An Introductory Guide to Preserving Intellectual Property Rights in Government Contracts

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Strategies for Preserving Patent Rights

Securing Innovation

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A. Background

- Traditionally, little need for flexibility for Intellectual Property
  - Large military industrial complex
    - Less incentive since plenty of bidders
  - Large Government labs
    - Less need for private sector aid in civilian agency
  - Universities less concerned about IP protection
    - IP seen as inimical to academic ideals
- Long corporate memory and lack of IP sophistication means need standard clauses

A. Background (Cont.)

- Present state
  - Increased interest in leveraging IP (patents and trademarks versus trade secrets)
- Increased need for flexible public-private collaborations for different needs
  - Funding only
    - Grants, prize authorities, venture funds, other transactions (OTs)
  - Collaboration with Government
    - CRADA, cooperative agreements, OTs
  - Straight contracts for R&D
    - FAR-based, OTs, space act, SBIR

1. Patents

- New and non-obvious developments
- Powerful tool for attracting investment
  - Tangible
  - Presumption of validity
- Powerful injunction/broad coverage
  - Patent injunction more damaging than damages
  - Value not truly reflected in reported decisions
- All development agreements address
  - Background and existing inventions
  - Improvements
  - Ownership versus license indemnification
- Traditional Government contract does not recognize greater importance of patents in knowledge based economy
  - Patent rights have become major mechanism for commercialization/obtaining financing

1. Patents (Cont.)

- Government contracting no different in requiring these elements
  - Specific exceptions do affect strategy
- No injunction/little strategic advantage
  - Success traditionally hinged on trade secret protection
    - Rights in data/computer software
    - Strategy was to carve out protected elements as limited rights/restricted rights
      - Protected elements used to circumvent CICA
- Grant of patent removes some trade secret protection
  - Aggressive patent program harmed ability to carve out protected elements
  - Still expensive to enforce against Government
- Patent rights are very rigid and non-negotiable
  - Strong public policies underlying clauses
  - Leads to unexpected problems

B. Timing as Affects Rights

- Patent rights generated according to events
  - Unlike trade secrets/copyrights (i.e., technical data and computer software)
  - Money not especially relevant
    - Private or Government money not part of inquiry as in data rights
    - Statement of work important
- Events
  - First conceived
  - First actually reduced to practice
    - Built prototype
    - Not merely filing patent application (constructive reduction to practice)
- Events need to occur within Statement of Work
- Significance is that the Government obtains no rights in background inventions not conceived or first reduced to practice
  - In same position as commercial company with same defenses
  - Exception: 28 U.S.C. § 1498 prevents injunctions and treble damages
  - Government supposed to obtain license, but not always done

B. Timing as Affects Rights (Cont.)

- If occurred, "subject invention"
  - Government gets Government purpose rights (at least)
  - Independent of delivery of developed item
- Subject inventions may exist if conceived/first reduced to practice outside of contract while within statement of work
  - *Mine Safety Appliances Co. v. United States*, 150 U.S.P.Q. 453 (Ct. Cl. 1966)
    - First actual reduction to practice of helmet within statement of work even though between contract phases since was "close and umbilical connection" to work
- Subject inventions may not exist if conceived/first reduced to practice during contract while outside of statement of work
  - *Rutgers v. United States*, 51 U.S.P.Q.2d 1642; 41 Fed. Cl. 764 (Fed. Cl. 1998)
    - Conception and actual reduction to practice occurred during contract, but not within statement of work even though later amendment to statement of work could have encompassed invention
  - *Boeing Co. v. United States*, 80 U.S.P.Q.2d 1108; 69 Fed. Cl. 1108 (Fed. Cl. 2006)
    - Evidence was inconclusive as to whether conception and actual reduction to practice occurred during contract
    - Was evidence that invention not within statement of work since proposals relied on Boeing's existing knowledge and work, and since the contract did not focus on area of invention

C. Unique Monitoring and Disclosure Requirements

- Report each subject invention
  - Report existence essentially immediately
    - If inventor identifies as subject invention: within 2 months
    - If contractor later determines is subject invention: within 6 months
  - Report if electing title
    - If do not, Government has option to file application
    - Within one year
  - Report filing of application
    - Report if filing abroad
    - Report if abandoning
    - Report if discontinuing maintenance fee

C. Unique Monitoring and Disclosure Requirements (Cont.)

- Annual Report
  - Inventions made during year
- Final Report
  - All inventions for entire contract period
- Small contractors have less rigorous reporting requirements
  - Unless required by supplements
- Similar monitoring requirements for CRADA, other transactions
  - Can at least negotiate lesser monitoring in other transactions

