Bayh-Dole and the Statement of Government Support

By Tamsen Valoir and William Ramey

The Bayh-Dole University and Small Business Patent Procedures Act[1] was passed three decades ago, in 1981. The Bayh-Dole Act allowed private ownership of government funded inventions, provided that the government retains a royalty-free right to practice the invention, a small business preference is followed in licensing the invention,[2] and that products from the invention are substantially manufactured in the United States.[3]

The Bayh-Dole Act also imposed certain procedural requirements relating to taking title to an invention, one of which is requiring a statement of government rights on each US patent application relating to a government funded invention:

> 35 U.S.C. § 202 (c)(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

Scripps Research Clinic Controversy

Although the Bayh-Dole Act has arguably been very successful and brought much technology to the marketplace,[4] at least one research institution has stumbled along the perilous path of commercialism. In 1992, the well known Scripps Research Clinic agreed to accept some $300 million in funding from a foreign pharmaceutical company over 10 years in exchange for the right of first refusal of all Scripps' research work.[5] Congress was appalled at the wholesale exportation of federally funded inventions and quickly pressured Scripps into revising the deal.[6] 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.

The Scripps' controversy piqued congressional interest in Scripps' reporting of federally funded inventions and the subsequent investigation showed that Scripps had failed to acknowledge federal funding in many US patent applications.[7] This prompted extending the investigation to other institutions, where upon it was discovered that federal funding of patented inventions was generally under-reported.[8]

Statement of Government Support

These results have prompted a general review of federal agencies ability to monitor the reporting requirements of the Bayh-Dole Act[9] and the development of the iEdison online reporting system to streamline the invention reporting requirements.[10]

One regulation that practitioners may not be aware of is 37 C.F.R. § 401.14(f)(4), which provides a more detailed statement of government support than is provided in the statute:

> (4) The contractor agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "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."

The National Institutes of Health (NIH) compliance office indicates that it no longer allows *any* leeway in the statement of government support; it must appear *exactly* as indicated in the regulations.

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This is for administrative convenience, because staff lack the capacity to discern which statements are legally equivalent and which are not, and it's simply impossible to timely review a wide variety of statements.

There are indications that audited institutions may be penalized for *not* including the statement of government support in provisional applications and Patent Cooperation Treaty (PCT) applications, in contradiction with the statute, which requires the statement only on "US patent applications." In conferring with the NIH about its policies regarding the statement of government support, the compliance department argues that its policies *are* correct, and points to the definition of "patent application" in the regulations.

> 37 C.F.R. § 401.2(m) The term patent application or application for patent includes a provisional or nonprovisional U.S. national application for patent as defined in 37 CFR 1.9 (a)(2) and (a)(3), respectively, or an application for patent in a foreign country or in an international patent office.

This does not solve the interpretation difficulties, however, because both the statute and the implementing regulations refer to "US patent application," not "patent application." Clearly, "US patent application" cannot be read to include "application for patent in a foreign country," so why should it be read to include applications filed "in an international patent office"?

Differences PCT and US Patent Applications

Indeed, a PCT application is not a "US patent application" for at least two reasons. First, a *PCT* application is not a *US* application. A US patent application has a US serial number and must be filed at the US Patent and Trademark Office (PTO). In contrast, a PCT application has a WO serial number and can be filed almost anywhere in the world, including the United States. Even when filed in the United States, however, the PCT application is handled by the US Receiving Office (RO/US), a separate department at the PTO. Likewise, the filing requirements for a US patent application and a PCT application are not the same. In a US patent application, an applicant must file a specification, with at least one claim and naming at least one inventor to be accorded a filing date, whereas an applicant is required to pay a filing fee and file a specification, with at least one claim and naming at least one applicant to be accorded a filing date in a PCT application. Accordingly, the differences between a US patent application and a PCT application are so extreme that it is improper to classify a PCT application as a "*US* patent application."

Additionally, a PCT application is *not* a *patent* application—something practitioners continually struggle to make clients understand. A PCT application will *never* mature into a patent; it is merely a placeholder application that holds an applicant's filing date for a period of time. To obtain a patent, one must still file a subsequent patent application in the national office where one desires to obtain a patent. The PCT application expires at a certain time and cannot mature into a patent, regardless of what the patentee does.

