

# BRIEFING PAPERS® SECOND SERIES

PRACTICAL TIGHT-KNIT BRIEFINGS INCLUDING ACTION GUIDELINES ON GOVERNMENT CONTRACT TOPICS

## Federally Funded Research And Development: Intellectual Property Rights

By Steven M. Masiello, Keric Chin, and Gale R. Monahan\*

The U.S. Government's response to the COVID-19 pandemic has seen an uptick in federal funding, channeled primarily through the Department of Health and Human Services (HHS) and the Department of Defense (DoD), for research and development of vaccines, diagnostics, treatments, and other medical countermeasures related to the novel coronavirus.<sup>1</sup> Over the past 20 months, the Biomedical Advanced Research and Development Authority (BARDA), which is part of the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), DoD, and other agencies, have announced dozens of new or expanded partnerships with industry worth billions of dollars. With opportunity, however, comes risk. Companies doing business with the federal government must understand the rules governing intellectual property (IP) rights under federal funding agreements and plan accordingly. Failure to do so can have significant negative consequences, especially for those companies staking their futures on their IP portfolios.<sup>2</sup>

Government IP rules are complex. The rules vary principally based on the type of federal funding agreement and on the federal agency that is providing the funding. Thus, for example, the rules governing the allocation of rights in technical data or computer software developed under a government procurement contract differ from those governing the allocation of technical data or computer software developed under a federal grant or cooperative agreement, just as the rules differ between civilian and defense agencies. Similarly, the rules governing the parties' respective rights in inventions developed under a

\*Steven M. Masiello is a Partner in Dentons where he is the chair of the U.S. Government Contracts practice and a leader of the firm's Global Government Contracts and Procurement group. Mr. Masiello serves as lead counsel in complex government contract matters across numerous industry segments concerning state, federal, and foreign military funded transactions in the U.S. courts, agency boards and under domestic and international alternative dispute resolution procedures. Keric Chin, a counsel in Dentons' Honolulu office, has extensive experience assisting clients in all facets of their business transactions with the federal government, including bid protests, government contracts counseling, compliance reviews, internal investigations, dispute resolution, and litigation. Gale Monahan is a partner in Dentons' Government Contracts practice where he focuses on government contracts counseling, litigation, and internal and government investigations. Mr. Monahan is a featured speaker in 2022 at the annual Thomson Reuters Government Contracts Year-in-Review Conference.

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procurement contract, grant, or cooperative agreement differ from those under so-called “other transaction” agreements.

This BRIEFING PAPER discusses the three basic types of federal funding agreements and the rules governing the allocation of IP rights under federal contracts, grants, and cooperative agreements and other transaction agreements, while highlighting the principal differences between the the allocation of rights in technical data and computer software under defense and civilian agency contracts.

## Understanding Federal Funding Agreements

As an initial matter, it is important to note that government IP rules vary based on the type of federal funding agreement, so understanding the different types of funding agreements is a critical first step to protecting a company’s IP. Broadly speaking, there are three types of agreements: (1) government procurement contracts; (2) grants and cooperative agreements; and (3) transactions other than contracts, grants, and cooperative agreements, also known as “other transaction” (OT) agreements.<sup>3</sup>

(1) *Procurement contracts*—Under the Federal Acquisition Regulation (FAR), the term “contract” has a very specific meaning. It refers to “a mutually binding legal relationship obligating the seller to furnish the supplies or services (including construction) and the buyer to pay for them.”<sup>4</sup> The key feature of a procurement contract is that it is used to acquire goods and services for the direct benefit or use of the government.<sup>5</sup> Government contracts have the least flexible and most prescriptive rules regarding the allocation of IP rights. The basic rules governing contracts are found in the FAR<sup>6</sup> and agency supplements thereto such as the Defense FAR Supplement (DFARS).<sup>7</sup>

