Insights: Alerts

NIST Revises Intellectual Property Rights Offered to Federally Funded Inventions and Licensing of Government Owned Inventions

Bayh-Dole Act-Related Regulatory Update

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Patent Intellectual Property (collectively, "IP") rights represent a significant element of many government contracts, including those for research and development, whether by commercial, non-profit or educational institutions. But did you know that if you develop a subject invention through the use of federal monies (whether in whole or part), the Government gains certain IP rights? As discussed in the Federal Acquisition Regulations ("FAR") Part 27 (48 C.F.R. Part 27), at the very least the Government may (with certain exceptions) gain a fully-paid up license in the IP. This is if the proper and timely reporting of the creation of an invention is made to the relevant agency by the inventor. Failure to timely provide that reporting may result in the inventor *losing* its patent rights and the IP rights transferring to the Government.

Background

Much of these reporting and IP issues arise out of the Bayh-Dole Act, also known as the University and Small Business Patent Procedures Act of 1980, P.L. 96-517 ("Bayh-Dole"). Prior to Bayh-Dole, in effect the Government received most, if not all, IP rights. Congress saw this as inequitable, particularly to predominantly small businesses and universities, and as a result, passed this law which granted rights in the IP to these small businesses and institutions of higher learning subject to the aforementioned notice and timing issues. After this law passed, it was expanded by Executive Order 12591 (the "EO") to also allow large businesses (including for-profit ones) to retain IP rights developed under federal monies.[1] This is the current state of this arena today.

Notwithstanding the foregoing, the Government continues to self-develop subject inventions and either by regulation obtain paid-up licenses in IP or take the IP/Patent rights due to inventors not complying with the notice and registration requirements. This creates a tremendous amount of IP that the Government controls, if not owns.

NIST's Involvement

The National Institute of Standards and Technologies ("NIST") has been tasked with managing the Federal

Government's immense portfolio of government-owned and licensed patents/IP on behalf of all federal agencies. As a result, in addition to the FAR, NIST has its own regulations located at 37 C.F.R. Parts 401 (entitled, “Rights to Inventions Made by Nonprofit Organization and Small Business Firms under Government Grants, Contracts and Cooperative Agreements”) and 404 (“Licensing of Government-Owned Inventions”) (collectively, the “NIST Regs.”), which regulates the use and licensure of government licensed and controlled IP. It is these regulations which have recently been changed and placed in to effect as of May 14, 2018.

It bears noting that the NIST Regs. cover all “subject inventions” even if not developed exclusively with federal monies. Likewise, they cover small and large businesses as well as high education institutions.

Tied to this is the fact that the Government may offer a contractor the use and benefit of government-owned or licensed IP rights for purposes of that contractor successfully performing a contract. Examples of this run the gambit and include instances such as where government personnel invent a new vaccine, weapon, or computer program. This is more the exception or lesser area of coverage in Government Contracts IP scenarios (with the development of IP and licensing/notification to the Government being the more common scenario), but it is key that all IP Rights be understood and recognized regardless of their type or the direction of licensure (from inventor to government or government to inventor).

NIST Regs. Change Highlights

With this in mind, the following represent just some of the highlights made by the recent NIST Regs. Rulemaking/Amendments:

1. Scope – The scope now clearly covers “*all* funding agreements with business firms *regardless of size*… and to nonprofit organizations, *except* for a funding agreement made primarily for educational purposes.” §401.1(b) (emphasis added).

Tied to this, the term “contractor” is now defined to consist of “any person, small business firm or nonprofit organizations, or [per EO 12591] any business firm regardless of size, which is a party to a funding agreement.” §401.2(b).

2. Timing[2] – As with the FAR provisions, a contractor is obligated to elect in writing whether or not to retain title in a subject invention by notifying the funding agency within two years of disclosure of the subject invention to that agency. This period can be shortened by the funding agency where the patent is disclosed to the public and that statutory one-year period has started under which patent protection can be obtained in the United States. §§401.2(n) & (o); 401.14.

