Government Owned, Government Operated (GOGO) Laboratories

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Road Map

- Introduction to NIH, a GOGO Laboratory
- GOGO definition and IP rights
- Licensing Principles
- Some Interesting Characteristics of Government Licenses
- Major Differences between GOGO and GOCOs
- Questions?
The National Institutes of Health

- The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the primary Federal agency for conducting and supporting medical research.
- $30.5 Billion* (2009 budget)
- 18,082 employees

*This amount excludes the $10 billion appropriated to NIH in 2009 for short-term stimulus purposes under the American Recovery & Reinvestment Act (ARRA) available for obligation across a two-year timeframe until September 30, 2010
NIH-OTT

- The NIH Office of Technology Transfer evaluates, protects, markets, licenses, monitors, and manages the wide range of NIH and FDA discoveries, inventions, and other intellectual property as mandated by the Federal Technology Transfer Act and related legislation.
A GOGO laboratory is Government Owned, Government Operated:
- usually owned or leased by the federal government,
- predominantly staffed by federal employees
- supported by nonfederal contract employees. Individual contract employees may be considered “work-for-hire” employees, while staff provided by a firm providing support staff to the laboratory may be covered by the intellectual property rights bestowed on the contracting firm under the provisions of the Bayh-Dole Act or Executive Order 12591.
- A major difference between federal and nonfederal employees can be found in 17 USC 105 (GOGO vs. GOCO)
GOGOs and IP

- GOGOs can seek patents;
- Can register Trademarks;
- Cannot copyright “work of the United States Government”; a work prepared by an officer or employee of the United States Government as part of that person's official duties, e.g., an employee at the GOGO (17 USC 105).
- Government is the owner/assignee of IP.
# Legal Authority for Licensing

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<th>35 USC 209</th>
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Licensing Principles

• Granting only the appropriate scope of rights
• Permit research uses
• Preference for non or partial exclusivity
• Specified fields of use
• Enforceable milestones and benchmarks
• Maximize development of products for the public good (mission driven)
• Ensure appropriate return on public investment
Factors Considered in Licensing

- Stage of Development
- Type of Product
- Market value of product
- Uniqueness of Material
- Scope of patent coverage
- Market timing
- Agency “content”
- Public Good (mission driven)
Some Interesting Characteristics of Non-exclusive and Exclusive Licenses

- Negation of warranties and representations
- Indemnification
- Reservation of Government Rights
- Manufacturing Sites
Negation of Warranties and Representations

- No warranties or representations are made
  - Licensor offers no warranties other than those specified in Article 1. (Article 1 is the inherent characteristics of a license).
  - Licensor does not warrant the validity of the patent rights and makes no representation whatsoever with regard to the scope of the licensed patent rights.
  - Licensor makes no expressed or implied warranties of merchantability or fitness for a particular purpose of any subject matter defined by the claims of the licensed patent rights or tangible materials related thereto (UCC provision, not applicable to licenses).
  - Licensor does not represent that it shall commence legal actions against third parties infringing patent rights.
Indemnification

• Generally speaking, the licensor may be called upon to indemnify and hold the licensee harmless against a breach of the licensor’s representations and against defects in the products incorporating the invention.

• This is not true in Government licenses. In fact, it is required that licensee maintain liability insurance.
Reservation of Government Rights

- The Federal agency has the right to terminate the license in whole or in part if the agency determines that licensee is not diligent in developing the technology, is in breach, has violated the Federal antitrust law in connection with its performance under the license or if such action is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license and such requirements are not reasonably satisfied by licensee.

- Codified in 35 USC 209 (d)(3)
Manufacturing Site

• A Federal agency shall grant the right to use or sell any federally owned invention in the United States only to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

• 35 USC 209 (b)
CRADAs and Licensing (FTTA)

• Federal Technology Transfer Act of 1986 (P.L. 99-502)—Also known as the FTTA, this act was the second major piece of legislation to focus directly on technology transfer. All federal laboratory scientists and engineers are required to consider technology transfer an individual responsibility, and technology transfer activities are to be considered in employee performance evaluations. This 1986 law also established a charter and funding mechanism for the previously existing FLC.
CRADAs and Licensing (FTTA) (Cont.)

