

The Government Purse Has Strings Attached



BY TAMSEN VALOIR, PHD
OF BAKER & MCKENZIE, LLP.

Tamsen is a partner in the Houston office of Baker & McKenzie, LLP. She has a JD and LLM in Intellectual Property, a doctorate in molecular biology from Rice University, and her practice is primarily in intellectual property in the area of biotechnology. tamsen.valoir@bakernet.com Special thanks to Gary Shapiro of the San Francisco office of Baker & McKenzie for valuable editorial review.

A 1979 audit of Government-held patents indicated that only about 140 of the 28,000 Government inventions had been developed, probably because companies were not willing to risk the capital without owning title to the invention. It wasn't that private ownership wasn't possible—it was—but the **presumption** called for Government ownership. The situation dramatically changed in 1981 when the Bayh-Dole Act changed the presumption in favor of private ownership.¹ Now, 25 years after the passage of the Bayh-Dole Act, there has been a significant increase in the volume of patenting, licensing and product development under Government funding,² but the Government purse is not without its strings. This article describes ten key issues about Government funding that a company should understand before accepting the Government's largesse.

1. APPLICATION OF BAYH-DOLE

The Bayh-Dole Act applies to inventions made by universities, non-profit institutions and both large³ and small businesses that have received federal money to fund their research.⁴ It applies to inventions "conceived or reduced to practice in the performance of work under a funding agreement."⁵ Therefore, most federal grants are covered, including Department of Health and Human Services (DHHS) funds, Small Business Innovation Research (SBIR)

grants, and Small Business Technology Transfer (STTR) grants. Further, Advanced Technology Program (ATP)⁶ and cooperative research and development agreement (CRADA)⁷ are subject to similar requirements with some modifications.⁸

Certain Department of Defense (DOD), Department of Energy (DOE) and National Aeronautics and Space Administration (NASA) grants may not be covered by Bayh-Dole, and title in those inventions may be retained by the Government, at its option. Therefore, one should always look to the funding agreement for these details.⁹ Further, the Bayh-Dole Act specifically excludes scholarships and educational funding¹⁰ and regulations exclude inventions made using instruments purchased with Government funds.¹¹

Even with these exceptions and ever-dwindling federal funding, much technology remains covered by the Bayh-Dole Act because the Government supports a significant percentage of basic research.¹² Partaking of this resource can have profound implications for patent rights and licensing policies, as explained below.

2. DISCLOSURE AND ELECTION REQUIREMENTS

Those who are covered by the Bayh-Dole Act must fulfill certain requirements in order to comply with the law and retain their patent rights. First, contractors—the recipients of federal funding—must disclose their inventions to the granting agency in a reasonable time after the invention becomes known. Second, they must also elect to take title within a certain time limit.¹³ In the event of failure to notify and elect title, the title 'may' pass to the Government.

This recently occurred in *Campbell Plastics Eng'g & Mfg. v. Brownlee*, 389 F.3d 1243, 1249 (Fed. Cir. 2004). In that case the Federal Circuit held that the Government had the right to take title to the invention because the contractor failed to disclose the inventions on "DD form 882," as required by the funding agreement. Arguably the contractor "continually disclosed all features of the invention," but the court held that **strict** compliance with the language of the contract was the better rule, stating that this would provide the best means of allowing the funding agency to monitor inventions:

While it is at least debatable whether the various progress reports and drawings Campbell Plastics submitted to the Army together convey a clear understanding of the nature, purpose and operation of the invention as well as the invention's physical, chemical, biological or electrical characteristics, we think the contract requirement of a single, easily identified form on which to disclose inventions is sound and needs to be strictly enforced. If we were to find Campbell Plastics's style of disclosure sufficient, methods of disclosure could vary widely from case to case. The Government never would be sure of which piece of paper, or which oral statement, might be part of an overall invention disclosure. But we do not so find. . . Sound policy is promoted by the rule of strict compliance with the method of disclosure demanded by the contract.