(2) *Grants and cooperative agreements*—Grants are awards of financial assistance to accomplish a public purpose, advance a national objective, address a public problem, or stimulate a particular activity desired by the awarding agency.<sup>8</sup> Like grants, cooperative agreements also provide financial assistance to accomplish a public purpose. Unlike grants, however, cooperative agreements normally require substantial involvement by the federal partner in carrying out and achieving the objectives of the agreement.<sup>9</sup> The IP rules for both grants and cooperative agreements are more flexible and less prescriptive than those under government contracts. The basic rules governing grants and cooperative agreements are found in the Office of Management and Budget’s (OMB’s) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (commonly known as the “Uniform Guidance”).<sup>10</sup>

(3) *Other transaction agreements*—The most flexible and least prescriptive type of funding agreement is the OT agreement. OTs are unique funding vehicles used by certain federal agencies for research and development purposes.<sup>11</sup> As the name suggests, OTs are transactions other than procurement contracts, grants, or cooperative agreements. Because federal procurement regulations and certain procurement statutes do not apply to OTs, OTs are more attractive to non-traditional government contractors that are unwilling or unable to comply with federal procurements rules. OT authority gives agencies the flexibility necessary to develop agreements tailored to a particular transaction. Congress has granted HHS several OT authorities for advanced research and development.<sup>12</sup> HHS relied heavily on its OT authorities for Operation Warp Speed, which was an interagency partnership intended to produce and deliver 300 million doses of safe and effective COVID-19 vaccines, with the initial doses available

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by January 2021, and HHS continues to use those authorities to fund COVID-19 related efforts.

## Intellectual Property Rights Under Contracts, Grants, And Cooperative Agreements

The government IP rules related to the allocation of rights in inventions and patents are broadly similar for contracts, grants, and cooperative agreements. The rules, however, diverge in important ways when it comes to the allocation of rights in technical data and computer software.

### Patents

For procurement contracts, grants, and cooperative agreements, the Bayh-Dole University and Small Business Patent Procedures Act of 1980 (Bayh-Dole Act), as amended, generally governs IP rights in inventions stemming from federally funded research.<sup>13</sup> Under the Bayh-Dole Act and its implementing regulations, the contractor (or grantee/awardee) normally retains title to any invention “conceived of or first reduced to practice” in the performance of the agreement (known as a “subject invention”), while the federal agency obtains a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the invention throughout the world.<sup>14</sup> To maintain ownership of a subject invention, however, the contractor must take certain steps to disclose the invention to the government, elect title to the invention, and file patent applications, all within specified time limits.<sup>15</sup> If the contractor fails to disclose, elect rights to, or file an application for a subject invention in accordance with the regulations, the contractor must, upon written request from the federal agency, assign title to the subject invention to the agency.<sup>16</sup> While uncommon, the government has exercised its rights to take title to an invention when a contractor fails to fulfill these requirements.<sup>17</sup> The contractor normally will retain a non-exclusive royalty-free license in each subject invention to which the Government obtains title, except if the contractor fails to disclose the invention.<sup>18</sup>

For foreign companies, it is also important to note that the Bayh-Dole Act and its implementing regulations contain a domestic manufacturing preference. This preference states that, absent a waiver by the agency, the contractor shall not grant to any person the exclusive right to use

or sell a subject invention in the United States, unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.<sup>19</sup> This, of course, will have significant implications for how foreign companies structure their manufacturing operations to meet this requirement.

There are also four circumstances under which the federal agency has the right to require that the contractor, an assignee, or exclusive licensee of the subject invention grant a nonexclusive, partial, or exclusive license to another party. These are known as “march-in rights.” A federal agency can exercise its march-in rights if it determines that such action is necessary (1) because the contractor has not taken, or is not expected to take effective steps to achieve “practical application” of the subject invention within a reasonable time; (2) to alleviate health or safety needs that are not reasonably satisfied by the contractor, assignee, or their licensees; (3) to meet requirements for public use specified by federal regulations where such requirements are not reasonably satisfied by the contractor; or (4) because the contractor or licensee of an exclusive right to use or sell a subject invention in the United States is in breach of the domestic manufacturing preference.<sup>20</sup> Since the inception of the Bayh-Dole Act, the government has never exercised its march-in rights. This, of course, could change in view of the current pandemic.

