



Agenda

- Overview
- Patent Rights Basics
- Technical Data and Software Basics
- Federal Acquisition Regulation (FAR) and FAR Supplements
- Uniform Guidance 2 CFR Part 200
- Other Transactions (OTs) and Other Agreements
- IP Litigation
- Best Practices

Overview

- Treatment of patents and technical data/computer software under government contracts varies depending upon:
 - Whether item/service is a commercial item/service
 - The contracting vehicle
 - Agency-specific regulations
- Contract Type
 - FAR-based contracts
 - Grants and agreements under Uniform Guidance, 2 CFR Part 200
 - Other types of agreements OTs, CRADAs, TIAs, etc.
- Government funding generally requires at least some government rights in both inventions and technical data

Patent Rights Basics

- Contract/agreement should include a clause setting forth the parties' respective rights in "subject inventions"
- Subject invention normally defined as any invention made in the performance of work under the contract/agreement
- Invention means any invention or discovery which *is or may be* patentable or otherwise protectable under 35 USC or the Plant Variety Protection Act.
- Standard patent rights will depend on type of contract/ agreement (as described in more detail in following slides)
 - Prior to the Bayh-Dole Act, the right to title in an invention generally was assigned to the government. The Act (35 USC 200-212, implemented by 37 CFR 401) changed this to allow small businesses and nonprofits to retain title. By Executive Order, among other things, this principle has been extended in most cases to contracts for all contractors; DOE and NASA being two exceptions

Patent Rights Basics - When Contractor Retains Title

- Reporting and disclosure obligations (when contractor retains title to a subject invention):
 - Contractor generally must disclose subject inventions within a certain amount of time after inventor discloses invention to contractor in writing (e.g., FAR-based contracts and DOD assistance agreements 2 months after internal disclosure; DOE– 6 months after becoming aware; but before first sale, public use or disclosure)
 - Disclosures required if conception OR 1st actual reduction to practice occurs under contract.
 - Contractor generally must elect to retain title within 2 years after disclosure which triggers 1 year filing deadline (period is shortened if necessary to protect patent rights).
 - DOE patent waiver (other than advance or class) required within 8 months from conception and/or first <u>actual</u> reduction to practice made under contract.
- Disclosure, election, filing and reporting obligations may be different under various agreements/clauses -- read the agreement!

Patent Rights Basics – Rights of Government

- Assignment to government is upon request:
 - Contractor fails to disclose or elect ownership within specified times (provide agency request title only within 60 days of learning of failure).
 - In countries where contractor fails to file patent application within specified time limits (unless it files before receiving a request to do so)
 - In countries where a decision to abandon is made
- Government shall have a nonexclusive, nontransferable, irrevocable, paid-up worldwide license to practice, or have practiced for or on its behalf, subject invention owned by Contractor.
- Receipt of annual reporting on utilization of subject invention
- March-in rights. Government retains right require licensing (even of exclusive licensee) if certain determinations made.

Patent Rights Basics

- Important to distinguish between the inventor's notification within the Company and the Company's disclosure to the agency
 - Inventor should have a **procedure** for notifying the Company of the invention.
 - This notification triggers the timelines for the Company to provide appropriate disclosures to the agency
- Inventor must disclose inventions to Company personnel responsible for patents
 - Depending on patent rights clause, some risk to the Company if inventor does not complete process timely

Technical Data and Software Basics - Definitions

- Data is defined as recorded information, regardless of form or the media on which it may be recorded; it includes technical data and computer software
- Technical data is defined as data (other than computer software) which are of a scientific or technical nature
 - Although computer software are not technical data (computer software are treated separately), most basic non-commercial data rights clauses that define technical data, including those in the FAR and DFARS, include computer software documentation in the definition of technical data
- Computer software means computer programs and recorded information comprising source code and other material that would enable the programs to be produced, created, or compiled; it does *not* include *computer data bases and software* documentation
- Computer Software Documentations means manuals, operating instructions that explain capabilities of computer software or provides user instructions

Technical Data - Special Handling

- Be able to demonstrate that pre-existing technical data was developed at private expense or with mixed funding
- When allowed, withhold disclosure of privately developed technical data. If contractor delivered protected data, do so only with written agreement to continue protection of such IP
- Properly legend all data delivered with less than unlimited rights and maintain adequate documentation to support markings
- Key strategies
 - Read the contract
 - <u>Identify all pre-existing data</u> in the proposal, if allowed, and protect
 - Properly legend technical data, both in proposals and before delivery
 - Do not give away technical data developed solely at private expense (i.e., limited rights data)
 - Watch for "free" licenses granted to prime contractors in subcontracts