Id. at 1248.¹⁴ Thus, a company participating in a Government funding program should ensure that adequate procedures are in place to provide all required notices and title elections on a continuing basis and should audit these procedures on a regular basis.

3. STATEMENT REQUIREMENTS

In addition to providing notice and title elections, all US patent applications related to Government funded inventions must contain a statement that "the invention was made with Government support and that the Government has certain rights in the invention."¹⁵ Evidence suggests that many institutions have failed in this regard. In 1992, the Scripps Research Clinic came to an agreement with the foreign owned Sandoz Pharmaceutical Corporation to receive some \$300 million over 10 years in exchange for the right of first refusal for Scripps' research work.¹⁶ Congress took exception to the wholesale exportation of federally funded inventions and quickly pressured Scripps into revising the deal.¹⁷ The new deal limited Sandoz' access to Scripps work, limited Sandoz' control over research and provided for additional licensing preferences and assistance to small businesses.

However, the controversy piqued Congressional interest in Scripps' reporting of federally funded inventions and a subsequent investigation showed that Scripps had failed to acknowledge federal funding in 43 patent applications.¹⁸ This prompted an investigation of other institutions, whereon Congress discovered that federal funding of patented inventions generally goes under-

reported,¹⁹ and that most agencies lack the ability to adequately monitor the reporting requirements of the Bayh-Dole Act.²⁰ Therefore, a web-based invention reporting system called Interagency Edison or “iEdison” was deployed in 1995.²¹ iEdison now collects invention data for some 25 different Government agencies and provides both a convenient place to provide notice of new inventions and a useful portal for Bayh-Dole related information.

A business interested in technology transfer from a Government funded entity should check all issued patents in which it has an interest. If some patents have the Government funding statement and some do not, this may indicate that the inventors and/or their institutions may have failed to follow the disclosure and statement requirements. Your company should take steps to determine if the inventor received Government funds during the research phase of all inventions. If so, review the funding agreement and determine which regulations apply to that agreement. Then ensure that the Government was notified of each invention, retention of title was elected, and the required statement appears in all patents and applications. We also recommend that a company require a patent owner to affirm in writing that it has both reported to the Government and made the statement of support for each separate patent and/or application.

4. GOVERNMENT LICENSE

Although the inventor or her employee may elect to retain title to the invention, the funding agency by law retains a nonexclusive, nontransferable, irrevocable, paid-up world-wide license to make and use or have made the patented technology.²² This may have little to no effect on a company’s technology strategy in the biomedical industry, where the Government has limited interests.²³

However, in the defense industry the Government is usually a significant customer, and the Government’s license can have significant impact. For example, a company can avoid royalties paid to owners on sales made to the Government, or the Government can avoid what it considers a hefty price by using product specifications in a competitive procurement process to obtain a better price from another contractor.

If your company benefits from the Government’s largesse, take steps to ensure that Government funded research is kept separate from privately funded research leading to product development and patented inventions. This is particularly important in the aerospace industry, where the Government may be the largest, if not

only, customer and where a royalty-free license to use an invention may have significant negative economic impact.

If it is too late to take this precaution, ensure that license agreements provide that payments are not strictly patent royalty payments (which can be avoided for government sales), but instead, specify a royalty on the technical know-how supplied in addition to the patent license. In the alternative, a royalty payment can be made in consideration for not having to keep separate accounts for Government sales for which no royalty would otherwise be due.

5. DATA RIGHTS

Although this article deals mainly with Bayh-Dole and patent rights, the company hoping to do business with the U.S. Government should also be familiar with “data rights” which provides the Government with unlimited rights in all data first produced in the performance of a contract and all data delivered under a contract, **unless provided otherwise** in the contract.²⁴ To avoid waiver of all rights, the company should clearly designate in the contract data as subject to “restricted” or “limited” rights²⁵ and should clearly spell out what will be delivered and under what type of use restrictions.²⁶

6. COMPULSORY LICENSE

The Act also provides for “march-in rights,” whereby the Government can require the inventor to grant reasonable licenses of the subject invention developed under the Government contract to third parties under certain circumstances, including where the owner fails to “achieve practical application of the subject invention” or where “necessary to alleviate health or safety needs.”²⁷ Although this “compulsory license” provision could potentially devastate a company, the Government has *never* granted such a forced license, and has only received only three compulsory license requests under the Bayh-Dole Act.²⁸ Thus, this provision has had negligible impact to date. Still, the situation could change in the event of a national emergency, and both investors and contract negotiators should be aware of this possibility.