- In addition, the FTTA enabled GOGO laboratories to
  - enter into CRADAs
  - negotiate licensing arrangements for patented inventions made at the laboratories
  - required that government-employed inventors share in royalties from patent licenses
  - exchange personnel, services, and equipment among laboratories and nonfederal partners
  - grant or waive rights to laboratory inventions and intellectual property, and
  - Grant permission for current and former federal employees to participate in commercial development, to the extent that there is no conflict of interest.
Some Differences between GOGO and GOCO Laboratories

- Exclusive Licenses
- FOIA
- Consideration
- Royalties
- Consulting
- CRADAs
Exclusive Licenses

• **Bayh-Dole Act of 1980 (P.L. 96-517)**—The Bayh-Dole Act of 1980, together with the Patent and Trademark Clarification Act of 1984 (P.L. 98-620), established more boundaries regarding patents and licenses for federally funded R&D. Small businesses, universities, and not-for-profit organizations were allowed to obtain title to inventions developed with federal funds.

• Government-owned and government-operated (GOGO) laboratories were permitted to grant exclusive patent licenses to commercial organizations.
Exclusive Licenses—Notice

• Notice of opportunities should be made available to interested parties in as much detail as possible and to as wide an audience as possible. Avoiding the appearance of showing preference to a particular organization or individual is of concern to all federal laboratories and their agencies. It should be noted that when a GOGO laboratory agrees to grant an exclusive license, it is required to advertise that intent in the Federal Register prior to granting the license.
Consideration

• A contract is formed when there is an offer, an acceptance and consideration (something of value).
• In most GOGOs this consideration is money or cross licenses (in some circumstances).
• GOCOs have more flexibility in obtaining consideration in other forms.
Royalties

• At GOGO laboratories there is a limit of royalties of $150,000 per year per person without presidential approval.

• At GOCO laboratories, the inventor is not subject to a limit on the amount of royalties he or she may receive per year.
GOGO Licenses in One Slide

• Licenses can be non-exclusive, partially exclusive, or exclusive.
• Must provide public notice prior to granting a partially exclusive or exclusive license.
• Licenses are subject to FOIA (business confidential information will be redacted).
• Consideration is usually in form of money or cross licenses.
• There is a cap on royalties for GOGO employees.
Collaborations

• **Executive Order 12591 (1987)**—Executive Order 12591, Facilitating Access to Science and Technology, was written to require that federal laboratories and agencies assist universities and the private sector by transferring technical knowledge. It required agency and laboratory heads to identify and encourage individuals who would act as conduits of information among federal laboratories, universities, and the private sector.

• It also underscored the government’s commitment to technology transfer and urged GOGOs to enter into cooperative agreements to the limits permitted by law.
Consulting—Personnel

- Consulting by Laboratory Personnel—In certain cases, nonfederal personnel in GOCO laboratories may provide consulting to a private-sector party to further the technology transfer process. The laboratory must approve these arrangements to ensure there are neither conflicts of interest nor potential intellectual property concerns. (Note: This does not apply to federal employees in GOGO laboratories.)
CRADA GOGO vs. GOCO

**Step 1 - Concept Definition**
- Develop concept
- Identify partners
- Identify resources

**Step 2 - Draft CRADA**
- Develop SOW
  - Discussions with partners
    - Financial obligations
    - Partnering issues
    - Intellectual property

**Step 3 - Review**
- Organization management
- Agency/lab legal staff
- ORTA
- Partner

**Step 4 - Formal Negotiations**
- Meet/negotiate w/ partner
- Accept/reject changes
- Agreement between principals
- Final draft meeting

**Step 5 for GOGO Labs - Final Negotiation/Signature Phase**
- Submit for partner signature
- Possible renegotiate/final revisions
- Final legal approval
- Lab technical director signature

**Step 6 for GOGO Labs - Agency Review**
- 30-day agency-level review
- Approve/reject/modify

**Step 5 for GOCO Labs - Submit for Local Agency Approval**
- Possible renegotiate/final revisions
- Final legal approval

**Step 6 for GOCO Labs - Submit for Signatures**
- Partner
- Laboratory

**Step 7 - CRADA Execution**
- Perform SOW tasks
- Progress reports

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Any Questions?

Thank you for your kind attention

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