PUBLIC CONTRACTING INSTITUTE

Life Sciences Contracting 101

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Topics

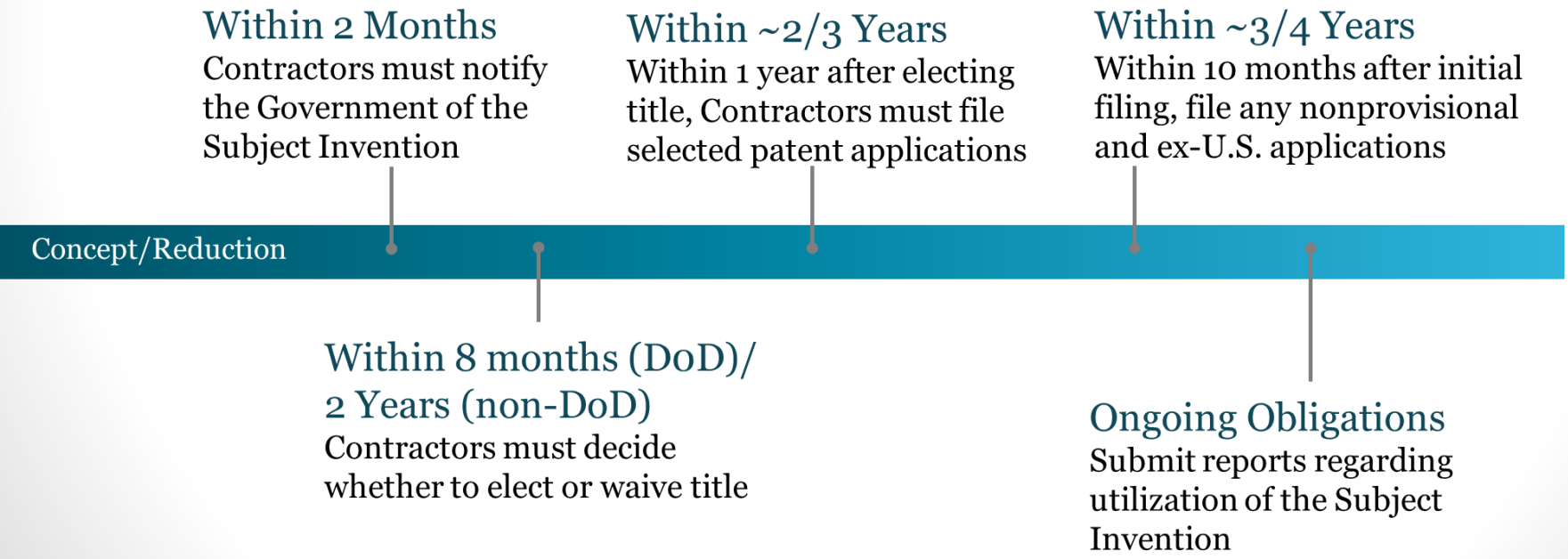
1. <u>Relevant Statutory and Regulatory Frameworks</u>
   - The Bayh-Dole Act and Other Sources of U.S. Government Intellectual Property Rights
   - Emergency Use Authorizations and Authorities, Expanded Access, and Stockpiling Authority
   - The Public Readiness and Emergency Preparedness or “PREP” Act
   - Indemnification and Other Liability Protections
   - The Defense Production Act
2. Commercial Contracting and General Compliance Obligations
3. Additional Considerations for Research and Development

The Bayh-Dole Act: Subject Inventions

- Government agreements typically cover "Subject Inventions"
  - Conceived or first actually reduced to practice in performance of agreement
  - Not tied to use of federal funds
  - Patentable subject matter
    (not necessarily patentable)
- Background inventions are generally protected if not first actually reduced to practice under an agreement
- Date of funding agreement may not matter

The Bayh-Dole Act: Recipient Obligations

- Notify the Government
- Elect to retain title
- File patent applications
- Report on patent utilization
- Subcontracting



The Bayh-Dole Act: Government Rights

- Government License
- March-In Rights
- Voidable Title
- Title-Seizing Authorities