The contractor must file its initial patent application relating to the subject invention within one year after it makes its title election 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.” §401.14.

As part of its contractual obligations, the contractor must require that it have its non-clerical and technical employees agree in writing to disclose promptly in writing any subject inventions. *Id.* at (f)(2).

3. Tailoring – Typically C.F.R. clauses and regulations are not allowed to be revised. The new regulations allow modification and tailoring of certain clauses in the NIST Regs. to be revised with approval of the Secretary of Commerce and Office of Management and Budget. §401.1(e).

4. Types of Agreement – While traditional “contracts”, grant and cooperative agreements have been long recognized as applying to these provisions, the NIST Regs. are now amended to clearly recognize CRADAs (Cooperative Research and Development Agreements) under which a government laboratory develops IP. Government labs while owned by the Federal Government are typically operated and maintained by universities, such as Lawrence Livermore Labs (University of California) and Fermilab (run by the University of Chicago), to name a few. Exceptions for CRADAs may apply to the standard clauses on IP Rights. Likewise, an exception for a subject invention which is developed under a naval nuclear propulsion or weapons-related program of the Department of Energy shall require assignment of the entire IP Rights. §401.3(a)(5).

5. Foreign Governments – Even if a contractor receives a license from an agency, it is possible for the agency, if it serves the national interest, to reserve the right to sublicense the IP Rights to foreign governments, their nationals or other international organizations under a variety of contract vehicles or agreements. This may impact the licensee's ability to control sale and distribution of the underlying IP in other jurisdictions or change those rights. This right may also be extended to future arrangements or treaties that the government enters into depending upon the language in the license agreement or contract vehicle and that the vehicle is to be performed over an extended period of time. §401.5(d).

6. Co-Inventor with Government Employee – Interestingly, the NIST Regs. address the situation where a subject invention is made by a combination of a government funding recipient (or its employee) and a government employee. A series of procedures has been developed and expanded upon to also address the situation where the co-inventors are involved across agencies and how priorities in patent rights are determined in these situations. §401.10.

7. FOIA Exemption – Given the sensitive nature of patent rights and applications, the NIST Regs. recognize that per 35 U.S.C. §205, agencies shall not disclose or release [under a FOIA request] copies of any materials relating to a patent application [whether pending at the U.S. Patent and Trademark Office or its foreign equivalent] filed by the contractor. This bar does not extend to other government agencies but is subject to a confidentiality obligation. §401.13.

8. Small Business Preference – As is typical across a number of government contracts subjects, these NIST Regs. provide a preference for the use of small business concerns in licensing a subject invention. This is limited however to those instances in which the contractor “determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposal from applications that are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal.” §401.14(k)(4).

9. Publication – A prospective licensee identifying an invention must notify the Agency thereof. The Agency is

obligated to publish in the Federal Register the subject invention-related information and likewise of any prospective license. §405.7.

Conclusion

In addition to the NIST Regs. and clauses therein, other agencies will have their own modifications or regulatory contract requirements as relates to subject inventions. Typically, it is not enough to look solely to the NIST Regs. as the end-all, be-all of IP rights regulation in the government contracts context. These often work hand-in-hand and understanding how they work together and what they mean in the context of more traditional, commercial IP rights is of critical import for an inventor wishing to (a) develop and invention and (b) hold and retain those rights.

While the foregoing discussion is certainly not exhaustive, it does provide some high-level “food for thought” for those entities which work with the Federal Government either as an inventor/licensor or licensee of IP Rights. A fascinating area of government contracts, one must tread carefully to not only preserve their IP Rights but to also meet the regulatory and statutory obligations arising therefrom.

[1] The topic of retaining and reporting on “subject inventions” covers a wide swath that is beyond the scope of this Article. Contact the Author if you have questions on that area of the FAR.

[2] Note that the following time limits are not all inclusive but only represent a few of the key deadlines and limitations associated with Government Contracts IP Rights.