions

Drug name	Use	DOD's and VA's expenditures
Procrit (epoetin alpha)	Treats severe anemia caused by such conditions as cancer, acquired immunodeficiency syndrome (AIDS), or surgery	$45.5
Xalatan (latanoprost)	Treats eye conditions, including glaucoma and ocular hypertension, in which increased pressure can lead to a gradual loss of vision	21.8
Epogen (epoetin alpha)	Treats severe anemia caused by such conditions as cancer, AIDS, or surgery	15.6
Neupogen (filgrastim)	Decreases the chance of infection in patients with cancer by promoting the growth of white blood cells	14.2
Taxol (paclitaxel)	Treats metastatic breast and ovarian cancer and Kaposi's sarcoma, as well as head and neck cancer, non-small-cell lung cancer, small-cell lung cancer, and bladder cancer	12.2
Zerit (stavudine)	Treats infection caused by the human immunodeficiency virus (HIV)	10.2
Total		**$119.5**

Sources: DOD and VA (data), GAO (analysis).

Note: Drug names are presented in terms of brand name products, and the corresponding generic drug name is included in parentheses.

We could not determine the extent to which the government holds rights to other types of biomedical products because (1) no databases exist showing the underlying patents for most of these products and (2) products such as hospital beds and wheelchairs may incorporate numerous components that might not be covered by identifiable patents. Our examination found no government rights to any of five medical devices for which the VA Medical Center in Milwaukee, Wisconsin, had spent more than $1 million during fiscal year 2002. The medical devices we analyzed included electric hospital beds, closed circuit televisions, blood pressure monitors, low-air-loss and air-pressure mattresses, and wheelchairs. Officials from VA and DOD believe that the government would rarely have patent rights to such products.

The Government Has Used Its Biomedical Licenses Primarily for Research

Officials from VA, DOD, and NIH said that their agencies use the government's licenses to biomedical inventions primarily in performing research. These officials could not tell us the extent of such usage, however, because researchers generally do not keep records. Instead, government researchers often use the technology and inform the patent owner of the government's rights only if there is a claim of infringement

or other question regarding the government's use. In fact, government scientists usually do not obtain licenses for any patented technology they may use in research. They told us that using technology for research purposes without obtaining permission is a generally accepted practice among both government and university scientists.

VA and DOD officials said they do not consider the government's licenses for procurements because they (1) would not be able to determine readily which products incorporate patented technologies or whether the government helped fund the technology's development, (2) believe they already receive favorable pricing through the Federal Supply Schedule and national contracts, and (3) are not required by law to do so. Similarly, the VA and DOD officials said they had not used the government's licenses to have a contractor manufacture biomedical products for federal use.

Biomedical Licenses Are Primarily Used for Research

DOD and NIH attorneys told us that the government primarily uses its biomedical licenses for research. According to these officials, the government's licenses are valuable because they allow researchers to use the inventions without concern about possible challenges alleging that the use was unauthorized. However, no governmentwide database exists to track how often government researchers actually use the licenses, and agencies did not have records showing how often or under what circumstances these licenses have been employed.

NIH officials said that their agency does not routinely document its researchers' use of patented technologies. Thus, they have no way to readily determine which patented technologies have been used or whether the government had an interest in them. However, the NIH officials cited additional reasons why NIH researchers seldom obtain licenses to conduct research: First, NIH researchers may not really need a license because they can work with the underlying principles behind the technology simply by using the information that has been published. Second, there is a prevailing practice not to enforce patent rights among federal agencies and nonprofit organizations that conduct academic research. Third, under 28 U.S.C. § 1498, federal agencies cannot be enjoined from using patented technology in conducting research; the patent owner's only recourse is to sue the government for a reasonable royalty.

An Army patent attorney told us that he advises researchers to inform him of any patented technologies they are using in their research. He also said, however, that this does not always happen in practice and that he and the researchers generally are not aware of a potentially infringing use until the

patent owner informs them. At that time, he researches the matter and seeks permission, obtains a license, or informs the patent owner of the government's interest if there is one. Because the attorney does not have records on government licenses, he has to research each case individually. He added that he had invoked the privileges of the licenses for research purposes but could not readily tell us how often this had occurred.