The Bayh-Dole Act: Government License

- Can be indirect defense through authorization and consent
- Can create price competition for Government sales and limit royalties on licensed technology
- Government can always intentionally infringe

The Bayh-Dole Act: March-In Rights

- March-in rights allowing the Government to mandate licensing, or directly license, Subject Inventions to a third party upon a determination that:
  - Timely and effective steps have not been taken to achieve practical application (i.e., public availability)
  - Health or safety needs exist that cannot be satisfied by a recipient, its assignee, or licensee
  - Licensing is required to meet public use requirements specified in agency regulations to the extent that they cannot be satisfied by a recipient, its assignee, or licensee
  - Domestic preference requirements have not been met

The Bayh-Dole Act: Title-Seizing Authorities

Department of Energy	NASA
Title to inventions conceived or first actually reduced to practice in the course of or under any contract, grant, agreement or other arrangement with or for the benefit of the DOE vests in the United States	An invention shall be the exclusive property of the United States if it is made in the performance of any work under any contract of the Administration which was made during working hours, or with a contribution from the Government

Recipient Licensing

- Exclusive License:
  - Unless waived, an exclusive license to use or sell a Subject Invention in the United States must require the licensee to manufacture substantially in the United States any products embodying, or produced through the use of, the Subject Invention
- Substantial Manufacturing:
  - Components (Buy American Act)
  - Substantial transformation (Trade Agreements Act)
  - Final assembly
  - Not necessarily applicable to non-U.S. markets
- Possible to secure a waiver

Assignments

- Nonprofit organizations must obtain an agency's approval to assign rights in subject inventions, including to for-profit collaborators
- Nonprofit organizations required to give preference to small business licensees

Funding Agreements vs. CRADAs

Government rights	Funding Agreements	CRADAs
Default License	35 U.S.C. §§ 200–12 37 C.F.R. Part 401 48 C.F.R. Parts X27	15 U.S.C. § 3710a
Title	Government	Government or laboratory contractor
March-in Rights	Yes	Not permitted
Examples	• Stockpile contracts • Funded development projects • University research grants	• Clinical trial agreements • Joint development agreements • Material transfer agreements • Demonstration agreements

Relevant Categories of Data

- Technical Data
  - Scientific or technical information (e.g., reports and schematics)
  - Computer databases
  - Computer software documentation
- Computer Software
  - Computer programs
  - Source code
  - Object code
- Administrative Data
  - Financial, cost, or pricing data
  - Contract management and administration data

Government Data Rights

Data Rights	Impact
Unlimited Rights	• Any use and purpose, including public disclosure and commercial development • Right to modify and make derivative works (i.e., new software)
Government Purpose Rights (DoD only) ~5 years	• Within Government and under Government contracts • No commercial use • Protections for third-party use or disclosure
Limited / Restricted Rights	• Within Government and limited disclosures to third parties (machine-by-machine for restricted computer software) • No commercial use or manufacture • Protections for third-party use or disclosure
Specifically Negotiated Rights	• Generally free to negotiate down to limited rights • More likely for cost share • Often available in non-standard agreements (e.g., OTAs and CRADAs)

Marking and Prior Identification

- Failure to mark can provide the Government with unlimited rights
  - Civilian agencies require marking to be “affixed”
  - Department of Defense requires marking on transmittal document/storage container, software notice, each page, and even portions of a page
- Non-commercial Department of Defense contracts require contractors to identify in advance any data that will be delivered with less than unlimited rights

Freedom of Information Act

- Proposal information is often exempt from disclosure unless incorporated into an award
- Unit pricing information can generally be protected if properly marked, but some authorities suggests that most if not all contract terms can be disclosed
- Federal employee Trade Secrets Act prohibits disclosure of most confidential commercial information, but it is not enforceable by private parties
- Available proposal materials can be considered a publication for patent protection purposes, as well as an offer for sale depending on how technology is described

