Federal Funded Inventions and Bayh-Dole Act Compliance: Do You Really Own What You Think You Own?

By Coe A. Bloomberg

"[A] patent without good title is not worth the paper it is written on."¹

In 1983, W. Daniel Hillis was a graduate student at M.I.T. There, he invented the technology eventually patented under US Patent No. 5,212,773, entitled Wormhole Communications Arrangement for Massively Parallel Processor ("773 patent").² In April 1983, M.I.T. notified the Navy that M.I.T. was treating Hillis' patent application, then in preparation, as having arisen under a Navy grant contract. The application was filed on May 31, 1983.³ M.I.T. wrote to Hillis, stating that it would waive its right to the invention if the patent application was amended to recite that the government had a royalty-free license to the invention.⁴ The Navy wrote to Hillis that it also was willing to authorize Hillis to retain ownership of the '773 patent if he would sign forms that granted the government a royalty-free license.⁵ Hillis did not sign the Navy's forms, nor did he amend his patent application.⁶ The '773 patent issued on May 18, 1993.

Eventually, the '773 Patent came into the hands of TM Patents, through purchase at a bankruptcy sale. In 1997, TM Patents sued IBM on the '773 patent.⁷ Notwithstanding the hefty price that TM Patents' co-plaintiff had paid for the patent, that sum apparently was small compared to the alleged value of the infringement damages.⁸ Not surprisingly, the case was hard fought. After years of discovery, Freedom of Information Act requests to the government, motions for summary judgment,⁹ extensive Markman proceedings,¹⁰ and related patent litigation against a third party,¹¹ the parties stood at the threshold of trial in late 2002. It was then that IBM moved to dismiss, contending that the plaintiff did not actually own the '773 patent. IBM urged that, because the plaintiff had failed to complete paperwork required by the Bayh-Dole Act, ownership of the patent had reverted to the government.¹² The court agreed and granted the motion.¹³

So it came to pass that, after the expenditure of millions to buy the '773 patent and (presumably) millions more in litigation to enforce it,¹⁴ TM Patents found itself without title to the patent in suit, and without a claim on which to sue.

TM Patents teaches a stark lesson in the importance of correctly documenting facts germane to ownership of intellectual property rights under the Bayh-Dole Act. It is a lesson important to lawyers who prepare and prosecute patent applications because they often are the first line of defense against a fatal mistake in Bayh-Dole compliance. It is a lesson important to transactional lawyers who handle the purchase and sale of patents and the companies that purport to own them, inasmuch as a due-diligence investigation into the issue of Bayh-Dole compliance may be needed to avoid title problems. Moreover, as TM Patents dramatically illustrates, it also behooves lawyers who litigate patents to be alert to facts bearing on Bayh-Dole Act compliance, for those facts potentially have case-dispositive importance when the asserted patent covers a government-funded invention.

That the documentation requirements of the Bayh-Dole Act are potentially costly to overlook does not mean that they are hard to learn or that compliance is hard to manage. The balance of this article reviews the history and rationale of the Bayh-Dole Act, explores and comments on the Act's documentation requirements, reviews public-record evidence of widespread noncompliance with those requirements, and offers some concluding comments on the implications of this noncompliance.

History of the Bayh-Dole Act

The impetus behind the Bayh-Dole Act¹⁵ was to promote the efficient commercialization of government-funded research and to create uniformity among the procedures of the various federal agencies that fund such research. The following Statement of the Need for the Legislation, contained in the Bayh-Dole Act's legislative history, neatly capsulizes the chaotic state of the law just before the Act's passage, as well as the growing urgency of the problem:
Testimony presented to the Subcommittee on Courts, Civil Liberties and the Administration of Justice ... indicates that the Federal Government is bearing an ever increasing share of the burden of financing basic research and development. This means that the effective commercialization of government financed research is becoming an ever more important issue for those who are concerned with industrial innovation. The patent policies governing the utilization of government funded research will become even more important when the research expected to flow out of recent Congressional enactments such as the Energy Security Act of 1980 begins to produce usable new technologies. ... At the present time U.S. companies desiring to use government funded research to develop new products and processes must confront a bewildering array of 26 different sets of agency regulations governing their rights to use such research. This bureaucratic confusion discourages efficient use of taxpayer financed research and development.17

Passed by Congress in 1980, the Bayh-Dole Act prescribes conditions upon which small business and not-for-profit recipients of federal funds may obtain title to patents resulting from research supported by those funds. Of course, the goals of increased productivity and agency uniformity could have been attained by simply allowing recipients of federal funds to patent the results of the research without complying with any regulations. Nonetheless, Congress was clear that it would not give patent rights away free. Representative Jack Brooks, Chairman of the Committee on Government Operations, emphatically stated the rationale for imposing conditions on the acquisition of patent rights in government-funded inventions:

Assigning automatic patent rights and exclusive licenses to companies or organizations for inventions developed at government expense is a pure giveaway of rights that properly belong to the people.