- FAR-based commercial item contracts
 - Rights in Technical Data
 - Government generally receives the same rights as commercial customers
 - Specify in standard commercial license agreements
 - Make sure license agreement is placed in the order of precedence clause where it controls
 - Rights in Commercial Computer Software
 - Acquired under the standard commercial license except provisions inconsistent with Federal procurement law or do not otherwise satisfy user needs
 - FAR 52.227-19(b)(2) includes required government uses of commercial computer software

- Rights in Technical Data Noncommercial FAR-based contracts
 - Contractor retains right to
 - Use, release to others, reproduce, distribute, or publish any data first produced under the contract
 - Establish claim to copyright subsisting in data first produced in the performance of the contract
 - Government rights will depend upon the type of agreement and whether data were developed in performance of the agreement, or for DFARS, whether federal funds were used to develop the data

- Rights in technical data Noncommercial FAR-based contracts
 - Depending on type of agreement, government generally gets:
 - Unlimited rights → government can use without restriction
 - Government purpose rights (this right generally used only in DoD contracts) →
 government can use for government purposes only, including for government
 procurement, for five years (unless longer period negotiated), then unlimited rights
 - Limited rights → may not be disclosed outside the government (very limited exceptions may apply, such as providing to support contractors subject to restrictions on use and further disclosure)
 - Restricted rights → the equivalent of limited rights for computer software
 - Specifically negotiated → the above standard license rights may be modified by mutual agreement, but cannot be less than limited rights

- Rights in technical data Noncommercial FAR-based contracts
 - For FAR-based contracts, the Government will receive unlimited rights in data and software developed or delivered in performance of contract, unless qualifies as limited rights data or restricted rights software
 - For FAR-based contracts, generally withhold limited rights data and restricted rights software from delivery; but if have to deliver, use legend

- Terms of non-procurement agreements include:
 - Uniform Guidance at 2 CFR Part 200
 - As supplemented by agency implementations, e.g.
 - Parts 900-999 Department of Energy
 - Parts 1100-1199 Department of Defense
 - Etc.
 - Terms and conditions of award from the instrument

- Patent Rights Grants and Cooperative Agreements
 - Approach may vary according to agency
 - Most agencies have their own financial assistance rules that track OMB guidance and regulations
 - DOD
 - Unlike DOE, DOD general policy and regulations provide awardee (small and large) the right to elect to retain title to subject inventions
 - Must comply with disclosure, election and filing requirements
 - Government gets a license to practice for government purposes

- DOE

- DOE policy is to take title in inventions made by large, commercial awardees and awardee gets nonexclusive, revocable, paid-up license
- Awardee may request a patent waiver to retain title (either an advance waiver for award or a waiver for identified invention later) or DOE may grant class waiver
- Advance waiver for inventions under a particular award (requested by awardee prior to, or within 30 days of, execution of agreement)
- Waiver of identified inventions under a particular award (requested by awardee at earlier of time invention is reported to DOE or eight months after conception or first actual reduction to practice)
- Class waiver appropriate for a particular class of persons or inventions (normally originated by DOE, but may be requested by awardee)
- Do not include confidential data in waiver request
- Waiver and regulations allow awardee to elect to retain title to inventions, subject to disclosure,
 election and filing requirements; government gets a license to practice for government purposes

- DOE Grants and Cooperative Agreements
 - Government generally has unlimited rights in:
 - Data first produced and/or delivered in the performance of the agreement, unless qualifies as limited rights data or restricted software
 - Form, fit, and function data delivered under the agreement
 - Manuals or instructional and training material for installation, operation, or routine maintenance and repair of items delivered under agreement
 - Limited rights data and restricted computer software must be identified by awardee and withheld from delivery

- Some DOE agreements are subject to Special Data Rights statute
 - If Special Data Rights statute applies, government generally gets unlimited rights in:
 - Data identified in agreement to be delivered without restrictions
 - Form, fit, function data
 - All data delivered under the agreement, but contractor may mark data produced under agreement as "protected data" (which may not be published, disseminated, or disclosed outside the government for a period of up to 5 years; unlimited rights in data after 5 years)
 - Data that qualifies as limited rights data must be identified and withheld from delivery; must furnish form, fit, function data in lieu