Emergency Use Authorizations

- Unapproved Product or Use – 21 U.S.C. § 360bbb-3 (Sec. 564)
  - Requires Secretary of HHS declaration of emergency or potential emergency based on determination that there is an actual or potential emergency involving:
    - For DHS, heightened domestic risk of attack with CBRN agent(s);
    - For DoD, heightened risk for U.S. military forces of attach with CBRN agent(s);
    - For HHS, an actual effect on, or significant potential to affect, national security or the health and security of U.S. citizens living abroad due to CBRN agent(s) or a disease or condition attributable to such agents; or
    - For DHS, material threat determination with similar scope as HHS
  - FDA issues authorization
    - Serious or life-threatening disease or condition caused by CBRN agent(s)
    - May be effective to prevent, diagnose, or treat the disease or condition
    - Known or potential benefits outweigh known or potential risks
    - No adequate, approved, and available alternative

EUAs: Contracting Considerations

- PREP Act protection
- Government agencies can submit and help to effectively communicating with FDA
- U.S. Government may be only customer
- Risk of price lock-in and changes to formulation
- Buy-back provisions
- Pre-EUA filings
- Risks associated with performance standards
- Continued clinical development is often required

Emergency Use Authorities

- Expiration Date Extensions, cGMP Deviations, and Emergency Dispensing and Instructions – 21 U.S.C. § 360bbb-3a (Sec. 564A)
  - Technically not EUAs
  - cGMP deviations can cover manufacturing, storage, labeling, and handling
- Enforcement Discretion
  - Frequent path outside of pandemic
  - Risks not triggering PREP Act protection

Expanded Access

- Use of Investigational Drugs or Devices for Diagnosis, Monitoring, or Treatment in Emergency Situations – 21 U.S.C. § 360bbb (Sec. 561)
  - No comparable or satisfactory alternative therapy
  - Sufficient evidence of safety and effectiveness
  - No interference with clinical investigations toward approval
  - Needs clinical protocol
  - Broader treatment application requires ongoing efforts to obtain approval

Stockpiling Authority

- Products Held for Emergency Use – 21 U.S.C. § 360bbb-3b (Sec. 564B)
  - Permits government entities at any level or persons acting on their behalf, including contractors, to transport and store products intended for emergency use
  - Must be held until approved, authorized for investigational use, or authorized for emergency use or under emergency use authorities
  - Typically relied on to enter into stockpile contracts for unapproved products or approved products intended for unapproved uses

PREP Act

- Provides immunity from claims under U.S. law in connection with products covered by an HHS declaration
- Declarations currently exist for:
  - COVID-19
  - Smallpox/orthopox (including monkeypox)
  - Marburg
  - Ebola
  - Nerve agents/insecticides
  - Zika
  - Pandemic influenza
  - Anthrax
  - Acute radiation syndrome
  - Botulinum toxin
- Immunity does not apply for claims brought under non-U.S. law (e.g., for donations)
- Immunity does not apply if plaintiff can demonstrate willful misconduct
- Immunity does not impact criminal or administrative liability, but arguably could cover infringement of intellectual property

PREP Act Coverage

Covered Countermeasure	Covered Persons and Geography	Recommended Activities	Authorized Distribution Channels
• Described in declaration as used for specific indication • Generally must be covered by IND, approval/clearance, EUA, or stockpiling authority	• Manufacturer, distributor, program planner, healthcare providers • Geography historically worldwide, but can be limited	• Typically includes manufacture, testing, development, distribution, and use of the product	• Historically required to be related to a federal contract or action by a public health authority • COVID-19 declaration was amended mid-pandemic to remove this limitation on distribution

Other Liability Protections

- Indemnification and Procedural Protections
  - Public Law 85-804
  - Contractual allocation of risk and research indemnities up to ceilings
  - SAFETY Act
- Immunity
  - Defense Production Act *(potentially only applies to breach of contract claims)*
  - 28 U.S.C. § 1498 *(only applies to patent and copyright infringement claims)*
  - Government contractor defense

The Defense Production Act

- Can be used to require Government work to be prioritized
- Can be used to allocate goods, services, or technology
- Compliance with directives provides immunity, but not for claims under non-U.S. law and potentially only for breach of contract claims resulting from prioritization
- Must be flowed down through supply chain
- There is typically a tradeoff between the benefit of more responsive suppliers and the drawback of prioritizing Government work over commercial operations

Questions?