The government has unique rights under 28 U.S.C.A. § 1498, separate and apart from its march-in rights, authorizing the government or another party acting on its behalf to infringe *any* U.S. patent and limiting the patent holder’s remedy for infringement to a suit against the United States in the U.S. Court of Federal Claims for reasonable and entire compensation. The government’s right to infringe a U.S. patent has been construed as the exercise of its power of eminent domain.<sup>21</sup> It is implemented by the FAR’s “Authorization and Consent” clause.<sup>22</sup>

Importantly, under 28 U.S.C.A. § 1498, liability for patent infringement exists against the United States for any use or manufacture by the government or by any person or entity acting on behalf of the government, such as in the performance of a government contract.<sup>23</sup> A government contractor thus can be shielded from liability for patent infringement when the patent is infringed pursuant to a government contract with the authorization and consent of

the government.<sup>24</sup> Accordingly, ensuring proper authorization and consent for potential acts of infringement is a crucial exercise for any government contractor.<sup>25</sup> An “Authorization and Consent” clause appears in most government contracts and generally entitles a contractor both to use any invention disclosed in a U.S. patent necessary for the performance of a government contract, and simultaneously, to avoid liability for patent infringement.<sup>26</sup> Alternatively, depending on the specificity of the contract’s requirements, authorization and consent may be implied under certain circumstances.<sup>27</sup> Contractors should be aware, however, that in some cases the government may require a contractor to reimburse it for liability for patent infringement arising out of a contract for commercial products or commercial services.<sup>28</sup>

### Technical Data And Computer Software

The other major categories of IP under federal funding agreements are technical data and computer software. The rules regarding the allocation of rights in technical data and computer software vary in significant but often subtle ways between government contracts, on one hand, and grants and cooperative agreements, on the other. They also vary between defense and civilian agencies.

(1) *Defense contracts*—DoD policies governing the acquisition and allocation of rights in technical data and computer software are found in DFARS Subparts 227.71 and 227.72.<sup>29</sup> For commercial technical data—that is, technical data pertaining to commercial items and processes—and commercial computer software, the allocation of rights is fairly straightforward.<sup>30</sup> With certain exceptions, DoD policy is to acquire only technical data and rights in technical data customarily provided to the public with commercial items or processes and commercial computer software under the same licenses customarily provided to the public.<sup>31</sup> Thus, technical data and computer software that qualify as commercial have the greatest protection. Companies should be aware, however, that DoD agencies generally have adopted a more expansive view of their rights in commercial technical data and computer software than supported by industry practice, and in some cases, federal law.

For non-commercial technical data and computer software, on the other hand, the allocation of rights is principally defined by the source of funding for the development of the computer software or the items,

components, or processes to which the technical data pertains, with the government obtaining the most rights (“unlimited rights”) in computer software or technical data pertaining to items, components, or processes developed exclusively with government funding, the least rights (“restricted/limited rights”) in computer software or items, components, or processes developed exclusively at private expense, and an intermediate level of rights in computer software or technical data pertaining to items, components, or processes developed with mixed funding (“government purpose rights”).<sup>32</sup> Notably, under the broadest license—“unlimited rights”—the government obtains the right, among other things, to disclose technical data or computer software “in whole or in part, in any manner, and for any purposes whatsoever, and to have or authorize others to do so.”<sup>33</sup>

The DFARS requires that contractors identify and properly mark any non-commercial technical data or computer software delivered to the government with less than unlimited rights. In this regard, the DFARS contains a specific set of legends for marking technical data and computer software, respectively. Critically, the failure to mark technical data or computer software or to use the proper legend for doing so will jeopardize the contractor’s ability to limit the government’s rights.<sup>34</sup> Defense agencies regularly challenge contractors’ assertions of limited or restricted rights based on the contractors’ failure to mark technical data or computer software or to use the prescribed legends.<sup>35</sup> Moreover, a failure to mark correctly also can jeopardize the commercial trade secret status of the technical data more broadly.<sup>36</sup>