A VA official said that, like NIH, VA researchers usually do not know whether the technology they use for research is patented. Furthermore, information about the government's interest in the development of products is difficult to obtain because extensive research would be required. She said that VA procures some research materials using Material Transfer Agreements with universities. For the most part, however, VA simply goes about its research assuming it has the right to use the technologies of others unless there is a challenge. She was unaware of any patent infringement cases that had been filed against VA.

The "General Research Exception" Is Cited in Using Patented Technologies

VA, DOD, and NIH have each relied, to some extent, on the concept that a researcher could use patented technology for research as long as the research is for purely scientific endeavors. According to agency officials, such use is a generally accepted practice within the research community on the basis of what some believe is a "general research exception." However, some agency officials questioned how this exception might be viewed in light of the decision rendered by the Court of Appeals for the Federal Circuit in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002). Concerning the availability of the experimental use exception to a university, the court ruled that the experimental use exception is very narrow and strictly limited, extending only to experimental uses that are not in furtherance of the infringer's legitimate business and are solely for the infringer's amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. The court also stated that the profit or nonprofit status of the user is not determinative of whether the use qualifies for the experimental use exception. Experimental use may infringe a patent when the use furthers the infringer's business. For example, the business of a research institution includes conducting research.

Some patent owners believe that allowing others to use their patented technologies for research purposes may pose no threat and may actually be to their benefit. In fact, representatives from corporations involved in the research and development of products in the biomedical area told us that they welcome additional research that will continue to advance the state of the art as long as such use is not merely an attempt to use the

patents for commercial purposes without obtaining a license. They said that there has been an unstated "gentlemen's agreement" among researchers in this regard that will not be affected by the *Madey* case. If true, government researchers may, as a practical matter, be able in many cases to continue using the patented technologies of others without obtaining licenses.

Licenses Have Not Been Used for Biomedical Procurements

VA and DOD procurement officials were unaware of any instances in which a federal agency had used the government's licenses to have contractors manufacture products that incorporate federally funded inventions. Furthermore, these procurement officials said that, as discussed above, the government's license does not provide an automatic discount for federal government procurements. They added that even if they wanted to use the license for procurements, they would not know which products incorporate federally funded inventions.

The VA and DOD officials also said that the government's licenses would probably not significantly reduce their procurement costs because they believe they already receive favorable pricing through the Federal Supply Schedule and national contracts. In particular, for a branded pharmaceutical to be listed on the Federal Supply Schedule, the manufacturer must agree to give the government a 24-percent discount over the nonfederal average manufacturer price.[8] Furthermore, the federal government has negotiated national contracts that provide even greater discounts for some pharmaceuticals.

Observations

The government's license under the Bayh-Dole Act provides protection against claims of patent infringement when federal agencies or their authorized funding recipients use federally funded inventions. Scientists working for federal agencies and their contractors generally are authorized to use federally funded inventions; however, agencies have not necessarily provided similar authorization in their grant agreements for scientists at universities and other institutions. The decision rendered by the Court of Appeals for the Federal Circuit in *Madey v. Duke University* calls into question the validity of the general research exception that many

[8]The Veterans Health Care Act of 1992 (P.L. 102-585) established a 76-percent ceiling for Federal Supply Schedule prices.

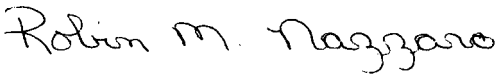
scientists have cited as a basis for using the patented technology of others in their research.

Agency Comments and Our Evaluation

We provided NIH with a draft of this report for its review and comment. NIH stated that because our report ties the exercise of the government's license rights to the needs of the federal government, we give the impression that the government's license rights are more limited than they actually are. While we agree with NIH that federal agencies and their funding recipients have unrestricted rights to use a federally funded invention for federal government purposes, it is important to recognize that they can use these rights only to meet needs that are reasonably related to the requirements of federal programs. NIH also provided comments to improve the report's technical accuracy, which we incorporated as appropriate. (See app. IV for NIH's written comments and our responses.)