The argument is made by proponents of the bill that it will spur productivity, a goal that is both necessary and desirable if the United States is to regain its position in the world economy. But that argument ignores the fact that the Federal Government is already paying half the costs of research and development in the United States at an annual cost of $30 billion. No companies or nonprofit organiza-
tions that I know of have been turning down that money because they are not now receiving automatic patent and exclusive licensing rights.18

As enacted, the recited policy and objectives of Bayh-Dole are to:

(1) promote the utilization of inventions based on government-funded research and development,

(2) encourage small businesses to participate in federally supported research and development,

(3) promote collaboration by commercial concerns with universities and non-profit organizations,

(4) promote competition in connection with inventions made by non-profit and small business entities,

(5) promote commercialization and public availability of U.S. inventions,

(6) ensure that the government obtains sufficient rights in federally funded inventions to meet its needs,

(7) protect the public against non-use or unreasonable use of inventions, and

(8) minimize administrative costs.19

Inventions subject to the Bayh-Dole Act are defined as any invention of a person, small business, or nonprofit organization “conceived or first actually reduced to practice in the performance of work under a funding agreement.”20 In the case of the invention of a product, conception requires the inventor have the idea of the structure of the product and possession of an operative method of making it.21 Actual reduction to practice, in the case of an invention of a product, is achieved by production of the product and, if its utility is not obvious, demonstrating its utility by testing.22

Under the Bayh-Dole Act, the Secretary of Commerce was empowered to issue regulations relating to disposition of patent rights and to establish standard funding agreement provisions.23 Regulations were duly issued at 37 C.F.R., Part 401. Following is a checklist-style survey of the key statutory and regulatory require-
ments that, as indicated in the introduction, are most significant to lawyers who prosecute applications, who
handle transactions, and who litigate disputes involving such patents.

**A Bayh-Dole Compliance Checklist**

1. File disclosure with the government for any government-sponsored invention within two months of learning of the invention. The Bayh-Dole Act's language requires that the funding agreement contain provisions to ensure that "the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters." By regulation, a reasonable time period has been set as two months. To help assure compliance, a not-for-profit or small business recipient of federal funding should have a policy requiring its researchers to sign invention disclosure agreements under which inventors and any federal funding are to be disclosed. Indeed, regulations require that the recipient of federal funding agree to require, by written agreement, that its employees (other than clerical and non-technical employees) disclose promptly to their employer each invention made under the funding agreement in order that the funding recipient employer can comply with Bayh-Dole disclosure requirements. The personnel for patent administration must, of course, cooperate closely with Bayh-Dole Act compliance personnel, if those functions are handled separately within the company.

2. File a written election with the government of an intent to retain title within two years after disclosure of invention. If a statutory patent bar date is upcoming, this two year time period can be shortened by the funding agency to a date not more than 60 days prior to the bar date. As to both the two-month and two-year notice provisions, the Act specifically states that if there is a failure to comply "the Federal Government may receive title."

3. File a US patent application prior to any statutory bar date. Filing a patent application before the bar date is, of course, vitally important for reasons beyond the Bayh-Dole Act. If, for example, a patent application is not filed within one year of a printed publication of the inventive subject matter, then the invention falls into the public domain; because of the statutory bar, it cannot be patented, and so the federal funding recipient cannot receive patent title, irrespective of whether the Bayh-Dole Act has been complied with in other respects.

4. File foreign patent applications within 10 months of the US application's filing date. As was true with respect to the initial disclosure requirement discussed at point 1 above, the statute talks in terms of filing foreign applications "within reasonable times," and the Commerce Department regulations quantify what is reasonable, in this case 10 months. If the federal funding recipient does not foreign file within 10 months of its US filing date, the government can file foreign applications. This 10-month deadline is something of a trap for the unwary practitioner who, in non-federally funded invention cases, may be used to thinking in terms of a foreign-filing deadline of 12 months, not 10.