C. Unique Monitoring and Disclosure Requirements (Cont.)

- Part of contract that has invention process in place
  - Also required to have documentation in place and to cooperate for prosecution of patents
- Usually required to ensure subcontracts include patent reporting requirements
- Failure to comply can be serious
  - Can result in forfeiture of title
  - Can result in withholding of final payment

D. Vehicle Dependent

i. Standard FAR/Bayh-Dole
- Bayh-Dole: 35 U.S.C. §§ 200-212
- FAR Parts 27 and 52.227-11 and 52.227-13
  - FAR 52.227-12 or DFARS 252.227-7038: Large Contractors
  - Supplements: X27 and X27.5227
- Grant
- Cooperative Agreements
  - DODGARS

ii. CRADA
- 15 U.S.C. § 3710a

iii. Other Transactions
- 10 U.S.C. § 2371 (DOD, DHS)
- 42 U.S.C. § 2451(c)(5) (NASA)
- 42 U.S.C. § 7256(g) (DOE)

1. Standard FAR/Bayh-Dole

- Applies to "procurement contracts"
  - Grants, contracts, and cooperative agreements
  - Statement of work includes research and development
    - FAR 27.300 envisions inclusion "if a purpose of the contract or subcontract is the conduct of experimental, developmental, or research work"
- Contracting officers are over-inclusive in use
  - Often included (improperly) in pure purchases of existing items
    - Can object if not proper
- Would likely apply even if not written into contract
  - *FilmTec Corp. v. Hydranautics*, 982 F.2d 1546, 25 U.S.P.Q.2d 1283 (Fed. Cir. 1992) & *FilmTec Corp. v. Allied-Signal Inc., 939 F.2d 1568, 19 U.S.P.Q.2d 1508 (Fed. Cir. 1991)*
    - In deciding title required under Saline Water Conversion Act, title obtained from inventor even though no evidence inventor required to assign rights to employer

1. Standard FAR/Bayh-Dole (Cont.)

- Regulations for procurement contract with R&D at least tangentially involved
  - FAR Part 27, FAR Supplements X27
  - Mandatory clauses: FAR 52.227, FAR Supplements X52.227
- Procurement statutes apply
  - 35 U.S.C. §§ 200-212 (Bayh-Dole)
    - Rights in inventions
    - March in
    - Licensing restrictions

1. Standard FAR/Bayh-Dole (Cont.)

- Clauses written at time when large contractors dominated R&D procurement market
  - Clauses written to protect Government by preventing suits against Government for items it developed
  - When drafted, were an improvement over existing clauses
    - Agencies varied over title vesting
    - Bayh-Dole actually an improvement
- Problem is in the lack of flexibility
  - No special license rights as in technical data and computer software

1. Standard FAR/Bayh-Dole (Cont.)

- Automatic ownership in certain inventions
  - Contracts performed outside US
  - NASA (non-small business)
  - DOE (atomic energy related inventions)
  - Waivable
    - Must know to request waiver
- Automatic rights in inventions made under contract
  - Not waivable

1. Standard FAR/Bayh-Dole (Cont.)

- Required monitoring
  - Annual and final reports on status of invention
    - Also reports on commercialization possible
  - If fail to follow, can lose invention
    - *In re Campbell Plastics Engineering & Mfg., Inc.*, ASBCA No. 53319 (2003), affirmed *Campbell Plastics Engineering & Mfg., Inc. v. Army*, 389 F.3d 1243, 73 U.S.P.Q.2d 1357 (Fed. Cir. 2004)
    - Not mandatory since Government must take affirmative action under clause
      - *Central Admixture Pharmacy Services Inc. v. Advanced Cardiac Solutions P.C.*, 82 U.S.P.Q.2d 1293 (Fed. Cir. 2007)
  - If fail to follow, might face delayed payment
    - Contract will remain open (with withholdings up to "$50,000 or 5 percent of the amount of the contract") if have not submitted reports of inventions (or reports that none generated)
    - Can be years of delay

1. Standard FAR/Bayh-Dole (Cont.)

- March in rights
  - If Bayh-Dole applies, Government can take right to license to others to patented invention if failing to commercialize
    - 35 U.S.C. § 203
- If invention is a subject invention and contractor retains title and has not granted a license, Federal agency has the right to grant a license itself to an applicant if the Federal agency determines that --
  - Such action is necessary because the Contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
  - Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the Contractor, assignee, or their licensees;
  - Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the Contractor, assignee, or licensees; or
  - Such action is necessary because the agreement required by paragraph (i) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