We will send copies of this report to interested Members of Congress; the Secretary of Defense; the Secretary of Health and Human Services; the Secretary of Veterans Affairs; and the Director, Office of Management and Budget. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you have any questions about this report, please contact me at (202) 512-3841. Key contributors to this report were Richard Cheston, Deborah Ortega, Bert Japikse, Frankie Fulton, and Lynne Schoenauer.



Robin M. Nazzaro
Director, Natural Resources
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Appendix I: Objectives, Scope, and Methodology

We examined the manner in which federal agencies administer, use, and benefit from intellectual property created under federally sponsored research programs related to public health, health care, and medical technology. Our objectives were to assess (1) who is eligible to use and benefit from the government's licenses to biomedical inventions created under federally sponsored research, (2) the extent to which the government has licenses to those biomedical inventions it procures or uses most commonly, and (3) the extent to which those eligible have actually used or benefited from these licenses.

To determine who is eligible to use and benefit from the government's licenses, we reviewed the applicable laws, regulations, and procedures, including an examination of relevant case law. We also obtained the views of a senior attorney responsible for handling these cases in the Office of General Counsel of the Department of Health and Human Services.

To assess the extent of the government's licenses to biomedical inventions, we concentrated on pharmaceuticals because (1) pharmaceuticals represent a major component of the federal government's biomedical procurements—an estimated $3.5 billion annually—and (2) government databases can be used to identify the underlying patents to pharmaceuticals approved by the Food and Drug Administration (FDA). In conducting our work, we first obtained data on the generic product name, total purchases by dollar amount, and number of prescriptions filled for the top 100 pharmaceuticals purchased by the Department of Veterans Affairs (VA) and the Department of Defense (DOD), which procure most of the government's biomedical products for use by their hospitals and other medical facilities. VA's data covered procurements for fiscal year 2001. DOD's data covered the 12-month period from July 1, 2001, to June 30, 2002, because the agency began consolidating its pharmacy program sales data on July 1, 2001.

For each of the VA and DOD pharmaceuticals, we used FDA's Electronic Orange Book to identify the corresponding brand name product(s) and their patents. We focused on brand name products rather than generics because the former often utilize technologies with protected active patents and typically generate higher sales, whereas generic drugs often enter the market only after a product's active patents have expired. We examined possible equivalent brand names to ensure that we identified the government's licenses to available alternative products. FDA's Electronic Orange Book included 210 of the 217 brand name products we reviewed. We also obtained patent numbers for three of the seven pharmaceuticals not included by examining their product Web sites. Using the patent

numbers, we then accessed the patent records in the U.S. Patent and Trademark Office's (USPTO) patent database to determine whether the government held any rights to the patented technologies of each brand name pharmaceutical. We identified any cases where the government was the owner or assignee or had a license to use the invention because it sponsored the research.

In addition to our own assessment, we examined the National Institutes of Health's (NIH) July 2001 report entitled *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests Are Protected.* NIH assessed the return to the taxpayers for therapeutic drugs that use NIH-funded technology and have sales of at least $500 million per year, making them "blockbuster" drugs. From a survey of the pharmaceutical industry, FDA, USPTO, and its own databases, NIH determined that the government had rights to 4 of the 47 blockbuster drugs it identified for 1999—Taxol, Epogen, Procrit, and Neupogen. We found that all 4 of these were among VA's top 100 pharmaceutical procurements and all but Taxol were among DOD's top 100.

To determine the extent of the government's ownership of or licenses to use other biomedical products, we explored several methods to locate relevant patent and licensing information for medical devices. However, we found that (1) there are no databases showing the underlying patents for most of these products and (2) products such as hospital beds and wheelchairs typically incorporate numerous components that may or may not be covered by identifiable patents. In addition, VA and DOD procurement officials informed us that they do not have agencywide data showing the most frequently purchased items because many devices are purchased at the local level.