7. US MANUFACTURE & SMALL BUSINESS PREFERENCE

Products produced with the use of a federally funded invention must qualify as substantially manufactured in the United States, although waivers are possible where this is not practical.²⁹ Further, except where infeasible, non-profit organizations must grant licenses to small business firms,³⁰ as defined by the Small Business Act.³¹ To this

INTELLECTUAL PROPERTY RESEARCH, INC.

We are a full service patent research company called upon to conduct Infringement, Right-To-Use, Clearance, Invalidity, State-Of-The-Art, Collection and Novelty searches in all mechanical, electrical and chemical disciplines (except biochemistry).

- Searches are conducted by experienced professionals onsite at the USPTO in Alexandria, VA.
- Our search results are based on patent-by-patent reviews conducted on EAST.
- All of our search results are deliverable electronically via our secure website.

www.ipresearch.biz

Email: info@ipresearch.biz

Ph: (703) 624-3840 Fax: (703) 491-6413

Researching Tomorrow...Today!®

author’s knowledge the Government has never “enforced” these provisions.³² However, foreign manufacture and failure to provide a small business preference may make it easier for the Government to enforce a compulsory license, and companies should ensure compliance in this regard.³³

8. GRANT PROPOSALS AS PRIOR ART

Grant proposals become public upon grant award and are indexed and abstracted in online databases. Therefore, unless an applicant takes steps to protect the confidential information therein,³⁴ competitors may use the grant proposals as prior art against patentees.³⁵ Further, with the advent of searchable grant databases, the chances of locating such damaging prior art is higher than most scientists realize. Therefore, a company would be well advised to designate the relevant portions of a grant application as confidential. If it is too late for this precaution, the grantee should advise its patent attorney, who should disclose this prior art to the Patent Office.


9. CLOUDING TITLE

While companies must understand the Bayh-Dole Act’s procedural requirements, infringers have not yet successfully used alleged failures to comply as a means of escaping the consequences of their infringement.³⁶ However, in at least one case, the accused infringer so piqued the funding agency’s interest in a subject invention that it launched an investigation into whether or not it should take title to the invention.³⁷ The pending investigation effectively precluded enforcement of the patent due to the cloud on the patent title. In view of the evidence that universities have grossly under-reported subject inventions and Congressional response thereto, it may become easier in the future to provoke

investigations and effectively prevent patent enforcement during the investigatory period.

10. FORMER GOVERNMENT EMPLOYEES

The hiring of former Government employees may also cloud ownership of title to the invention. The Government obtains the entire right, title and interest to and in all inventions made by a Government employee which bear a direct relation to or result as a consequence of the official duties of the inventor.³⁸ In at least one instance, the Government has taken title after the fact to an invention conceived by a Government employee shortly after his transfer to the private sector, thus depriving his later employer of ownership of technology that it thought it owned.³⁹ Therefore, a private organization must exercise caution in hiring former Government employees. A former Government employee who “invents” shortly after a lateral move to private industry will raise red flags with the Government.

Many other provisions of Bayh-Dole are not covered in this short article, especially with regard to non-profit organizations, which also have restrictions on assignments and royalty sharing requirements. However, I have touched on ten of the most important features of Bayh-Dole that a technology company should address when directly accepting Government funds or when purchasing technology from another entity that has accepted federal funds. If these rules impact your company’s intellectual property developments or acquisitions, you should consult a patent attorney who is knowledgeable about government contracts for additional information. 

