

## E-ALERT | Government Contracts

January 18, 2013

### HHS PROPOSES TO AMEND ACQUISITION REGULATIONS REGARDING APPLICATION OF BAYH-DOLE ACT AND DATA RIGHTS

On January 10, 2013, the Department of Health and Human Services (“HHS”) issued a [notice](#) to amend its Federal Acquisition Regulation (“FAR”) supplement to add two clauses, 352.227-11, “Patent Rights-Exceptional Circumstances” and 352.227-14, “Rights in Data-Exceptional Circumstances.” These new provisions differ in several key respects from FAR 52.227-11 and 52.227-14, and would be used in lieu of those clauses when an HHS agency makes a determination that “exceptional circumstances” exist such that the standard FAR provisions are not adequate.

Below, we summarize the important implications of the proposed new clauses, which will be of particular interest to those contractors and subcontractors working under an agreement involving a determination of exceptional circumstances (“DEC”), or contemplating working with HHS agencies in the future. Though the proposed clauses do not appear to put forward dramatic changes to HHS’s [existing policies concerning DEC](#)s, they serve as an important reminder that contractors seeking to do business with HHS agencies must be ever vigilant with respect to their intellectual property rights and data, particularly when a DEC has been approved.

Comments to the proposed rules are due by March 11, 2013.

#### I. DETERMINATIONS OF “EXCEPTIONAL CIRCUMSTANCES”

The Bayh-Dole Act provides that a contractor may generally elect to retain title to a subject invention (*i.e.*, those inventions conceived or first actually reduced to practice during the performance of a Government-funded project), although the Government retains certain rights, including a non-exclusive, non-transferable, irrevocable, paid-up, world-wide license to the subject invention. These provisions are incorporated into most contracts using standard FAR clause 52.227-11. However, an agency can make a determination that exceptional circumstances exist such “that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives” of the Bayh-Dole Act. In other words, the contractor may not retain any intellectual property rights to certain inventions that fall under the DEC.

Though exceptional circumstances determinations have been made in the past, they [are atypical](#), partly because the agency must meet a high bar in showing that an exception to the general rule of contractor retention of patent rights would better serve the policies of the Bayh-Dole Act. DEC

DECs tend to be used to make third-party data available to researchers in order to accelerate commercialization. For example, the National Institute of Neurological Disorders and Stroke (NINDS), a department of the NIH, [proposed utilizing a DEC](#) to implement a program to stimulate the development of new drugs. In that situation, NINDS determined that academic and industry researchers had discovered many small molecule compounds that might be transformed into valuable drugs, but without assurances of retaining full patent rights to analogs of their compounds, they would not share their data with potential NIH contractors with medicinal chemistry facilities capable of transforming these compounds into a sufficient state of readiness to begin preclinical

studies. In particular, researchers feared NIH contractors running the chemistry facilities could elect to retain title to developed analogs under the Bayh-Dole Act. Thus, NINDS' DEC, which was eventually approved and [incorporated into its solicitation](#), required contractors to offer a first right of assignment of any invented analog compound to the research contributor, and though contractors could retain all rights to methods of manufacturing analog compounds, the contractors would be required to agree to negotiate licenses to enable commercialization of the compounds.

Another reason DEC are atypical is that current regulations require an agency seeking a DEC to obtain a deviation from FAR 25.227-11 because at present, there is no FAR clause that implements the “exceptional circumstances” exception to the Bayh-Dole Act. Obtaining a deviation requires [significant justification and authorization](#) by the agency head. However, the proposed rules, which amend the FAR to formalize parts of the DEC process, would eliminate the need for the agency to seek a deviation—lifting one barrier to the imposition of a DEC, and perhaps signaling that DEC will become more commonplace going forward in projects involving HHS agencies.

## II. PROPOSED CONTRACT CLAUSE 352.227-11

According to HHS, contract clause 352.227-11 “Patent Rights-Exceptional Circumstances” is designed to “ensure that providers of proprietary material(s) to the government will retain all their preexisting rights to their material(s), and rights to any inventions made under a contract or subcontract (at all tiers).” The proposed clause would be inserted into contracts after a DEC is in place. In many respects, the clause appears intended to provide some certainty and clarity regarding terms to contractors and subcontractors seeking to work on an HHS project involving a DEC.

Proposed contract clause 352.227-11 also establishes a three-part classification scheme for subject inventions developed under a contract that is subject to a DEC:

- A “Class 1” subject invention is a subject invention expressly defined in the DEC, which will not be retained by the contractor, but be assigned to a third party, or as directed by the agency;
- A “Class 2” subject invention is also defined in the DEC, and will be subject to regular Bayh-Dole provisions (as provided in FAR 52.227-11), but the contractor must also grant a license to a third party, or as directed by the agency; and
- A “Class 3” subject invention is one that is neither a Class 1 nor a Class 2 subject invention, and is subject to regular Bayh-Dole provisions under which the contractor may retain patent rights.

Generally speaking, those contributing intellectual property and data to a project governed by these new provisions will need to ensure that the DEC includes specific language appropriately classifying key subject inventions as falling within Class 1, 2 or 3. Similarly, those seeking access to technology or data developed under a solicitation subject to a DEC will have an interest in the classification of certain subject inventions. For all involved, appreciating the nuances of the DEC and navigating the agency structure will be key to understanding and protecting their intellectual property rights.

## III. PROPOSED CONTRACT CLAUSE 352.227-14

Contractors and contributors should also be mindful of limitations to sharing data that is the subject of a DEC. Proposed Contract Clause 352.227-14 pertains to “Rights in Data-Exceptional Circumstances” and applies to data, computer programs and computer databases. The clause pertains to the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of the contract. After defining certain terms, the clause sets forth an allocation of rights, with the differences from FAR 52.227-14

relating to contractors' and subcontractors' rights to publish data first produced or specifically used in the performance of the contract.

Though the existing FAR provisions (FAR 52.227-14) do not place any significant restrictions on the right of a contractor or subcontractor to publish data acquired or findings made during a Government project, proposed clause 352.227-14 would place limitations on contractors and subcontractors seeking to publish information. Specifically, contractors and subcontractors must:

- provide the Contracting Officer a copy of any proposed publication or other public disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure;
- upon request of the Contracting Officer, delay publishing by up to six months;
- agree to use material(s) provided only for the purpose for which they were provided, and no other purpose; and
- take precautions to protect information designated as Confidential.

The restrictions above appear to recognize that data utilized and generated in the performance of a project that is the subject of a DEC may, in fact, form the basis of a third party's intellectual property rights. Thus, the rule specifies that the restrictions on public disclosure above are intended to ensure that "information concerning possible inventions made under this contract is not prematurely published thereby adversely affecting the ability to obtain patent protection on such inventions."

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We are well positioned to advise clients on the impact of these new requirements. If you have any questions concerning the material discussed in this client alert, please contact any of the undersigned.

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