Provisional Applications

Arguably a "provisional application" is not a "US patent application" either. The statute is always careful to distinguish a patent application from a provisional application, and many of the sections applicable to patent applications do not apply to provisional applications. For example, patent term does not start from a provisional application, a provisional is never published, no claim is required for a provisional, etc. Furthermore, like the PCT application, the provisional application will *never* mature into a patent; it is merely a placeholder application. Indeed, it is telling that the entire statute is *devoid* of any references to a "provisional patent application," because such term is a non-sequitor.

Even the information posted at iEdison states that the initial patent application must be filed within one year of election of title and further provides that "[t]he term initial patent application means a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3)."[11] However, statements made at iEdison cannot take precedence over a regulation, and the regulations define a patent application as including a provisional application. Since no one has challenged the regulation as outside the scope of statutory authority, practitioners should probably include the statement in all provisional applications.

Academic institutions often send papers or posters to patent practitioners, requesting an emergency filing in advance of a pending presentation. Commonly, practitioners affix a cover sheet on and file the papers or posters without any modification. However, practitioners should make it a practice step that, in addition to adding a cover sheet, a statement of government support should be added to the specification. Of course, this assumes that the academic institution has had time to research, collect, and provide this information to the patent practitioner, and this does not always happen with last-minute filings.

The authors can devise no rational basis for requiring the statement of government funding on a PCT application when the statute and the regulations require it only on a US patent application. Agency policy statements require the statement only on "US patent applications," and iEdison confirms that the statement is required only on non-provisional US patent applications and not on PCT applications.[12] Why then are agency auditors insisting that the statement of government support should appear on PCT applications?

Readers may be rolling their eyes at these technical intricacies and wondering, "What's the harm? Why not just include the statement everywhere?" That is a fair response, certainly on a going forward basis, but what about all of the applications that have already been filed?

Who will pay for revising thousands of provisional and/or PCT applications to now include the statement (assuming that there even was a procedure for modifying a provisional application or PCT application in this way). At an estimated $500 to prepare the amendment, a hundred applications would cost $50,000 to modify. The expense is a lot to expect an academic institution to bear for a policy that is outside of the statutory framework. Should the lawyers absorb the cost since they failed to include the statement? Arguably that is not fair either given the clear wording of the statute.

The NIH compliance office iterates that a provisional application filed in the United States is a "US patent application" and that the statute requiring the statement of government support applies to PCT application if there will be a national stage patent application that enters the United States.

On further discussion, however, the NIH compliance office clarifies that there is a difference between what is required at iEdison and what may or may not be required in an audit. If the first filed patent that is reported under the statute is a provisional or a PCT application, then the automated system will require the statement of government support. What an auditor requires in the field may vary with the agency and the auditor, but the compliance office does admit that the statute does not apply to PCT applications, and their requirements seem to be based on complying with the timelines imposed under the Bayh-Dole Act.

Rules for Contractors

Funding recipients (known as contractors under the Bayh-Dole Act) must disclose their inventions to the federal government in a reasonable time after the invention becomes known to administrative personnel responsible for patent matters.[13] In the event of failure to notify the federal government, the title "may" pass to the government,[14] though in fact the federal government claims title infrequently.[15]

The authors can devise no rational basis for requiring the statement of government funding on a PCT application when the statute and the regulations require it only on a US patent application.

The contractor must also make a written election within two years after this disclosure if the contractor elects to retain title to a subject invention.[16] If, however, some event begins a statutory bar period, the period for making election may be shortened to a date that is not more than 60 days prior to the statutory bar date.[17] Further, the contractor must agree to file a patent application prior to any statutory bar dates,[18] and the application must include a statement that "the invention was made with government support and that the government has certain rights in the invention."[19]

Interestingly, the regulations also require patent applications to be filed within a year of electing title, or prior to any statutory period relating to publication, sale, or public use (*e.g.*, one year), and require international or non-US filings to be made within 10 months of the initial filing or six months from the date that the foreign filing license is

granted.[20] It is not clear why the period for foreign filing should be shortened, or whether the agencies are enforcing this shorter foreign filing limit.

