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Noncompliance With Bayh-Dole Leads to Army Getting Patent Title

Among the many incentives used by the federal government, "To promote the Progress of Science and useful Arts,"[1] as stated in the U.S. Constitution, are: (1) providing direct funding to researchers; and (2) providing funding through the Bayh-Dole Act,[2] allowing researchers at small businesses and nonprofit organizations to apply for and to receive patent rights arising out of inventions that are developed with this funding.

Thus, recipients of federal grants can reap the benefits of a limited property right against the public, even though the public, through its tax dollars, funds the development of the inventions that give rise to those rights.

When an inventor receives federal funding, in order to avail himself of potential patent rights, he must agree to abide by a number of strict requirements. These requirements are designed to protect the public's investment in the research. Unfortunately, historically, recipients have not fulfilled their obligations, and the funding agencies have not mandated compliance.[3]

'Campbell Plastics' Case

However, a recent action by the U.S. Army, which was affirmed by the U.S. Court of Appeals for the Federal Circuit, may signal an increased concern of funding agencies to force recipients to honor those obligations. In *Campbell Plastics v. Brownlee*,[4] the court held that failure of a recipient of federal funds to meet certain requirements of its funding agreement can cause the recipient to lose its patent rights even absent any particularized harm to either the funding agency or the public.

When Bayh-Dole was enacted approximately 25 years ago, the country was in the middle of a recession and there was concern that America was failing to keep pace with its foreign competitors.[5] At the same time, the federal government was funding an increasingly larger percentage of the country's basic research. In order to maximize the ability of this funding to spur innovation and to allow America to compete more effectively in the global market, Congress decided that it needed to allow the recipients of those funds to obtain valuable patent rights without being forced to comply with an overly burdensome bureaucracy. These goals were embodied in the Bayh-Dole Act.

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Under Bayh-Dole, a "nonprofit organization" or "small business firm" (generically referred to as a "contractor") that develops an invention with the support of federal funding may elect to retain title to that "subject invention." The conditions for being able to take title are embodied in a funding agreement between the contractor and the funding agency. Many of these conditions are codified in 35 USC §202, entitled Disposition of Rights.

Standard Funding Agreement

The standard funding agreement requires the recipient to agree to abide by a number of obligations, including allowing the funding agency the opportunity to determine whether it wishes to take title to the invention with ample time to comply with U.S. and foreign patent laws, providing the government with a license to use the invention even if it does not take title, and ensuring that steps are taken to attempt to commercialize the invention.[6]

One of the specific obligations is the disclosure of "each subject invention to the Federal Agency within two months after the inventor discloses it in writing to the contractor personnel responsible for patent matters."[7]

The standard funding agreement is silent as to the effect of a breach of many other obligations, but explicitly notes that breach of this obligation will allow, but does not require, the funding agency to take title to the invention if the agency does so within 60 days after learning of the breach.[8]

In *Campbell*, a rare case that involves the exercise of this right by a funding agency, Campbell Plastics entered into a contract with the Army to develop certain components of an aircrew protective mask. Campbell was obligated to disclose any subject invention to the government in accordance with certain substantive requirements. The contract, as usual, required that the government could obtain title to the invention if the contractor failed to disclose the invention within two months of when the inventor disclosed it in writing to the contract person responsible for patent matters. Additional requirements included that the recipient of the funding furnish interim reports every 12 months and a final report within three months after completion of the project. Finally, the contract specified that all reports were to be submitted on a particular type of form.

Campbell Plastics submitted a series of progress reports and drawings to a representative of the Administrative Contracting Office of the Army. However, they were not submitted on the requisite form. Approximately one-year after the parties entered into the contract, an Army representative reminded Campbell that an interim report was to be submitted, preferably on the specified form. Within two weeks, Campbell submitted the requisite form, but did not disclose an invention. Approximately eight months later, Campbell again submitted the requisite form without disclosing an invention. Campbell made no other submissions to the

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Army on the requisite form; however, Campbell did continue to send information to the Army on its research and development.

Approximately five years after entering into the contract, Campbell filed a patent application on its invention. The Patent Office forwarded the application to the Army for the purpose of making a secrecy determination. The application issued as a patent in approximately 18 months and eight days after issuance, Campbell notified the Army of the patent.

The Army asserted that Campbell had forfeited title to the invention because it failed to comply with the disclosure requirements of its contract. The parties agreed that Campbell had not disclosed the invention to the Army on the specified form and that the Army had received an enabling disclosure a few months prior to the filing of the patent application. However, they disagreed as to whether Campbell's failure to comply with the specific terms of the contract was sufficient to divest it of title.

On appeal, there were two main issues: (1) whether failure to disclose the invention in the specified manner was an issue of form over substance and should prevent the Army from taking title; and (2) whether the Army had discretion to take title when arguably it had not been harmed.

First, the court focused on the funding agreement and concluded that based on its clear and unambiguous language, Campbell's failure to properly and timely disclose the subject invention gave the government the right to take title. The court noted that this strict interpretation was consistent with the policy of Bayh-Dole, which provides the government with the right to take title after receiving notification of an invention, and that requiring contractors to disclose inventions in the proscribed manner provides an effective safeguard of that right.