1. Standard FAR/Bayh-Dole (Cont.)

- Strong public policies underlying Bayh-Dole
  - Government helped in most important phases generally:
    - Conception: paid contractor to think up solution
    - Actual reduction to practice: first prototype usually the most expensive to build/riskiest
  - Government help not for purpose of allowing patent holder to withhold technology
    - Ignores possibility that withholding of specific claimed invention is to improve market for other like invention
    - Loose analogy is to best efforts clauses
  - Strong pressure to ensure is in any R&D contract

1. Standard FAR/Bayh-Dole (Cont.)

- Problem: Most commercial companies object
  - Counterargument: March in rights never been used
- Ripe for abuse
  - NIH is petitioned periodically to exercise march in rights
    - Cell pro petition
    - Norvir petition
    - Xalatan Petition
- Represents question on value of patent and exclusivity

1. Standard FAR/Bayh-Dole (Cont.)

- Miscellaneous provisions of potential concern
  - Preference for American Industry
    - Requires that, prior to the subject invention being *exclusively* licensed, the contractor must require the exclusive licensee to manufacture the subject invention substantially in the United States
      - 35 U.S.C. § 204 requires preference
      - Can be waived
      - If fail to comply, is grounds for march in to allow Government to grant non-exclusive license on own
  - Commercialization reports
    - Option to require reporting of commercial sales, gross revenue, development status, and "such other data and information as the agency may reasonably specify"
- Provisions are potentially more problematic than the never-used march in right

1. Standard FAR/Bayh-Dole (Cont.)

- Mandatory flowdown to subcontracts from prime contract
  - Prime not beneficiary, but must ensure reporting performed
    - FAR 27.304-3(c) explicitly prohibits a prime contractor from using "their ability to award subcontracts as economic leverage to acquire rights for themselves in inventions resulting from subcontracts."
- Unclear remedy if "forget" to place in subcontract for R&D
  - Might be read into subcontract since 35 U.S.C. § 202 applies to "funding agreements," which include "any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement."
    - *Technical Development Corp. v. United States,* 171 U.S.P.Q. 353 (Cl. Ct. 1971) - Subcontractor a joint adventurer

1. Standard FAR/Bayh-Dole (Cont.)

- Benefits to Government Provisions
  - Can be authorization and consent clause
    - Provides affirmative defense to charge of infringement
    - Can be explicit: FAR 52.227-1
    - Can be implicit: Due to contract requirement or order
      - *Sevenson Environmental Services Inc. v. Shaw Environmental Inc.*, 477 F.3d 1361, 81 U.S.P.Q.2d 1906 (Fed. Cir. 2007) (authorization and consent applies where Government selected method which infringed third party patent)

1. Standard FAR/Bayh-Dole (Cont.)

- Authorization and consent is a defense
  - Not jurisdictional
  - Must be established by the accused
- Established on a contract by contract level
  - Example: *Duke v. Madey*, 413 F.Supp.2d 601, 79 U.S.P.Q.2d 1877 (M.D. N.C. 2006)
    - Discussing which contracts sufficiently tied to infringement such that defense applies

1. Standard FAR/Bayh-Dole (Cont.)

- If authorization and consent not applicable, it is not an available infringement defense
  - *Zoltek Corp. v. United States,* 442 F.3d 1345 (Fed. Cir. 2006) (discussing limit of 28 U.S.C. § 1498 and Authorization and Consent as applied only to 35 U.S.C. § 271(a) and does not apply to 35 U.S.C. § 271(g) infringement)
    - *Zoltek Corp. v. United States,* No. 96-166 C (Fed. Cl. January 23, 2009)(authorizing transfer of venue to allow suit to proceed against contractor under 35 U.S.C. § 271(g) since 28 U.S.C. § 1498(c) precludes action against Government but does not exempt contractor)
- Consistent with state laws
  - *State of Texas v. Herbert W. Holland*, 2007 Tex. LEXIS 314, 50 Tex. Sup. J. 642 (Tex. 2007)
  - *A.C. Aukerman Co. v. State of Texas*, 902 S.W.2d 576 (Tex. App.—Houston [1st Dist.] 1995, writ denied)

1. Standard FAR/Bayh-Dole (Cont.)

- Benefits to Government Provisions
  - No indemnification for Government unique items
    - Government can indemnify for patent suits related to commercial item
      - FAR 52.227-3
      - Possible waiver: FAR 52.227-5
  - If no requirement to indemnify Government
    - Best of both worlds: no injunction, no willful infringement, and no need to pay
      - Free legal defense from DOJ