(2) *Civilian agency contracts*—The policies and procedures governing the allocation of rights in technical data and computer software for civilian agencies are found in FAR Subpart 27.4. Like the DFARS, the FAR generally distinguishes between commercial and non-commercial technical data and computer software. In this regard, the FAR provides that “the Government shall acquire only the technical data and the rights in that data customarily provided to the public with a commercial item or process,”<sup>37</sup> and that the government shall acquire commercial computer software or commercial computer software documentation “under licenses customarily provided to the public to the extent such licenses are consistent with Federal law and otherwise satisfy the Government’s needs.”<sup>38</sup>

Unlike the DFARS, however, the allocation of rights in non-commercial data—which includes both technical data and computer software—is principally based on whether the data is “first produced in the performance of [the] contract.”<sup>39</sup> The government obtains unlimited rights in data that is first produced (either with mixed funding or exclusively with government funds) in the performance of a civilian agency contract, and limited or restricted rights in data that is not first produced in the performance of the contract *if* such data is delivered to the government with its consent. Under the FAR, the government expects that the contractor normally will protect its data qualifying for limited rights data status and restricted computer software status by withholding such data from delivery to the government and delivering form, fit, and function data instead.<sup>40</sup> To the extent the government requires the contractor to deliver data developed at private expense—*i.e.*, limited rights data or restricted rights software—as an exception to the general policy, the contractor must mark the data with the proper legend.<sup>41</sup> As with defense contracts, “[d]ata delivered to the Government without any restrictive markings shall be deemed to have been furnished with unlimited rights.”<sup>42</sup>

(3) *Grants and cooperative agreements*—For grants and cooperative agreements, the government’s rights in data and computer software are not predicated on the source of funding for their development. Rather, the government’s rights are predicated on whether the data or computer software is “produced” or “developed” under the federal grant or agreement.<sup>43</sup> The government generally has the right to obtain, reproduce, publish, or otherwise use the data produced under a federal award and to authorize others to do so for government purposes, while the contractor retains ownership of the data and the right to copyright any works.<sup>44</sup> The take-away for contractors is to clearly identify the data that will be developed under their grants and cooperative agreements, irrespective of the source or sources of funding used for their development, and to segregate such data from data produced prior to or separately from the federal grant or agreement.

### Other Transactions

For OT awards, there is no prescribed method for allocating rights in inventions, patents, technical data, or computer software, meaning allocation of IP rights under an OT agreement is subject to negotiation between the federal agency and awardee. The rationale for exempting

OT agreements from the typical IP provisions found in government contracts, grants, and cooperative agreements is to promote engagement with non-traditional contractors that might not be amenable to such provisions. Nevertheless, companies should be aware that federal agencies tend to resort to the more familiar types of IP provisions found in the FAR and DFARS when negotiating OT agreements.

## Conclusion

It bears repeating that government IP rules are complex. This PAPER provides a high-level overview of those rules primarily to alert prospective contractors and awardees to the risks associated with federal funding agreements. As with many topics, however, the devil is in the details.

## Guidelines

These *Guidelines* are intended to assist you in understanding the rules governing IP rights under federal funding agreements. They are not, however, a substitute for professional representation in any specific situation.

1. Understand the types of funding opportunities and agreements that your company is pursuing and the applicable IP rights provisions for each.
2. Ensure that researchers and scientists maintain records establishing when inventions are conceived and first actually reduced to practice in order to delineate between inventions that are subject to the Bayh-Dole Act and its implementing regulations and those that are not.
3. Develop policies and procedures for reporting, electing title to, and filing patent applications for subject inventions under federal grants, cooperative agreements, and contracts.
4. Establish a clear audit trail for the source of funding used to develop computer software; the items, components, and processes to which technical data pertain; and technical data that is not related to any items, components, or processes.
5. Develop policies and procedures for identifying and properly marking technical data and computer software that will be developed or delivered under a federal funding agreement.
6. Educate company personnel on the critical importance of adhering to the government IP requirements.