ENDNOTES

1. Bayh-Dole Act as codified at 35 U.S.C. §§ 202-212, effective date July 1, 1981. There are many acts affecting technology transfer to the private sector, including, but not limited to, the Stevenson-Wylder Technology Innovation Act (1980), Small Business Innovation Development Act (1982), National Cooperative Research Act (1984), National Cooperative Research and Production Act (NCRPA), Federal Technology Transfer Act (1986), Omnibus Trade and Competitiveness Act (1988), National Competitiveness Technology Transfer Act (1989), National Cooperative Research and Production Act (1993), and the Technology Transfer Commercialization Act (2000).
2. See e.g., AUTM U.S. Licensing Survey: FY 2004 indicating that 3,800 US patents were issued to the responding Universities in 2004, compared with 250 in 1980, and have spun off 4,543 companies since 1980, two-thirds of which are still operating. Universities and other non-profits also brought 567 products to market in 2004 alone.
3. Exec. Order No. 12,591, 562 FED. REG. 13,414 (1987).
4. 35 U.S.C. § 201(e).
5. *Id.*
6. 15 U.S.C. § 278n; 15 C.F.R. § 295.8.
7. 15 U.S.C. § 3710a; 37 C.F.R. § 401.
8. Similar rules can apply to other Government contracts, see e.g., 48 C.F.R. §§ 52.277.11-52.277.13.
9. See e.g., 42 U.S.C. § 2182, § 2457, and § 5908.
10. 35 U.S.C. § 212.
11. 37 C.F.R. § 401.1 (a)(2).
12. Pat K. Chew, *Faculty-Generated Inventions: Who Owns the Golden Egg?*, 1992 WIS. L. REV. 259, 296-97 (1992) (“The National Institute of Health (NIH), National Science Foundation, and the Department of Defense provide about 80% of total federal funding of academic research, with NIH providing almost 50% of the total.”); *CRS Reports 95-307: U.S. National Science Foundation: An Overview* at <http://www.ncseonline.org/NLE/CRSreports/science/st-6.cfm#Back8> (“While total national R&D funding is at a high, the federal government’s share of support for R&D has declined, losing ground to industry. The federal government provided 60% of R&D support in 1967, 46.3% in 1987, and 30.5% in 1997.”).
13. 35 U.S.C. § 202(c)(1).
14. See also, *Southern Research Institute V. Griffin Corp.*, 938 F.2d 1249, 1254-5 (11th Cir. 1991) (refusing to review the USDA’s refusal to grant the contractor patent rights upon proper election of title where the USDA claimed that the Bayh-Dole Act did not apply and it had already licensed the invention anyway, and stating “we conclude that by 202(e) Congress has committed the refusal to assign or transfer patent rights to the discretion of the various federal agencies that acquire those rights in a manner putting such discretionary refusal beyond judicial review. In this case, the USDA declined to transfer its patent rights in ‘A Method for the Control of Insects’ to SRI, and we are without the statutory guidance to meaningfully assess that inaction, and thus without authority to review it. The district court’s holding on this count is affirmed for the somewhat different reasons we have discussed.”).
15. 35 U.S.C. § 202(c)(6).
16. Anderson, Christopher, *Agencies Set Rules On Financial Disclosure; Research-Funding Agencies*, 265(5169) SCIENCE 179 (1994).
17. *Id.*
18. *Id.* (“The Scripps Research Institute is back in the congressional doghouse... now it stands accused of failing to disclose that the research behind 43 patent applications was partially funded by the government.”).
19. Teresa Riordan, *Patents Keeping Track of Federally Aided Technology Is the Subject of a Congressional Hearing Today*, THE NEW YORK TIMES, Late Ed., Section D; Page 2; Column 4 (July 11, 1994) (“A number of institutions spot-checked by the Inspector General... ‘appear to have a rather dramatic under-reporting of Federal involvement in technology that is later patented.’”).