Thus, the NIH seems to imply that, because one is reporting an invention at a reasonable time, usually with the filing of a patent application, that application, regardless of type, should have the statement of government support. This explanation seems a bit weak when the statute and regulations allow an institution two years to elect title and provide that a patent should be filed within one year of electing title, giving as much as three years in the absence of a statutory bar date. Thus, there is usually sufficient time to await the US application filing in order to provide the statement of government support. It is no wonder that the institutions have struggled with compliance when the requirements are inconsistently applied.

The NIH's expansion of the term US patent application to include provisional and PCT applications has the potential to harm university technology transfer departments and frustrate the purposes of the Bayh-Dole Act.

There is of course a way to avoid including the statement in a PCT application since there is more than one way to enter the United States from a PCT filing. Section 371(c) is the national phase filing route from a PCT application, but one could also file an ordinary patent application, merely claiming priority to a PCT application. Thus, there would be no intent to file a US application from the PCT application, and arguably there would be no reason to include the statement in the PCT. The compliance branch of the NIH indicates that to the extent § 371(c) is sidestepped, then no statement should be required in a PCT application, but of course there is more than one funding agency and the funding agreement itself can impose additional requirements.

Nonetheless, administrative personnel facing an auditor who wants to know why the PCT application lacks the statement can reply that the statement is not required on any non-US applications and that the PCT application will not be used to generate a § 371(c) US filing. With regard to provisional applications, it may be that the statement was omitted because the filing was an emergency filing and there was not time to ferret out the funding details and that the statement will nonetheless appear on the US patent application, if and when one is filed. In addition, one can always point an auditor to iEdison, which indicates that the statement is not required on a provisional application.

Conclusion

The NIH's expansion of the term US patent application to include provisional and PCT applications has the potential to harm university technology transfer departments and frustrate the purposes of the Bayh-Dole Act. In addition to the cost of amending PCT and provisional applications, agency enforcement policies risk setting unfortunate precedent for arguing that a patent is unenforceable for compliance failures. Additionally, the funds spent on amendments are funds that could have been spent on additional patent filings, thus negatively affecting the commercialization prospects of some government funded inventions. Finally, agency compliance penalties are yet unknown, but to the extent that government funding is restricted because of alleged compliance difficulties, these policies also frustrates innovative efforts at their source.

Regardless of whether the Bayh-Dole Act is being correctly applied or not, the auditing activity by funding agencies suggests that the statement should appear in all three types of patent applications,[21] lest your client's experience an unfavorable audit and have their funding restricted.

In conclusion, although no statement of government support is legally required on a PCT application, potentially more restrictive auditing procedures indicate that it may be good practice to include the statement of government rights on every type of patent application. Whether one adds the statements to previously filed provisionals and PCT application is an issue of cost and risk balancing. It is doubtful that a PCT application or a provisional application will ever be amended to include the statement, but one can certainly show the auditor an amendment, even if it is never entered. Institutions should discuss the cost and practicalities of amending provisional applications and PCT applications and compare against the potential cost, if any, of non-compliance in making such decisions.