Because of these limitations, we identified five medical devices for which the VA Hospital in Milwaukee, Wisconsin—a major procurer of medical devices—had spent more than $1 million during fiscal year 2002. This approach also provided only limited information. We examined the government's rights to each device by identifying it in the General Services Administration's on-line supply catalog, which includes the items on the Federal Supply Schedule, and reviewing the corresponding item descriptions. However, we found that the catalog does not provide patent or licensing information for any of the products. We also were unable to determine from the USPTO patent database the specific patents used for each medical device. Finally, our examination of product Web sites found that they do not provide information on the products' patented

technologies or address whether the government has license rights to them.

To examine how the government has used its licenses to federally funded inventions, we interviewed DOD, NIH, and VA officials who procure biomedical products or who are involved in scientific research. Also, we researched relevant statutes and case law and met with knowledgeable officials in NIH and industry to determine whether a general research exception exists regarding patent infringement that applies to government and other researchers conducting research for purely scientific reasons.

We conducted our work from April 2002 through April 2003 in accordance with generally accepted government auditing standards. We did not independently verify the data that VA, DOD, or NIH provided or the data obtained from the USPTO and FDA databases. However, agency officials addressed each of our questions regarding their data.

Appendix II: The Top 100 Pharmaceuticals Procured by VA on the Basis of Dollar Value, Fiscal Year 2001

Dollars in millions

Rank	Drug name	Amount procured[a]	Active government rights
1	Simvastatin	$121.7	No
2	Olanzapine	99.6	No
3	Lansoprazole	63.8	No
4	Gabapentin	61.2	No
5	Metformin hydrochloride	59.6	No
6	Epoetin alfa[b]	53.3	Yes
7	Risperidone	49.9	No
8	Sertraline hydrochloride	49.3	No
9	Glucose test[c]	42.4	Unknown
10	Fluoxetine hydrochloride	39.3	No
11	Felodipine	36.5	No
12	Clopidogrel bisulfate	36.1	No
13	Ipratropium bromide	34.6	No
14	Goserelin acetate	34.3	No
15	Lisinopril	28.9	No
16	Paroxetine hydrochloride	27.7	No
17	Albuterol sulfate and ipratropium bromide	24.8	No
18	Divalproex sodium	24.0	No
19	Rosiglitazone maleate	23.9	No
20	Bupropion hydrochloride	22.0	No
21	Amlodipine besylate	20.8	No
22	Atorvastatin calcium	20.2	No
23	Interferon alfa-2b and ribavirin[d]	20.0	No
24	Buspirone hydrochloride	19.5	No
25	Insulin[e]	19.4	No
26	Bicalutamide	19.0	No
27	Beclomethasone dipropionate	18.9	No
28	Celecoxib	18.8	No
29	Finasteride	17.4	No
30	Salmeterol xinafoate	17.2	No
31	Enoxaparin sodium	16.5	No
32	Diltiazem[e]	16.3	No
33	Oxycodone hydrochloride	16.0	No
34	Latanoprost[f]	16.0	Yes
35	Donepezil hydrochloride	15.7	No
36	Lamivudine and zidovudine	15.4	No
37	Nifedipine	15.2	No
38	Fexofenadine hydrochloride	15.1	No
39	Cyclosporine	15.0	No
40	Fluticasone propionate	14.9	No