- Patent Rights "Other Transactions"
 - Allow for creative IP allocations to meet the parties needs
 - FAR and Bayh-Dole Act do not apply, so IP rights can be negotiated
 - Possibilities:
 - Deferral of government rights
 - Limitations in event that project is terminated early
 - Limitations on definition of "subject invention" covered by agreement (more next)
 - "Springing" rights

Technical Data - DoD OTs

- DOD guidance states the government should receive rights in all technical data and computer software developed under the OT, regardless of whether it is delivered, and all rights in delivered technical data and computer software regardless of whether it was developed under the OT
- Negotiation possible: deferral of government rights, limit rights to deliverable, limited data delivery, limited rights if early termination, etc.

- Patent Rights CRADAs
 - If a party decides not to retain, other party has option to title
 - Each party has right to retain title (lab/non-federal party)
 - Non-federal party has right to exclusive license in a field of use, for compensation, in lab invention for up to 6 months after CRADA completion
 - DOE may take title in an invention if lab or non-federal party does not take title
 - DOE retains nonexclusive, nontransferable, irrevocable government purposes license in any lab/non-federal party invention
 - DOE gets "march-in rights" if parties do not promptly attempt to achieve practical application of invention, for health and safety reasons, or failure to "substantially manufacture" in US

Technical data – CRADAs

- Rights subject to agency policies, but technically negotiable
- DOE as example: Generally, government, lab, non-federal party have unlimited rights in all data produced in performance unless marked as "Proprietary" or "Protected CRADA" Information
 - Proprietary developed at private expense outside of CRADA, confidential/trade secret information, properly legended – may not be disclosed
 - Protected CRADA produced during performance, otherwise would have been treated as proprietary, legended – may not be disclosed outside government/lab/non-federal partner for five years
- Other agencies: Negotiate provisions to protect proprietary data

- Patent Rights Technology Investment Agreements (TIAs)
 - TIA is awarded under cooperative agreement or "other transaction" authority, depending upon the patent rights included:
 - If the TIA includes Bayh-Dole Act terms (e.g., it includes patent rights clause consistent with 37 CFR 401.14), it is a type of cooperative agreement
 - If it does not comply with Bayh-Dole Act (e.g., patent rights clause is not entirely consistent with 37 CFR 401.14), it is an "other transaction"
 - TIA that is OT provides more room to negotiate patent rights clause; does not have to include Bayh-Dole patent rights clause
 - Regardless, government usually will offer awardee ownership of the subject invention
 - Government usually will want a nonexclusive, irrevocable, paid-up license to practice/have practiced the subject invention throughout the world for government purpose

Technical Data – TIAs

- Rights are negotiable
- Applicable regulations direct agreements officer to develop overall strategy after considering interests
- Agreements officer directed to generally seek irrevocable, world-wide license for the government to use, modify, reproduce, release, or disclose for government purposes the data that are generated under the TIA
- Data delivered with restrictions on use should be properly marked with a restrictive legend

IP Litigation – 28 U.S.C. § 1498

- Provide contractors with immunity from patent and copyright infringement (1)
 "for the government." and (2) with "authorization or consent of the
 government".
 - "For the government" means that the government derives a benefit from the use or manufacture of the patented technology. See generally <u>Advanced Software</u> <u>Design Corp. v. Fed. Rsrv. Bank of St. Louis</u>, 583 F.3d 1371, 1378 (Fed. Cir. 2009).
 - Authorization can be express or implied. An implied authorization to infringe may be found under the following conditions: (1) the government expressly contracted for work to meet certain specifications; (2) the specifications cannot be met without infringing on a patent; and (3) the government had some knowledge of the infringement. Larson v. United States, 26 Cl. Ct. 365, 370 (1992). See also TVI Energy Corp. v. Blane, 806 F.2d 1057 (Fed. Cir. 1986)

IP Litigation – 28 U.S.C. § 1498

- Creates an independent cause of action for direct infringement by the Government or its contractors
 - Not identical Title 35, for example, though the scope is determined by 35 USC 154(a)(1).
 - The scope of the Government's waiver of sovereign immunity depends on (1) the invention being claimed in a U.S. patent; (2) the invention was used or manufactured for the United States; and (3) without license of the owner.
 - Agrieved patent holder can sue for "reasonable and entire compensation."
 - Injunctive relief is not available.