Notes

1. As codified at 35 U.S.C. §§ 202-212.
2. 35 U.S.C. § 202 (c)(7)(D) (1998) (funding agreement must contain "a requirement that, except where it proves infeasible after a reasonable inquiry, in the licensing of subject inventions shall be given to small business firms").
3. 35 U.S.C. § 204.
4. *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.
5. Anderson, Christopher, "Agencies Set Rules On Financial Disclosure; Research-Funding Agencies," 265(5169) *Science* 179 (1994) ("The new agreement, signed this week, ends a furor that erupted in December 1992 when Sandoz announced its intention to invest $ 300 million over 10 years in return for right of first refusal to nearly all research at Scripps. Members of Congress and officials at the National Institutes of Health (NIH), which awards Scripps about $ 70 million a year in research grants, also questioned provisions that appeared to give Sandoz unusual control in shaping Scripps research and imposing restrictions on researchers.").
6. Anderson, Christopher, "Scripps to get less from Sandoz; Sandoz Pharmaceutical Corp. limits investment in Scripps Research Institute," *Science* 264: 1077 (1994) ("One of the more controversial partnerships in biomedicine is back on track, now that the two parties—[Switzerland-based] Sandoz Pharmaceutical Corp. and the Scripps Research Institute of La Jolla, California—have bowed to political pressure and agreed to limit Sandoz's investment in and access to discoveries at the federally funded institution.") *Id.* ("[Representative Ron Wyden (D-Or),] is particularly pleased with a promise by Scripps to help small businesses, such as start-up biotech companies, in licensing technology that Sandoz passes over. Scripps intends to give small businesses 6 months to claim such research, as well as to open an office to assist them and to reinvest some of its Sandoz royalty income to improve ties with such companies.").
7. Teresa Riordan, "Patents Keeping Track of Federally Aided Technology Is the Subject of a Congressional Hearing Today," *NY Times*, p.D2 (July 11, 1994) ("The Inspector General's office focused on the Scripps Research Institute in La Jolla, Calif., finding that Scripps had acknowledged government financing in 51 of 121 patents reviewed. Investigators considered that a suspiciously low number given that Scripps, the largest non-profit bio-medical research institution in the United States, gets $70 million of its annual $120 million budget from N.I.H. and other Government sources. . .").
8. *Id.* ("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.'") (quoting Representative Ron Wyden, Democrat of Oregon).
9. 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 US House Of Representatives, *Federal News Service* (Jan. 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.").
10. *https://s-edison.info.nih.gov/iEdison/.*
11. *See https://s-edison.info.nih.gov/iEdison/timeline.jsp.* The iEdison invention reporting tips provide that the "initial patent application must be filed within 1 year of election of title" and that the "term initial patent application means a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3)."
12. *See e.g.,* PHS Grants Policy Statement—Appendix 9 ((4) The grantee institution agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with Government support under (identify the grant) awarded by (identify the federal agency). The Government has certain rights in the invention."). *See also* NSF Grant Policy Manual § 730(2) ("4.The grantee agrees to include, within the specification of any U.S. patent application and any patent issuing thereon covering a subject invention, the following statement: "This invention was made "with Government support under (identify the grant) awarded by the National Science Foundation. The Government has certain rights in this invention."). *See also supra* n.11.
13. 35 U.S.C. § 202(c)(1) (1999) ("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, and that the Federal Government may

receive title to any subject invention not disclosed to it within such time.").

14. 35 U.S.C. § 202(c)(1).
15. Pat K. Chew, "Faculty-Generated Inventions: Who Owns the Golden Egg?," 1992 *Wis. L. Rev.* 259, 296-297 (1992) (stating that the government claims title infrequently and citing in support a telephone interview with employees of NIH). This author has been unable to locate a single instance of the government taking title to an invention because of procedural failures. *Cf.* Southern Research Institute v. Griffin Corp., 938 F.2d 1249, 1224-1225 (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 that "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.").
16. 35 U.S.C. § 202(c)(2) (1998) ("That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: Provided, That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained [*sic*: "filed for"] in the United States, the period for election may be shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory period: And provided further, That the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.").
17. 35 U.S.C. § 202(c)(2).
18. 35 U.S.C. § 202(c)(3) (1998) ("That a contractor electing rights in a subject invention agrees to file a patent application prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and shall hereafter file corresponding patent applications in other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times."). Presumably, this section refers only to statutory bar dates within the contractor's control, such as public disclosures or offers for sale by the contractor, and does not refer to public uses by third parties, over whom the contractor has no control or knowledge. Indeed, many of the federal regulations implementing this provision specifically refer to public use and sale by the contractor. *See, e.g.*, 10 C.F.R. § 784.12 (1998), 14 C.F.R. § 1274.912 (1998), 37 C.F.R. § 401.14 (1998), 45 C.F.R. § *650.4* (1998), 48 C.F.R. § 52.227-11 (1998). *Cf.* 43 C.F.R. § 6.2 (1998), which doesn't limit public uses to those by the contractor.
19. 35 U.S.C. § 202(c)(6) (1998) ("An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.").
20. 37 C.F.R. § 401.14(c)(3) ("(3) The contractor will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The contractor will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications where such filing has been prohibited by a Secrecy Order. (4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the agency, be granted.").
21. (1) US non-provisional applications, (2) US provisional applications, and (3) PCT applications.