**ENDNOTES:**

<sup>1</sup>Under the Trump Administration, the bulk of federal funding for research and development was funneled through Operation Warp Speed (OWS). OWS was an interagency partnership between the Department of Health and Human Services (HHS) and the Department of Defense (DoD) that coordinated federal efforts to accelerate the development, acquisition, and distribution of COVID-19 medical countermeasures. Most of the money awarded under OWS was for vaccine development and acquisition, although OWS also encompassed therapeutics, diagnostics, and ancillary supplies. In January 2021, the incoming Biden Administration announced that it would restructure and rename the interagency effort. See Siddalingaiah, Cong. Research Serv., CRS Insight IN11560, Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials (Mar. 1, 2021), available at <https://crsreports.congress.gov/>.

<sup>2</sup>See generally Masiello, Bareis & Pratt, “Managing Intellectual Property Issues With the U.S. Government: A User’s Guide,” 16-3 Briefing Papers 1 (Feb. 2016).

<sup>3</sup>Another category of federal funding agreements not discussed here is cooperative research and development agreements (CRADAs), which are formal research and development agreements between one or more federal laboratories and one or more non-federal partners. 15 U.S.C.A. § 3710a.

<sup>4</sup>FAR 2.101.

<sup>5</sup>See 31 U.S.C.A. § 6303.

<sup>6</sup>See FAR pt. 27.

<sup>7</sup>See DFARS pt. 227.

<sup>8</sup>See 31 U.S.C.A. § 6304.

<sup>9</sup>See 31 U.S.C.A. § 6305.

<sup>10</sup>2 C.F.R. pt. 200.

<sup>11</sup>The agencies include, but are not limited, to the Department of Defense, the Department of Energy, the Department of Health and Human Services, the Department of Homeland Security, the Department of Transportation, the National Aeronautics and Space Administration, and the National Institutes of Health.

<sup>12</sup>See, e.g., 42 U.S.C.A. § 247d-7e (BARDA).

<sup>13</sup>35 U.S.C.A. § 200 et seq. As a matter of policy, coverage of the Bayh-Dole Act was extended to include businesses of any size by the Presidential Memorandum on Government Patent Policies of the Heads of Executive Departments and Agencies (Feb. 18, 1983) and by Executive Order 12591 in 1987. FAR 27.302.

<sup>14</sup>35 U.S.C.A. § 202(c)(4); see 35 U.S.C.A. § 201 (defining “subject invention”).

<sup>15</sup>35 U.S.C.A. § 202(c)(1)–(3); 37 C.F.R. § 401.14(c) (contracts, grants, and cooperative agreements); FAR 52.227-11(c) (contracts); 2 C.F.R. § 200.315(c) (grants and cooperative agreements).

<sup>16</sup>35 U.S.C.A. § 202(c)(1)–(3); 37 C.F.R. § 401.14(d) (contracts, grants, and cooperative agreements); FAR

52.227-11(d) (contracts); 2 C.F.R. § 200.315(c) (grants and cooperative agreements).

<sup>17</sup>See, e.g., *Campbell Plastics Eng’g & Mfg., Inc. v. Brownlee*, 389 F.3d 1243 (Fed. Cir. 2004), 46 GC ¶ 457 (upholding the U.S. Army’s right to demand title to a method for fabricating a sonic-welded gas mask where the contractor failed to disclose the invention).

<sup>18</sup>37 C.F.R. § 401.14; FAR 52.227-11(b)(2).

<sup>19</sup>35 U.S.C.A. § 204.

<sup>20</sup>35 U.S.C.A. § 203.

<sup>21</sup>*Decca, Ltd. v. United States*, 640 F.2d 1156, 1166 (Ct. Cl. 1980).

<sup>22</sup>FAR 52.227-1. Under 2 C.F.R. § 910.362(g), 28 U.S.C.A. § 1498 does not apply to grants, but it does apply to cooperative agreements.

<sup>23</sup>See, e.g., *Evans v. McDonnell Aircraft Corp.*, 270 F. Supp. 778, 780 (E.D. Mo. 1967) (“The purpose of this section is to relieve contractors working for the United States Government from liability for infringement of patents in manufacturing anything for the government and to limit patentee, and those claiming through him, to suit against the United States Government in the Court of Claims.”).