IP Litigation – Limitations on Damages – SOL/Damages

- Limitations on Damages
 - Patent and Copyright infringement claims 6 year SOL. <u>28 U.S.C. §2501</u>
 - No recovery for copyright infringement more than 3 years prior to filing complaint. <u>28 USC</u> §1498
 - Assignment of Claims Act: "[a]n assignment may be made only after a claim is allowed, the amount of the claim is decided, and a warrant for payment of the claim has been issued." 31 U.S.C. § 3727. Voluntary assignments of unliquidated claims against the US are ineffective.
- Copyright Litigation Considerations
 - Registration
 - Satutory damages available
- Claims arising in a foreign country are not applicable (1498(c)), but....
 - Importation of products made outside the US by a process patented in the US and imported by a Government contractor may be subject to 1498 liability. 35 USC §271(g); Zoltek Corp. v. U.S., 672 F.3d 1309 (Fed. Cir. 2012)

IP Litigation – Patent Considerations - Indemnity

- 48 C.F.R. 52.227-3 Patent Indemnity for Delivery of Commercial Items
 - a) When Does Contractor indemnify Government?
 - US Patents (other than those withheld under a Secrecy Order)
 - Manufacture or delivery of supplies, performance of services,
 - Construction, alteration, modification or repair of real property (contruction work)
 - b) No indemnity
 - a) unless
 - Contractor informed of suit or action as soon as practicable by Government
 - Contractor given opportunity to participate in defense
 - b) if
 - Infringement results from compliance with **specific written instructions of the CO** in connection with i) change in supplies delivered or materials or equipment to be used or direction of manner of performance
 - Infringement arises from addition or change made after performance
 - Claimed infringement is unreasonably settled without consent of Contractor
- Alternate Clauses: Alt. I (excluded items); Alt II (included items); Alt. III (communication services)

Best Practices

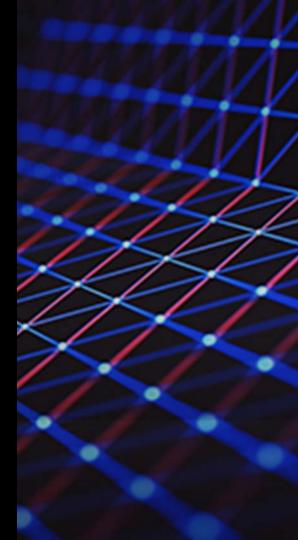
- Seek an appropriate contract vehicle and negotiate when possible
- Read the contract terms: understand the IP clauses and rights granted to the government, negotiate when appropriate
- Have an established procedure for inventors to disclose inventions within the company
- Clearly document all technical data developed at private expense that the company is bringing to the contract
- Implement systems for compliance and reporting

Coronavirus COVID-19 Resources

We have formed a multidisciplinary **Coronavirus/COVID-19 Task Force** to help guide clients through the broad scope of legal issues brought on by this public health challenge.

To help keep you on top of developments as they unfold, we also have launched a resource page on our website at www.morganlewis.com/topics/coronavirus-covid-19

If you would like to receive a daily digest of all new updates to the page, please visit the resource page to subscribe using the purple "Stay Up to Date" button.



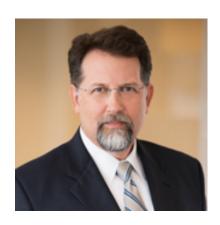
Biography



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Sheila Armstrong represents a broad range companies in all aspects of government contracting including FAR-based contracts, grants and other financial assistance agreements and Other Transaction Agreements (OTAs). She routinely counsels both prime and subcontractors in a variety of contractual and civil settings. Sheila's experience includes proposal preparation, contract negotiation, subcontracting, teaming arrangements, intellectual property rights in government contracts, contract compliance, audits, investigations, mandatory disclosures, and procurement fraud. She also routinely provides support to clients on novation and due diligence issues. Sheila frequently advises clients with respect to General Services Administration (GSA) and Veterans Affairs (VA) Federal Supply Schedule contracts.

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Kenneth J. Davis develops strategies for securing and enforcing intellectual property rights for clients in the mechanical, electrical, and life sciences sectors. A coleader of both the firm's Intellectual Property MedTech Working Group and its Consumer and Manufactured Products Working Group, Ken advises startups, multinational corporations, and research organizations with technology interests in orthopedic and drug delivery devices, consumer products, automation and artificial intelligence, clean energy, infrastructure and industrial equipment, materials handling, packaging, food and beverage, financial services, and industrial design.

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