Second, the court addressed the issue of whether the Army acted within its discretion when it invoked forfeiture of the patent. The court held that the language of the contract provided this discretion, and that the only inquiry that the court could make was whether the Army abused its discretion under the four-part *McDonnell Douglas*[9] test. The court emphasized that the government need not have been harmed in order to insist on forfeiture to remain within the bounds of its discretion, and concluded that the Army acted reasonably when it took title to the invention.

Campbell is thus significant for at least three reasons. First, it reminds universities and other recipients of federal funding that if they do not wish to place their patent rights in jeopardy, they must strictly adhere to the terms of their funding agreements. If a recipient is not in compliance with certain of its obligations, the funding agency need not have a reason, other than simple breach of contract, to take title. The funding agency will not be subject to heightened court review simply because one party to the funding agreement was the federal government.

Second, *Campbell* suggests that the government (after going through the appropriate rule-making process), as well as private parties, may wish to include strict notice provisions that provide that in the case of late, absent or informal notice, upon breach the other party automatically receives title, a license, a credit or other self-enforcing relief. Although, this type of provision may seem draconian, parties to agreements might more closely monitor their obligations to provide formal notice if their failure to do so would trigger the loss of rights.

Third, *Campbell* provides an opportunity to compare the potentially broad discretion retained by funding agencies to control patent rights under the disposition of rights provision of Bayh-Dole, with the limited discretion of funding agencies to control patent rights under the march-in rights provision of the statute.[10] As noted above, under *Campbell*, the disposition of rights provision of Bayh-Dole and the standard funding agreement, the government has broad discretion to take title when it does not receive the proscribed form of notice of the development of an invention. Any court review will focus only on whether there was a breach of contract, and if the government exercised a delineated remedy.

In contrast, march-in rights, which ostensibly are safeguards that protect against the failure of an invention to become commercially available, provide less discretion to the funding agency. The march-in provision provides that the government may require the granting of licenses or issue a license itself, if an invention is not satisfactorily commercialized. On its face, this right would appear to be a valuable tool for the government to protect against the stereotyped greedy patent holder. However, the statute has not been interpreted to provide a vehicle to address situations in which a patent holder offers an article covered by a patent at a high price. Thus, although one might think that the fact that any invention is developed with the assistance of federal funding, the federal government would be able to institute some type of pressure to ensure that the product is reasonably priced, it does not.

In the recently decided matter *In re Norvir*,[11] NIH was asked either to march-in and to require that the patent holder license certain patents on reasonable terms or to issue the license itself. NIH determined that the reason for the request was that some members of the public thought that the price of the drug was too high, and that price alone was not a sufficient basis on which to compel that the patents be licensed.

The director of NIH emphasized that under the march-in provisions, a license may be granted on four circumstances: (1) when practical application of the subject invention has not been achieved or is not expected to be achieved in a reasonable time; (2) when the action is necessary to alleviate health or safety needs; (3) when the action is necessary to meet requirements for public use specified by federal regulation that the contractor has failed to meet; or (4) when the U.S. industry preference of 35 USC §204 of the act has not been met.

The director further noted that the issue of drug pricing should be addressed by Congress and not by NIH. Thus, *In re Norvir* illustrates that the march-in provision vests funding agencies with little discretion to control patent rights, while in contrast, *Campbell* vests the funding agencies with broad discretion to take title upon a showing of a breach of certain provisions of the funding agreement.

The recent decision of the Federal Circuit in *Campbell* implicitly condones aggressive enforcement of contract obligations between funding agencies and recipients of those funds. For recipients of those funds, as well as persons who counsel them, the decision is a clear reminder to adhere diligently to their obligations under those contracts. Further, *Campbell* may soon lead courts to confront the issue of failure to comply with other obligations in a funding agreement, even if there is no express reference to the government's right to take title. Although the resolution of that issue is not clear, recipients should, in order to protect themselves, strictly comply with all provisions of their funding agreements, not only the one at issue in *Campbell*.

1. U.S. Const. Article I, §8.
2. 35 U.S.C. §200 et seq.
3. GAO/RCED-99-242, Reporting Requirements for Federally Sponsored Inventions Need Revision (Aug. 1999).
4. 2004 WL 2535385 (Fed. Cir. Nov. 10, 2004).
5. H.R. REP. 96-1307(I), 1980 U.S.C.C.A.N. 6460.
6. 37 C.F.R. §401.14; 48 C.F.R. §52.227-11.
7. 37 C.F.R. §401(c)(1); 48 C.F.R. §52.227-11(c)(1).
8. 37 C.F.R. §401(d); 48 C.F.R. §52.227-11(d).
9. *McDonnell Douglas Corp. v. United States*, 182 F.3d 1319 (Fed. Cir. 1999).
10. 35 U.S.C. §202.
11. Office of the Director, NIH June 29, 2004 (http://ott.od.nih.gov/Meeting/March-in-norvir.pdf).