20. *Prepared Statement Of The Honorable June Gibbs Brown Inspector General, Department Of Health And Human Services Before The Subcommittee On Labor, HHS And Education Committee On Appropriations U.S. House Of Representatives*, FEDERAL NEWS SERVICE (January 12, 1995) (“In one case, involving oversight of extramural research inventions, we found that: the National Institutes of Health (NIH) have limited its oversight of grantees by not requiring documentation for some Federal requirements; lacks a systematic process for ensuring that grantees submit all required invention information; and does not fully utilize its invention database to monitor grantee compliance.”).
21. www.iedison.gov/ or <https://s-edison.info.nih.gov/iEdison/>
22. 35 U.S.C. § 202(c)(4).
23. Cf. In the case of a national health emergency the Government’s interest may significantly increase. For example, in the anthrax scare of 2001 the Federal Government pressured Bayer into reducing the price of CIPRO by half to avoid a possible compulsory license, although authority for the compulsory license did not arise under the Bayh-Dole Act, but rather under the U.S. Government’s general right to use patents for a reasonable royalty under 28 U.S.C. § 1498. See, *HHS, Bayer Agree To Cipro Purchase* at <http://www.cptech.org/ip/health/cl/cipro/dhhs10242001.html>
24. See 48 C.F.R. § 52.227-14.
25. Reference to the regulations for details of what these designations encompass is recommended.
26. 48 C.F.R. § 27.4.
27. 35 U.S.C. § 203.
28. CellPro petitioned to license a patent it was accused of infringing and a non-profit organization petitioned for a march-in right to reduce the prices of Norvir and Xalatin.
29. 35 U.S.C. § 204.
30. 35 U.S.C. § 202 (c)(7)(D).
31. See 35 U.S.C. § 201(h) or 37 C.F.R. § 401.2 (g).
32. Cf. Scripps case discussed briefly, *infra*.
33. Non-profit institutions have additional requirements under Bayh-Dole, including a requirement to share royalties with the inventors.
34. 45 C.F.R. § 612.8(a)(3) (providing for protection from publication of designated trade secret content).
35. *E.I. du Pont de Nemours & Co. v. Cetus Corp.*, 19 U.S.P.Q.2d (BNA) 1174 (N.D. Cal. 1990).
36. *Gen-Probe, Inc. v. Center for Neurologic Study*, 853 F. Supp. 1215, 1218 (S.D. Cal. 1993) (noting that “no court has concluded that a private right of action exists under Section 202”); see also *Ciba-Geigy Corp. v. Alza Corp.*, 804 F. Supp. 614, 628 (D.N.J. 1992) (holding that a third party attempting to enforce the grant of additional licenses because of the contractors failure to substantially manufacture the patented product in the U.S. had no private right of action to enforce §§ 202-204); *Platzler v. Sloan Kettering Inst. for Cancer Research*, 787 F. Supp. 360, 366 (S.D.N.Y.), *aff’d*, 983 F.2d 1086 (Fed. Cir. 1992), *cert. denied*, 507 U.S. 1006 (1993) (denying that a private right of action existed where the inventors sought to force a non-profit organization to share royalties with the inventors); *Southern Research Inst. v. Griffin Corp.*, 938 F.2d 1249, 1254 (11th Cir. 1991) (holding that the court had no authority to review the USDA’s denial of patent rights to the contractor who elected to retain rights). Cf. A Government licensee can maintain its own infringement suit, at least where the license agreement so provides. *Nutrition 21 v. United States*, 930 F.2d 862, 866 (Fed. Cir. 1991); *Embrex, Inc. v. Service Eng’g Corp.*, 1998 U.S. Dist. LEXIS 15143, *21-22 (E.D.N.C. 1998) *aff’d* by 216 F.3d 1343.
37. *VDI Tech., Inc. v. Price*, 1994 U.S. Dist. LEXIS 12913, *20-21 (D.N.H. 1994) (dismissing all infringement claims as unripe because the agency’s investigation clouded the patent’s title, and therefore the alleged owner lacked standing to bring the infringement claim).
38. 15 FED. REG. 389 (1950), modified by Executive Order 10930, 26 FED. REG. 2583 (1961) and Executive Order 10930, 26 Fed. Reg. 2583 (1961); see also 37 C.F.R. § 501.
39. *In re Wynne*, 229 U.S.P.Q. (BNA) 842 (Comm’r Pat. 1986).