2. CRADA

- CRADA
  - Improve IP provisions and allow more flexible cooperation
    - Problem: cannot provide funding
    - Can assign government employee invention rights to contractor
    - Bayh-Dole does not apply
- Cooperative Research and Development Agreement (CRADA)
  - First authorized by the Federal Technology Transfer Act (FTTA) of 1986
  - Authority found at 15 U.S.C. § 3710a
  - Used for cooperative research and development efforts in which the Government contribution is not money
  - Purpose must be consistent with the mission of the Government laboratory party

2. CRADA

- When should a CRADA be considered?
  - When the Government has technology, data, or expertise that is desirable to exploit for commercial benefit
  - Permits a company to leverage the resources of Government laboratories
  - To further develop or enhance existing technology using the Government's know-how, personnel, facilities or IP (but not money)
- Potential Government Partners
  - GOGO, Government Owned Government Operated Laboratory
  - GOCO, Government Owned Contractor Operated Laboratory

2. CRADA (Cont.)

- Potential Non-Government Partners, § 3710a(a)(1)
  - Just about anyone (e.g., partnerships, corporations, non-profits, industrial organizations)
  - Exception: No foreign governments
- Other Considerations
  - CICA not applicable so competition is not required
  - Subcontracts
    - Must be acknowledged in the agreement
    - Only signatories to the CRADA may fully participate

2. CRADA (Cont.)

- IP Considerations
  - Preexisting IP
    - Identify preexisting IP to both your company and the Government
    - Establish rights in the preexisting IP as part of CRADA negotiation process
  - CRADA IP
    - Government created-negotiated in advance?
    - Company created-protected adequately?

2. CRADA (Cont.)

- Key Provisions
  - Licensing IP
    - General authority to license is set forth at § 3710a(a)(2)
    - Specific authority states that a laboratory may grant, …**in advance**, to a collaborating party patent licenses or assignments, or options … in any invention made in whole or in part by a laboratory employee under the agreement…§ 3710a(b)(1)

2. CRADA (Cont.)

- Key Provisions, cont.
  - Licensing IP
    - Subject to 35 U.S.C. § 209, can option or license pre-existing Fed owned invention related to subject of CRADA …§ 3710a(b)(1)
      - Exclusive license for pre-negotiated field of use
      - If multiple collaborating parties then may choose a collective license
      - GOVERNMENT RETAINED LICENSE IN ALL CASES: the government retains a nonexclusive, nontransferable, irrevocable, paid-up license for the invention
      - Limited provision for the Government to compulsorily license any exclusively licensed invention

2. CRADA (Cont.)

- Key Provisions, cont.
  - Licensing IP
    - Under agreements … pursuant to subsection (a)(1) …, the laboratory shall ensure that a collaborating party may retain title … § 3710a(b)(2)
    - Retention of title by the collaborating party will be subject to a nonexclusive, nontransferable, irrevocable, paid-up license for the invention granted to the Government

2. CRADA (Cont.)

- Key Provisions, cont.
  - Things the Government party can do § 3710a(b)(3):
    - (A) accept, retain, and use funds, personnel, services, and property from a collaborating party and **provide personnel, services, and property to a collaborating party (but not money)**;
    - (B) use funds received from a collaborating party in accordance with subparagraph (A) to hire personnel to carry out the agreement who will not be subject to full-time-equivalent restrictions …;

2. CRADA (Cont.)

- Key Provisions, cont.
  - Things the Government party can do § 3710a(b)(3), cont.:
    - (C) permit a Government employee or former employee to commercialize invention made by the employee; and
    - (D) waive in advance, in whole or in part, any right of ownership the Government may have to any subject invention made under the agreement by the collaborating party, subject to a nonexclusive, nontransferable, irrevocable, paid-up license for the invention granted to the Government

2. CRADA (Cont.)

- Key Provisions, cont.
  - Enforcement § 3710a(b)(4): Collaborating party in an exclusive license in any invention made under the agreement shall have the right of enforcement

2. CRADA (Cont.)

- Key Provisions, cont.
  - Contract considerations § 3710a(c)
    - The laboratory director in deciding what cooperative research and development agreements to enter into shall –
      - (4)(A) give special consideration to small business firms, and consortia involving small business firms; and
      - (4)(B) give preference to business units located in the United States which agree that products embodying inventions made under the CRADA or produced through the use of such inventions will be manufactured substantially in the US

3. Other Transactions

- 10 U.S.C. § 2371: Prototyping authority
  - Inspired by NASA's 1958 Space Act
- DoD, DOE and DHS unique (although other agencies requesting)
  - IP totally flexible, funding sources flexible
  - Bayh-Dole does not apply
- Generally used like CRADAs (but not required)
  - Difference: No restrictions on spending
  - Fairly flexible
  - Can be as flexible as OTs not restricted by procurement statutes (seen as the basis for OT authority)
- If doing research only
  - Technology Investment Agreement (TIA) is comparable
  - TIA similar to Cooperative Agreements, but Bayh-Dole does not apply