<sup>24</sup>28 U.S.C.A. § 1498(a), ¶ 2.

<sup>25</sup>See, e.g., *Carrier Corp. v. United States*, 534 F.2d 244, 249 (Ct. Cl. 1976) (“Since [28 U.S.C.A. § ] 1498(a) expressly provides that any use of a patented invention for the Government must be authorized or consented to, it is plain that the Government can limit its authorization and consent as it did in this instance.”).

<sup>26</sup>See FAR 27.201-1(b) (prescribing the use of the clause at FAR 52.227-1, “Authorization and Consent”).

<sup>27</sup>Notably, the Defense Production Act of 1950, 50 U.S.C.A. § 4501 et seq., which President Trump invoked in March 2020 to require certain U.S. companies to manufacture articles for use in COVID-19 countermeasures, does not expressly exempt manufacturers from patent infringement suits. While that statute permits the government to prioritize contracts for the manufacturing of certain articles and to control the allocation of scarce supplies, it does not invoke the protections of 28 U.S.C.A. § 1498.

<sup>28</sup>FAR 52.227-3.

<sup>29</sup>DFARS Subparts 227.71 and 227.72 implement a number of statutes, including most notably former 10 U.S.C.A. § 2320 and 10 U.S.C.A. § 2321. Although 10 U.S.C.A. §§ 2320 and 2321 addressed technical data rather than computer software, it is longstanding DoD policy to apply the same or similar requirements to both technical data and computer software, since many issues are common to both. 72 Fed. Reg. 51188 (Sept. 6, 2007). Notably, the National Defense Authorization Act for Fiscal Year 2021, Pub. L. No. 116-283, div. A, tit. XVIII, §§ 1801 & 1833, 134 Stat. 3388, 4151, 4226, 4228–30, 4231–33 (Jan. 1, 2021), transferred the provisions of 10 U.S.C.A. §§ 2320 and 2321 to 10 U.S.C.A. §§ 3771–3775

and §§ 3781–3786, respectively, effective January 1, 2022.

<sup>30</sup>DFARS 227.7102-1 (technical data—commercial items); DFARS 252.227-7014(a)(1) (commercial computer software).

<sup>31</sup>DFARS 227.7102 (commercial items, components, and processes), 227.7202 (commercial computer software).

<sup>32</sup>DFARS 252.227-7013(b)(1)–(3).

<sup>33</sup>DFARS 252.227-7013(a)(16), 252.227-7014(a)(16).

<sup>34</sup>DFARS 227.7103-10(c) (“Technical data delivered or otherwise provided under a contract without restrictive markings shall be presumed to have been delivered with unlimited rights and may be released or disclosed without restriction.”); DFARS 227.7203-10 (computer software).

<sup>35</sup>See, e.g., *Cubic Defense Applications, Inc.*, ASBCA No. 58519, 2018-1 BCA ¶ 37,049; *Night Vision Corp. v. United States*, 68 Fed. Cl. 368, 380 (2005), 47 GC ¶ 515;

see also *L-3 Commc’ns Westwood Corp. v. Robichaux*, Civ. A. No. 06-279, 2008 WL 577560 (E.D. La. Feb. 29, 2008).

<sup>36</sup>*GlobeRanger Corp. v. Software AG*, 27 F. Supp. 3d 723 (N.D. Tex. 2014); *L-3 Commc’ns Westwood Corp. v. Robichaux*, Civ. A. No. 06-279, 2008 WL 577560 (E.D. La. Feb. 29, 2008).

<sup>37</sup>FAR 12.211.

<sup>38</sup>FAR 12.212(a).

<sup>39</sup> FAR 52.227-14(b)(1)–(2).

<sup>40</sup>FAR 52.227-14(g).

<sup>41</sup>FAR 52.227-14, Alt. II (DEC 2007), Alt. III (DEC 2007).

<sup>42</sup>FAR 52.227-14(f)(1).

<sup>43</sup>2 C.F.R. § 200.315.

<sup>44</sup>2 C.F.R. § 200.315.

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