

Doing business with the US government

There are a number of issues that companies would do well to consider before they accept funds from the US government for R&D

By **Tamsen Valoir**

The Bayh-Dole Act was passed in the United States in 1981 and allows for private ownership of government-funded inventions. Since its enactment, it has stimulated considerable research and development using government funds. However, companies receiving government money should be aware of a few of the legal requirements imposed by the Act before committing significant resources to these endeavours. This article highlights 10 points that every company should know before accepting government funds for R&D.

Application of Bayh-Dole

The Bayh-Dole Act applies to inventions made by universities, non-profit institutions and both large and small businesses that have received federal money to fund their research. It applies to inventions "conceived or reduced to practice in the performance of work under a funding agreement". Therefore, most federal grants are covered, including NIH and DOD funds, Small Business Innovation Research (SBIR) grants and Small Business Technology Transfer (STTR) grants. With some minor modifications, Advanced Technology Program (ATP) and Cooperative Research and Development Agreements (CRADA) are also covered.

The Act specifically excludes scholarships or other funding given to an awardee primarily for educational purposes and regulations exclude inventions made using instruments purchased with government funds. But even with these exceptions, and dwindling federal funding, much biomedical and defence-related

research remains covered by the Bayh-Dole Act because the government supports a significant percentage of this work. Partaking of this resource can have profound implications for patent rights and licensing policies.

Disclosure requirements

Those who are covered by the Act must fulfil certain requirements in order to comply with the law and retain property rights. First, inventors must disclose their inventions to the federal government in a reasonable time after the invention becomes known to administrative personnel responsible for patent matters. In the event of failure to notify the federal government, the title 'may' pass to the government.

In 1994, Congress discovered that federal funding of patented inventions generally goes under-reported. That prompted the development of a central online reporting system called i-Edison (<https://s-edison.info.nih.gov/iEdison>) and suggests that the government will be more active in monitoring the reporting requirement. This recently occurred in *Campbell Plastics Eng'g & Mfg v Brownlee* (389 F3d 1243, 1249 (Fed Cir 2004)). In that case, the Federal Circuit held that the government could 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.

Statement requirements

In addition to providing notice of inventions to the government, all US patent applications must contain a statement that “the invention was made with government support and that the government has certain rights in the invention”.

Any business interested in technology transfer from a government-funded entity should check the first column of 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.

Take steps to determine whether 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 and that the required statement appears in all patents and applications. A buyer should also require a seller to warrant that it has both reported to the government and made the statement of support for each separate patent and/or application.

Government licence

Although the inventor or her employee may elect to retain title to the invention, the funding agency by law retains a non-exclusive, non-transferable, irrevocable, paid-up world-wide licence to make and use or have made the patented technology. This may have little to no effect on a company's technology strategy in the biomedical industry, but in the defence industry, where the government is a significant customer, it can have a major 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 too hefty a margin, 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 basic research and its government funds are kept separate from 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 licence to use an invention may cause significant negative economic impact.

If it is too late to take this precaution, ensure that any licences provide that payments are not made in exchange for the patent licence. Instead, put a royalty on the technical know-how supplied in addition to the patent licence. As an alternative, a payment can be made in consideration for not having to keep separate accounts for government sales. You may also discover that a reduction in price for direct government sales may be necessary to prevent the government from seeking a better price elsewhere.

Compulsory licence

The Act also provides for “march-in rights”, whereby the federal government can require the inventor to grant reasonable licences to third parties under certain circumstances. Although this compulsory licence provision could potentially devastate a company that expects and needs an exclusive licence to technology, the government has never granted such a forced licence and has received only three compulsory licence requests, each relating to a medical product. Thus, this provision has had negligible impact to date.

US manufacture and small business preference

Products produced with the use of a federally funded invention must qualify as substantially manufactured in the United States. Further, except where unfeasible, non-profit patentees must grant licences to small business firms.

To my knowledge, the government has never enforced these provisions, although it did use the threat of enforcement to pressure the Scripps Research Institute into modifying licence terms with Sandoz Pharmaceuticals Corp in 1993. However, foreign manufacture and failure to provide a small business preference may make it easier for the government to enforce a compulsory licence and companies should ensure compliance in this regard.

Grant proposals as prior art

Grant proposals become public upon grant and are indexed and abstracted in online databases. Unless an applicant takes steps to protect the confidential information therein, litigators may use the grant proposals themselves as prior art against patentees. A company interested in patents derived from research described in a grant proposal would do well to ensure that the attorney prosecuting patents for federally

Although this article deals mainly with patent rights, the company hoping to do business with the US government should also be familiar with data rights. These provide 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. To avoid waiver of all rights, the company should clearly designate data as subject to “restricted rights” or “limited rights” and should clearly spell out what will be delivered and under what type of use restrictions in the contract.

funded inventions knows of this source of prior art and should also take steps to disclose it to the USPTO or to designate the relevant portions of a grant application as confidential.

Clouding title

While companies must recognise and follow 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. However, in at least one case, the accused infringer piqued the funding agency's interest in a subject invention sufficiently to begin an investigation as to whether it would take title to the invention. The pending investigation effectively precluded enforcement due to the cloud on the patent's title. Further, in view of the Congressional response to under-reporting inventions, it may become easier in the future to provoke investigations and effectively prevent patent enforcement during the investigatory period.

Former government employees

Hiring of former government employees may sometimes complicate the ownership of the invention. The government obtains the entire right, title and interest to and in all inventions made by a government employee that bear a direct relation to, or result as a consequence of, the official duties of the inventor.

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 technology that it thought it owned. Therefore, a private organisation 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.

Other obligations

These issues constitute some of what a technology company might encounter when participating in technology transfer with entities that have received federal grants for research. However, there are additional requirements, especially as related to non-profit institutions, which have royalty sharing requirements and assignment restrictions.

Therefore, if your technology transfer team encounters any of these concerns, consult with a qualified attorney for additional information. ■

*Tamsen Valoir PhD is a partner in the Houston office of Baker & McKenzie, LLP
tamsen.valoir@bakernet.com*