5. Include in the US application a statement of government rights therein. The Bayh-Dole Act states that, when the federal fund recipient elects to take title, "the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention." In addition, the Commerce Department regulations require that the following specific language be placed in such US patent applications:

   This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention.

This five-point checklist applies to all inventions covered by the Bayh-Dole Act. There are numerous further requirements that may come into play, depending on which particular government agency funded the work. For example, a federal agency may require annual reports on the use of an invention covered by the Bayh-Dole Act. The federal funding recipient, and its assignee, may not grant an exclusive license in the United States unless the exclusive licensee agrees that products covered by the invention "will be manufactured substantially in the United States."

If the federal agency that provided the Bayh-Dole Act funding determines that the recipient has not taken steps to achieve practical application of the invention; that health and safety needs are not being reasonably satisfied by the recipient, assignee, or licensee; that requirements for public use are not being reasonably satisfied; or that an exclusively licensed product has not been manufactured substantially in the United States, the government can exercise "march in rights." Upon the exercise of march in rights to Bayh-Dole Act inventions, the government can insist that the technology be licensed to a "responsible applicant."

There are still further specific Bayh-Dole Act provisions relating to not-for-profit organizations. A nonprofit organization cannot assign its rights without government approval, unless the assignee is an organization that has management of inventions as one of its primary functions. Nonprofits must share royalties with the inventor. The balance of a not-for-profit's royalties (after payment for expenses) must be used for...
scientific research or education. In addition, non-profit institutions are required to seek to license Bayh-Dole Act inventions preferentially to small business.

**Evidence of Widespread Lack of Bayh-Dole Act Compliance**

Public-record evidence demonstrates that noncompliance with Bayh-Dole requirements has been widespread, suggesting that it is probably not rare to find that the title to a patent has been compromised by Bayh-Dole Act noncompliance-related problems. In 1998, the General Accounting Office (GAO) carried out a review of the administration of the Bayh-Dole Act at 10 major universities. The GAO contacted eight governmental agencies regarding the state of their record keeping related to approximately $12 billion in annual federal grants. The report concluded that the agencies did little policing of their grant programs for Bayh-Dole Act compliance, relying mainly on the grant recipients themselves to ensure that the federally funded inventions were being dealt with in a manner consistent with Bayh-Dole Act regulations. As the report put it:

The agencies’ monitoring activities consisted largely of collecting and recording the information the universities provided. The agencies generally did not have data for some areas, such as whether the universities were giving priority to small businesses in licensing or how they ensured substantial domestic manufacture under exclusive licenses.

Following receipt of the 1998 GAO report, Senator Hatch, Chair of the Senate Judiciary Committee, requested that the GAO make a further study to determine whether federal agencies ensure that the Bayh-Dole Act provisions of disclosure, reporting, retention, and licensing were being complied with and whether the federal agencies were exercising their rights to use the royalty-free licenses to which they were entitled.

In order to answer these questions, the GAO compared data maintained by the Patent and Trademark Office (PTO) against agency and grant recipient data for more than 2,000 patents issued as a result of federal funding.

The report’s summary of its conclusions paints a dismal scene:

Federal agencies and their contractors and grantees are not complying with provisions on the disclosure, reporting, retention, and licensing of federal sponsored inventions under the regulations implementing the Bayh-Dole Act and Executive Order 12591. In our review of more than 2,000 patents issued in calendar year 1997 as well as an Inspector General’s draft report on 12 large grantees of the National Institutes of Health, we found that the databases for recording the government’s royalty-free licenses are inaccurate, incomplete, and inconsistent and that some inventions are not being recorded at all. As a result, the government is not always aware of federally sponsored inventions to which it has royalty-free rights.

An example of the factual support for this GAO conclusion is set out below:

We selected 1,746 cases for further review, of which 72 represented cases in which only confirmatory licenses were on record and 1,674 represented cases in which only government interest statements were on record. About 92 percent of the 1,746 cases were concentrated in the five federal agencies—NIH, the National Science Foundation (NSF), the Department of Defense (DOD), the Department of Energy (DOE), and the National Aeronautics and Space Administration (NASA)—that provide the bulk of research and development funds to contractors and grantees.