Dollars in millions

Rank	Drug name	Amount procured[a]	Active government rights
41	Quetiapine fumarate	$14.4	No
42	Citalopram hydrobromide	14.3	No
43	Carvedilol	14.0	No
44	Fentanyl[e]	13.5	No
45	Venlafaxine hydrochloride	12.3	No
46	Albuterol[e]	11.6	No
47	Lovastatin	11.3	No
48	Rofecoxib	11.2	No
49	Levofloxacin	11.1	No
50	Filgrastim[g]	11.1	Yes
51	Triamcinolone[e]	10.7	No
52	Fosinopril sodium	10.7	No
53	Carbidopa and levodopa	10.2	No
54	Terbinafine hydrochloride	10.2	No
55	Interferon beta-1a[c]	10.1	Unknown
56	Sumatriptan[e]	10.0	No
57	Warfarin sodium	10.0	No
58	Paclitaxel[h]	9.5	Yes
59	Tramadol hydrochloride	9.2	No
60	Nefazodone hydrochloride	9.2	No
61	Mycophenolate mofetil[e]	8.7	No
62	Amoxicillin and clavulanate potassium	8.6	No
63	Etanercept[i]	8.4	No
64	Nitroglycerin	8.2	No
65	Loratadine	8.1	No
66	Stavudine[j]	7.9	Yes
67	Fluconazole	7.9	No
68	Alendronate sodium	7.5	No
69	Lamivudine	7.4	No
70	Efavirenz	7.4	No
71	Irinotecan hydrochloride	7.3	No
72	Ranitidine hydrochloride	7.3	No
73	Tamsulosin hydrochloride	7.3	No
74	Cetirizine hydrochloride	7.2	No
75	Sotalol hydrochloride	7.0	No
76	Phenytoin[e]	6.9	No
77	Terazosin hydrochloride	6.9	No
78	Carbamazepine	6.9	No
79	Clozapine	6.7	No
80	Irbesartan	6.7	No
81	Brimonidine tartrate	6.7	No
82	Amiodarone hydrochloride	6.6	No

Dollars in millions

Rank	Drug name	Amount procured[a]	Active government rights
83	Glipizide	$6.5	No
84	Mirtazapine	6.4	No
85	Carboplatin	6.3	No
86	Mesalamine	6.1	No
87	Indinavir sulfate	5.8	No
88	Potassium chloride	5.8	No
89	Nelfinavir mesylate	5.6	No
90	Rituximab[c]	5.6	Unknown
91	Nicotine	5.6	No
92	Omeprazole	5.6	No
93	Tacrolimus	5.5	No
94	Alprostadil	5.4	No
95	Sildenafil citrate	5.1	No
96	Rabeprazole sodium	5.0	No
97	Azithromycin dihydrate	5.0	No
98	Flutamide	4.2	No
99	Ondansetron[e]	4.0	No
100	Pioglitazone hydrochloride	3.5	No

Sources: VA (data), GAO (analysis).

Note: The table provides each drug's name on the basis of the active ingredients as they are listed in FDA's Electronic Orange Book.

[a]Based on VA's prime vendor purchases, excluding any direct purchases.

[b]Patent and licensing information about epoetin alpha was obtained from NIH. Two brand name epoetin alpha products, Epogen and Procrit, appear to use federally sponsored technology.

[c]A patent search for this item was not completed because we did not find a related listing in the Orange Book or locate the product's patent information.

[d]Interferon alpha-2b and ribavirin is not listed in the Orange Book. However, we obtained relevant patent information from the Web site devoted to the interferon/ribavirin product, Rebetron, http://www.rebetron.com/pro/rebetron/pi.html, accessed on August 26, 2002.

[e]Variations of the drug name appeared in the Orange Book, and we examined the patents underlying each relevant product.

[f]Xalatan, a brand name latanoprost product, appears to use federally sponsored technology.

[g]Patent and licensing information about filgrastim was obtained from NIH. A brand name filgrastim product, Neupogen, appears to use federally sponsored technology.

[h]Taxol, a brand name paclitaxel product, appears to use federally sponsored technology.

[i]Relevant patent information was obtained from the Web site for the etanercept brand name product, Enbrel, http://www.enbrel.com/hcp/about_enbrel/indications.jsp, accessed on August 1, 2002.

[j]Zerit, a brand name stavudine product, appears to use federally sponsored technology.

Appendix III: The Top 100 Pharmaceuticals Dispensed by DOD on the Basis of Dollar Value, July 1, 2001–June 30, 2002