3. Other Transactions (Cont.)

- Allows parties to negotiate IP without statutory encumbrances
  - No standard form
    - Allows contracting partner to submit own form
  - One of the few vehicles in which Government participates in a battle of the forms
- While negotiable, agreements will often contain standard IP rights clauses in at least initial drafts
  - Standard IP clauses from Bayh-Dole and FAR represent important public policy statements and corporate memory
  - Familiar and no need for Government to explain variances to Congress

3. Other Transactions (Cont.)

- If want non-Bayh-Dole rights
  - Explain problem
    - Need to commercialize product
    - Need to reduce regulatory burden
    - Need to obtain investment
- Can at least negotiate
  - "'Other Transactions' (OT) Guide for Prototype Projects"
    - Encourages negotiations on IP "to accomplish program objectives and foster government interests" if other than Bayh-Dole rights
  - Little guidance on what is required (probably a detriment)

3. Other Transactions (Cont.)

- Contractors can better protect crown jewels
  - Meaningful IP protection
  - Government can tailor IP provisions to reflect benefit to Government
    - If Contractor taking all risk, Government rights reduced
    - Could limit patent rights to only one arm of service or only to DoD
- Negotiate march in rights to not frighten investors while ensuring commercialization
  - Reduce triggers for march in
- Reduce administrative reports and/or triggers
  - Eliminate withholding, number of reports, domestic preference for exclusive licensing
- Could use 28 U.S.C. § 1498 as shield to allow prototype to be built to defeat blocking patents without having to retain IP rights under Bayh-Dole/FAR
- Could use to govern other IP rights lacking clauses
  - Secure trademark rights

3. Other Transactions (Cont.)

- Newer mechanism allows flexibility
  - Not always appropriate to retain IP rights where the retention prevents commercialization
  - Government need for IP can be downstream (not always recognized in standard IP provisions)
- Allows government to enter battle of the forms
  - Commercial firms have own draft agreements with which they are comfortable
  - Reviewing Government-specific terms and conditions is expensive (even if the terms are often analogous)
  - All joint development agreements account for IP, Government IP provisions not unheard of
- Not enough people aware
  - Not enough Government IP people to handle, little meaningful IP guidance
  - Makes contracting officers conservative (less to justify if things go wrong)
  - Need Government IP Counsel involved

3. Other Transactions (Cont.)

- Contractors misunderstand customer
  - FAR and Bayh-Dole reflect long-term corporate memory of Government needs
    - All large, long-term companies have it (E.g., IBM)
  - When negotiating, should account for these and demonstrate how variance represents better deal
  - E.g., March in rights: note that IP developed reflects only one possible solution, and that commercial market will define
    - Lack of commercialization of developed IP does not mean not commercial market for solution
- Focused on procurement of prototypes directly
- Government often wants contribution from contractors
  - Cost sharing
  - IP rights (downstream)
- Still restrictions on foreign contractors

4. **Beyond** Other Transactions

- Newer solutions involve commercialization of entire industry
- New solutions go beyond OT
  - Venture Funding
    - In-Q Tel
    - Venture funds to try to develop commercial solutions that will benefit government
  - Prize Authorities
    - Set up prizes to attract talent to solve problem
      - E.g., DARPA's desert race, X Prize, H Prize
  - No requirements for funding or rights in IP
    - Can truly tailor to meet actual need

4. Beyond Other Transactions (Cont.)

- Venture Fund Benefit
  - Relies on commercial market to develop product, Government merely provides help in form of investment
    - Similar to how commercial companies (drug companies) use investment to spur research in area of interest for long term benefit
  - Allows Government to spur growth of desirable technology industry
  - Familiar business model (important)
- Prize Authority Benefit
  - Allows smaller entities (garage inventors, high schools, engineering departments) to participate
    - Maximizes competition in research
    - Generates excitement in field

4. Beyond Other Transactions (Cont.)

- Problems:
  - No guidance
  - No protection under 28 U.S.C. § 1498
    - Can be enjoined by competitor based upon patent
- Venture Fund Problem:
  - Potentially more invasive than Bayh-Dole
  - Government is not licensee, but part owner of company
    - Currently, In-Q-Tel only has observer seat, but not required
    - Government interest in voting/company direction may be different from shareholders interest in profit
- Prize Authority
  - Useful for only where is well defined goal
  - No guarantee that industry will develop
- Mention since one should keep eye out for similar mechanism