For each case, we contacted the funding agency to determine why the patent database and the Government Register were in disagreement. We asked the agencies to review their files to determine whether they in fact were responsible for funding the research that led to the inventions, whether they had received the reports required from the funded organizations, and whether they had filed confirmatory licenses with PTO or verified that government interest statements were recorded on the patents. As shown in appendixes II and III, the agencies were able to explain a number of these cases; however, they were not able to resolve 1,222, or 70 percent, of the 1,746 cases forwarded to them.

**Conclusion**

There is convincing reason to believe that Bayh-Dole Act requirements are not being complied with for most federal grants. And, as illustrated by the TM Patents case discussed at the beginning of this article, noncompliance may result in a loss of patent title.
of the GAO report is that grant recipients cannot expect the granting agency to be proactive in making sure that Bayh-Dole Act requirements are met. Because grant recipients, and those who would become their successors in title to any patent rights that arise from the funded research, are the ones who stand to lose from noncompliance, they would be well advised to rely on themselves, and not on any vigilance by the granting agency, to make sure that Bayh-Dole Act requirements have been satisfied. To judge by the GAO report, there is urgent need for grant recipients to implement compliance protocols and for those who would license or purchase the resulting patents from them to give Bayh-Dole Act compliance a prominent place on their due-diligence checklists. If past failures to comply are found, remedial action with the agency involved should be examined.

From a patent litigation standpoint, Bayh-Dole Act compliance issues are important for the bearing that they have on whether the alleged patent owner genuinely has title, absent which there may be, as there was in TM Patents, cause for dismissal of the action due to the plaintiff’s lack of standing to sue.

References
2. Id. at 353.
3. Id. at 354.
4. Id. at 355.
5. Id. at 356.
6. Id. at 357.
8. See TM Patents, 121 F. Supp. 2d at 360. TM Patents’ common-law creditors, had paid $27 million for title to the bankrupt’s patents including the ‘773 patent. The hope was for TM Creditors to recoup this money, and more, for the bankrupt’s creditors via patent infringement litigation. IBM was itself a trade creditor, but the court characterized IBM’s trade claims as “apparently infinitesimal in relation to what was at stake in connection with the enforcement of the parties’ various patents . . . .” Id. at 363.
9. See id.
10. See id. at 353.
13. TM Patents, 121 F. Supp. 2d at 353, 357.
14. See id. at 371.
15. The reported decisions do not disclose how much TM Patents spent on the litigation, but “millions” seems a reasonable surmise. According to the AIPPA 2003 Report of the Economic Survey, the estimated median cost, through the end of discovery, of a patent infringement suit with more than $25 million at risk was $2.5 million, with the estimated median cost of the entire litigation approaching $4 million. See American Intellectual Prop. Law Ass’n, 2003 Report of the Economic Survey 22 (2003).
18. Bayh-Dole legislative history, supra n.16, at 22.
20. Id. § 201(e).
24. Id. § 202(c)(1).
25. 37 C.F.R. § 401.14(c)(1) (2003). This regulation also describes the nature of what information must be disclosed, such as “whether a manuscript describing the invention has been submitted for publication.”
26. Id. § 401.14(f)(2).
27. Id.
29. See id. § 102.
30. Id. § 202(c)(1)-2.
31. Id. § 202(c)(3).
32. Id. § 102(b).
33. Id. § 202(c)(3).
34. Id.
35. 37 C.F.R. § 401.14(c)(3).
37. Id. § 202(c)(4).
41. 37 C.F.R. § 401.14(g); see also 35 U.S.C. § 203(a).
42. 35 U.S.C. § 203(a); 37 C.F.R. § 401.14(g).
44. 35 U.S.C. § 202(c)(7)(B); 37 C.F.R. § 401.14(k)(2).
48. The agencies surveyed were: Health and Human Services (principally NIH), National Science Foundation, Department of Defense, National Aeronautics and Space Administration, Department of Energy, Department of Agriculture, Environmental Protection Agency, and Department of Commerce.
51. Id. at 1.
52. Id. at 2.
53. Id. at 7.
54. Further analysis of the impact of Bayh-Dole Act non-compliance on ownership of patent rights can be found in Professor Locke’s article, “Patent Litigation over Federally Funded Inventions and the Consequences of Failing to Comply with Bayh-Dole,” 8 Va. J.L. & Tech. 3 (2003).