Rank	Drug name	Active government rights
1	Omeprazole	No
2	Simvastatin	No
3	Atorvastatin calcium	No
4	Celecoxib	No
5	Rofecoxib	No
6	Lansoprazole	No
7	Loratadine	No
8	Gabapentin	No
9	Esomeprazole magnesium	No
10	Clopidogrel bisulfate	No
11	Alendronate sodium	No
12	Fluoxetine hydrochloride	No
13	Sertraline hydrochloride	No
14	Paroxetine hydrochloride	No
15	Amlodipine besylate	No
16	Pravastatin sodium	No
17	Pioglitazone hydrochloride	No
18	Oxycodone hydrochloride	No
19	Fluticasone propionate and salmeterol xinafoate	No
20	Metformin hydrochloride	No
21	Rosiglitazone maleate	No
22	Venlafaxine hydrochloride	No
23	Olanzapine	No
24	Zolpidem tartrate	No
25	Amoxicillin and clavulanate potassium	No
26	Cetirizine hydrochloride	No
27	Lisinopril	No
28	Fluticasone propionate	No
29	Fexofenadine hydrochloride	No
30	Raloxifene hydrochloride	No
31	Tolterodine tartrate	No
32	Estrogens, conjugated	No
33	Bupropion hydrochloride	No
34	Ciprofloxacin[a]	No
35	Pantoprazole sodium	No
36	Rabeprazole sodium	No
37	Levofloxacin	No
38	Diltiazem hydrochloride	No
39	Donepezil hydrochloride	No
40	Citalopram hydrobromide	No
41	Etanercept[b]	No
42	Montelukast sodium	No

Rank	Drug name	Active government rights
43	Epoetin alfa[c]	Yes
44	Blood sugar diagnostic[d]	Unknown
45	Tamsulosin hydrochloride	No
46	Fentanyl[a]	No
47	Azithromycin dihydrate	No
48	Risperidone	No
49	Loratadine and pseudoephedrine sulfate	No
50	Estrogens, conjugated and medroxyprogesterone acetate	No
51	Tramadol hydrochloride	No
52	Sumatriptan[a]	No
53	Interferon beta-1a and albumin[d]	Unknown
54	Somatropin recombinant	No
55	Losartan potassium	No
56	Sildenafil citrate	No
57	Oxybutynin chloride	No
58	Carvedilol	No
59	Fenofibrate[e]	No
60	Amlodipine besylate and benazepril hydrochloride	No
61	Acetaminophen and hydrocodone bitartrate	No
62	Topiramate	No
63	Filgrastim[f]	Yes
64	Metoprolol succinate	No
65	Nifedipine	No
66	Tamoxifen citrate	No
67	Quetiapine fumarate	No
68	Valsartan	No
69	Budesonide	No
70	Salmeterol xinafoate	No
71	Latanoprost[g]	Yes
72	Bicalutamide	No
73	Clarithromycin	No
74	Mometasone furoate	No
75	Warfarin sodium	No
76	Calcitonin, salmon	No
77	Methylphenidate hydrochloride	No
78	Finasteride	No
79	Divalproex sodium	No
80	Mesalamine	No
81	Albuterol sulfate and ipratropium bromide	No
82	Mirtazapine	No
83	Amphetamine aspartate and amphetamine sulfate and dextroamphetamine saccharate and dextroamphetamine sulfate	No

Rank	Drug name	Active government rights
84	Ipratropium bromide	No
85	Lorazepam	No
86	Potassium chloride	No
87	Hydrochlorothiazide and losartan potassium	No
88	Estradiol[a]	No
89	Triamcinolone[a]	No
90	Verapamil hydrochloride	No
91	Isotretinoin	No
92	Enoxaparin sodium	No
93	Buspirone hydrochloride	No
94	Risedronate sodium	No
95	Meloxicam	No
96	Albuterol[a]	No
97	Ethinyl estradiol and norgestimate	No
98	Ranitidine hydrochloride	No
99	Valacyclovir hydrochloride	No
100	Amiodarone hydrochloride	No

Sources: DOD (data), GAO (analysis).

Note: The ranking of the drugs is based on the dollar sales volumes for prescriptions filled through national mail order pharmacies and the retail pharmacy network. Dollar sales volumes are not provided here because, at the time of the data request, complete information regarding DOD's pharmaceutical-dispensing activities was not available. The table provides each drug's name on the basis of the active ingredients as they are listed in FDA's Electronic Orange Book.

[a]Variations of the drug's name appeared in the Orange Book, and we examined the patents underlying each relevant product.

[b]Relevant patent information was obtained from the Web site for the etanercept brand name product, Enbrel, http://www.enbrel.com/hcp/about_enbrel/indications.jsp, accessed on August 1, 2002.

[c]Patent and licensing information about epoetin alpha was obtained from NIH. Two brand name epoetin alpha products, Epogen and Procrit, appear to use federally sponsored technology.

[d]A patent search for this item was not completed because we did not find a related listing in the Orange Book or locate the product's patent information.

[e]DOD listed "fenofibrate, micronized," while the Orange Book listed only "fenofibrate." However, the Orange Book provided additional information specifying which fenofibrate products are micronized. Accordingly, we limited our work to such items.

[f]Patent and licensing information about filgrastim was obtained from NIH. A brand name filgrastim product, Neupogen, appears to use federally sponsored technology.

[g]Xalatan, a brand name latanoprost product, appears to use federally sponsored technology.

Appendix IV: Comments from the National Institutes of Health

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

APR 22 2003

Ms. Robin Nazzaro
Director, Natural Resources and
Environment
U.S. General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Ms. Nazzaro:

Thank you for the opportunity to review and comment on the draft report entitled, *Technology Transfer: Agencies' Rights in Federally Sponsored Biomedical Inventions* (GAO-03-536). Enclosed are the comments of the National Institutes of Health. We offer several general and technical comments that we believe will enhance the clarity and accuracy of the document. As you are aware, we offered more extensive comments at the exit conference and are pleased that some of these are reflected in the draft report.

Sincerely,

Elias A. Zerhouni, M.D.
Director

Enclosure

See comment 1.

Note: Page numbers in the draft report may differ from those in this report.

See comment 2.
See comment 3.

See comment 4.

National Institutes of Health Comments on the U.S. General Accounting Office Draft Report Entitled *Technology Transfer: Agencies' Rights in Federally Sponsored Biomedical Inventions*, GAO-03-536, April 2003

General Comment

Language throughout the draft report gives the impression that the government's right to use government licenses to federally funded inventions is more limited than it actually is. For example, the phrases "for the benefit of specific federal missions," and "where there is a legitimate government need" are used often. It would be more accurate to use statutory language when discussing this government right. Therefore, we suggest that the report use language from 35 U.S.C. 202(c)(4) which states "the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."

Technical Comments

Page 7, footnote 5, there is no place in the text associated with footnote 5.

Page 7, second paragraph, 4th sentence, delete "generally".

Page 9, delete the first paragraph concerning dominant and subservient patents. It is not clear that this paragraph is supported by case law as it relates to subject inventions [At least none that has been cited by the GAO]. The paragraph implies that an owner of a valuable patent developed entirely at private expense which dominated a subject invention would have to license the patent to the government under the same terms as the government's license in the subject invention if necessary to practice the subject invention, i.e. "royalty free". If true, this could have a chilling effect on participation of private entities in government funding agreements and Cooperative Research and Development Agreements.

The following are GAO's comments on the National Institutes of Health's letter dated April 22, 2003.

GAO's Comments

1. We agree with NIH that federal agencies have unrestricted rights to use a federally funded invention for government purposes. It has, indeed, a "nontransferable, irrevocable, paid-up license" to practice the invention. Or it may authorize someone to practice the invention on its behalf. However, these rights cannot be taken so as to undermine the rights that the Bayh-Dole Act clearly intends to accord to inventors. Specifically, the government's license permits it to practice the invention to meet its needs, i.e., to meet needs that are reasonably associated with the requirements of federal programs, not to act outside of those constraints that normally distinguish public- from private-sector activities.

2. We deleted the footnote.

3. We deleted "generally" from the sentence.

4. We disagree. Related issues have been discussed in several court decisions. See, for example, *AMP, Inc. v. United States*, 389 F.2d 448, 454 (Ct. Cl. 1968), cert. denied, 391 U.S. 964 (1968). Regarding NIH's concern that adherence to these cases might have a chilling effect on the willingness of private entities to participate as funding recipients, we point out that the parties can negotiate intellectual property rights dealing with these issues on a case-by-case basis. Moreover, the scope of any exception is limited as required to permit use of the government's license in the subservient patent.

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